Introduction

The Wake Forest University School of Medicine Faculty Handbook (the “handbook”) is intended to be used by all persons who hold a faculty appointment with the Wake Forest University School of Medicine (hereinafter at times the “School of Medicine” and at times “WFUSOM”), whether tenured, tenure track or non-tenure track, or full or part-time (i.e., Adjunct), regardless of employer or location. It is a compilation of basic policies and procedures of interest and concern to members of the faculty and administration.

The handbook provides convenient access to information compiled from a variety of sources. It is intended to be informational rather than contractual in nature. "Much of the material contained in the handbook consists of extracts from official University and WFUSOM documents, such as policy resolutions of the Wake Forest University (the “University”) Board of Trustees or rules adopted by the WFUSOM Campus. Accordingly, the handbook is not to be construed as modifying rights or obligations defined in official University documents, and users of the handbook should consult the appropriate official document, in its entirety, for specific guidance.

Handbook policies are continually updated. For the most recent version of policies, faculty should access PolicyTech, the institutional policy site or contact the Office of Faculty of Affairs. Wake Forest University School of Medicine reserves the right to change policies and procedures at any time and without prior notice. Additionally, errors and omissions in published documents (written or electronic) may be corrected at any time.

The University’s Board of Trustees will from time to time adopt policies (including, but not limited to those described above) of general application relating to the members of the faculty, and may also authorize the faculties, the administration or both, to adopt such policies. Those policies may be changed from time to time in accordance with the needs of the University, and the right to make such changes is reserved to the University. Nothing in this Handbook is intended to create an express or implied contract of employment. Appropriate policies will be developed in consultation with the School of Medicine Faculty Executive Council (FEC) and the Faculty Representative Council (FRC) regarding the process for revision of certain policies contained in the handbook. Those procedures will be subject to approval of the Board of Trustees or the President, as required. Policies that pertain to a single academic unit only will be subject to review by the Office of the Provost.

Faculty members should consult with their employer’s (example: Atrium Health Wake Forest Baptist, The Charlotte-Mecklenburg Hospital Authority, Carolinas Physician Network, LLC, etc.) Human Resources department for employment-related policies and expectations. It is important to note that employment status and the faculty appointment are separate.

When applicable, faculty members should also refer to their employment agreements for additional information regarding the provisions of their faculty appointment.

Wake Forest University School of Medicine reserves the right to change policies and procedures at any time and without prior notice. Additionally, errors and omissions in published documents (written or electronic) may be corrected at any time.
Wake Forest University School of Medicine maintains policies that apply to all faculty. Faculty members are strongly urged to familiarize themselves with these policies on the institutional policy site.

This version (version 1.0 dated X Month, XXXX) of the School of Medicine Faculty Handbook was compiled by the Faculty Handbook Working Group:

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CHAPTER ONE

HISTORY AND GUIDING PRINCIPLES

History of Wake Forest University School of Medicine

Wake Forest University School of Medicine (WFUSM), originally established as a four-year medical school in Winston-Salem, North Carolina, has a rich and storied history dating back to the early 20th century. The school's journey is marked by significant developments in medical education, research, and healthcare delivery.

Early Beginnings

The roots of Wake Forest University School of Medicine can be traced back to the establishment of the original medical school, the Wake Forest College School of Medicine, in 1902.

Creation of Four-Year School and Move to Winston-Salem

On August 3, 1939, The Bowman Gray Fund was established and offered to Wake Forest College to establish a four-year medical school to be located in Winston-Salem, North Carolina and to be name the “Bowman Gray School of Medicine” of Wake Forest College. Also on August 3, 1939, North Carolina Baptist Hospital invited Wake Forest College to use the Hospital’s Winston-Salem campus to locate the new four-year school.¹ The new Bowman Gray School of Medicine became operational in 1941. The medical school changed its name to the “Wake Forest University School of Medicine” in 1997.

Growth and Expansion

Over the years, the school expanded its facilities and programs. It became known for its commitment to excellence in medical education, research, and patient care. North Carolina Baptist Hospital, which is now part of the Atrium Health Wake Forest Baptist health system, played a crucial role in providing clinical training opportunities for medical students.

Wake Forest University School of Medicine and Atrium Health received the needed accreditation approval and notification to proceed with phased plans to open second campus in Charlotte, allowing Wake Forest University School of Medicine to bring nationally ranked education and research programs to students and expand the ability to train the best medical providers for diverse communities. The second medical school campus is currently under development on a 20-acre site in midtown Charlotte, at the corner of South McDowell Street and Baxter Street and adjacent to US-277. The initial class of Wake Forest University School of Medicine – Charlotte’s first-year medical students are anticipated to matriculate in 2025.

In addition to providing outstanding education and supporting research, Wake Forest University School of Medicine – Charlotte will also become a nucleus for collaborative efforts in Charlotte that will bring about

¹ Wake Forest College also moved to Winston-Salem in 1956, and in 1967 changed its name to Wake Forest University
new innovations in health technology and research, much like the Innovation Quarter in Winston-Salem, where the School of Medicine’s Bowman Gray Center for Medical Education is located.

Research and Innovation

The School of Medicine has been at the forefront of medical research and innovation. It has contributed significantly to various fields, including cardiology, cancer research, neuroscience, aging, metabolic conditions, and regenerative medicine. The institution's commitment to research has led to numerous breakthroughs and advancements in healthcare.

Evolving Curriculum

The curriculum at the School of Medicine has adapted to the changing needs of the medical field. It emphasizes hands-on clinical experiences, interprofessional collaboration, and a focus on patient-centered care. Plans for the newer Charlotte campus include a medical school curriculum focused on problem-based learning.

The Wake Ready curriculum was launched in 2017-18 as a result of a comprehensive review, revision, and redesign. This was the culmination of nearly a year and a half of work by faculty, staff, and students at the School of Medicine. Curricular integration is a bedrock of the curriculum. Basic, clinical, and health system sciences are fully integrated with a focus not just on disease but on wellness and preventive care. The Wake Ready curriculum integrates pedagogical methods that develop professionalism, critical thinking, problem solving, and active learning skills through standardized patient encounters, simulated clinics, case-based learning, small-group learning, and peer-assisted learning. The three phases of the curriculum include Foundations (MS1-2, 18 months), Immersion (MS3), and Individualization (MS4).

Expanding Influence

The school's influence and reach have extended beyond North Carolina. It has established collaborations with other medical institutions, research organizations, and international partners, contributing to global healthcare initiatives. The Wake Forest University School of Medicine continues to be a leading institution in medical education and research. It is committed to training the next generation of healthcare professionals, conducting groundbreaking research, and serving the healthcare needs of its community. The school's history is a testament to its enduring commitment to excellence in medicine and patient care.

Wake Forest University Baptist Medical Center and Wake Forest University Health Sciences

In 1975, The Medical Center of Bowman Gray School of Medicine and North Carolina Baptist Hospital was incorporated. This corporation was subsequently re-named Wake Forest University Baptist Medical Center (“WFUBMC”) in 1998. In 2001, Wake Forest University incorporated Wake Forest University Health Sciences (“WFUHS”) and transferred to it the operations of the School of Medicine. On July 1, 2010, Wake Forest University (“WFU”), WFUHS, North Carolina Baptist Hospital (“NCBH”) and WFUBMC entered into the first Medical Center Integration Agreement (“MCIA”). Under the MCIA, all aspects of the operations and assets of WFUHS and NCBH, including subsidiaries, affiliates and joint ventures, were placed under the governance and management of WFUBMC.
Atrium Wake Forest Baptist Health

In October of 2020, WFUBMC and The Charlotte-Mecklenburg Hospital Authority created Atrium Health, Inc. (“Atrium Health”) and each agreed to be managed by Atrium Health through a joint operating agreement known as the Enterprise Agreement. Additionally, WFU, WFUBMC, CMHA and Atrium Health entered into an Academic Affiliation Agreement whereunder, along with the Enterprise Agreement, WFUBMC and specifically through the School of Medicine became the Academic Core of the Atrium Health Enterprise.

Advocate Health

In December of 2022, Advocate Aurora Health and Atrium Health formed Advocate Health, and the parties entered into a joint operating agreement whereunder Advocate manages Advocate Aurora and Atrium Health, and their affiliated entities (such as WFUBMC). Advocate Health focuses on best meeting patients’ needs by refining how, when and where care is delivered. The Advocate Aurora and Atrium Health brands continue to be used in their respective traditional markets, with Wake Forest University School of Medicine serving as the academic core of the combined entity.

In addition to delivering the best health outcomes and making care more accessible and affordable, Advocate Health is committed to being a force for meaningful social impact. The organization aims to bring medical innovations to patients more quickly, address the root causes of health inequities, advance population health, enable career advancement and achieve carbon neutrality by 2030.

STATEMENT OF PURPOSE

The goal of the Wake Forest University School of Medicine is to foster excellence in medical education, research, and patient care. While the specific mission statement may have evolved over time, it encompasses the following key principles:

1. Education: The School of Medicine is dedicated to providing high-quality medical education and training to students, preparing them to become compassionate, competent, and ethically responsible healthcare professionals. This mission includes a commitment to fostering lifelong learning, interprofessional collaboration, and the development of critical thinking skills.

2. Research: The institution is committed to improving health by advancing scientific knowledge and discovery through cutting-edge research across various medical disciplines. This research contributes to the improvement of healthcare practices, the development of innovative treatments, and the overall betterment of human health and health equity.

3. Patient Care: The school aims to provide exceptional patient care through its affiliated healthcare facilities, including Atrium Health Wake Forest Baptist. This mission includes a focus on patient-centered care, clinical excellence, and a dedication to improving the health and well-being of the communities it serves.

4. Community Engagement: The School of Medicine is committed to being actively involved in the communities it serves, both locally and globally. This mission involves addressing healthcare
disparities, promoting public health and health equity, and collaborating with diverse partners to enhance the overall health of the community.

5. Innovation and Service: The School of Medicine encourages innovation in healthcare delivery, medical technologies, and education. It also emphasizes a commitment to service, ensuring that students, faculty, and staff actively engage in improving the health of individuals and communities.

COMMITMENT TO JUSTICE, EQUITY, DIVERSITY, AND INCLUSION

The School is committed to ensuring justice, equity, diversity, and inclusion are woven into its culture and all of its practices. A foundational diversity and inclusion statement provides a basic framework for defining diversity and inclusion for the school.

Diversity and Inclusion Statement

Diversity

Diversity as a core value embodies inclusiveness, mutual respect and multiple perspectives and serves as a catalyst for change resulting in health equity. In this context, we are mindful of all aspects of human differences such as low socioeconomic status, race, ethnicity, language, nationality, sex, gender identity, sexual orientation, religion, geography, disability and age.

Inclusion

Inclusion is a core element for successfully achieving diversity. Inclusion is achieved by nurturing the climate and culture of the institution through professional development, education, policy, and practice. The objective is creating a climate that fosters belonging, respect, and value for all and encourages engagement and connection throughout the institution and community.

PROFESSIONALISM AND PURSUIT OF EXCELLENCE

WFUSM is committed to creating and maintaining an environment that supports and encourages respect for every individual, and promotes the development of professionalism among medical students, residents, faculty, staff and volunteers. All faculty, staff, and learners on the School campuses and across all instructional sites share responsibility for creating a positive and supportive learning environment. Our goal is to create a culture that enhances patient care, learning, scholarship and research, commitment to the health care needs of society, and the ability of all members of the School of Medicine community to interact and carry out their responsibilities in a supportive and respectful fashion.

All faculty, staff, and learners are expected to display and practice professionalism attributes that are core to the WFUSM values such as that are taught and assessed include respect for patients, responsibility in actions, honor and integrity, reverence for human life, compassion, and dedication to teamwork, and ethical decision-making.

PURSUIT OF EXCELLENCE
As a core value, WFUSM strives for the pursuit of excellence for faculty, learners, and staff. Our teams are engaged, empowered, and cared for in order to support the challenge environment in the classroom, clinics, and research space. We support our faculty, learners, and staff in order for them to produce innovative educational, research and health care practices, equipping them to provide exemplary patient care and research discoveries to lead medicine and translational science into the 21st century, making WFUSM the best place to care, learn, teach and discover.

**PRO HUMANITATE**

The School of Medicine aligns its principles with the Wake Forest University motto ‘pro-humanitate’ which is a calling to use our knowledge, talents and compassion to better the lives of others.
CHAPTER TWO

APPOINTMENT, PROMOTION AND TENURE

Wake Forest University School of Medicine (“WFUSM”) seeks to recruit, retain, and promote faculty of the highest caliber. All faculty members are valued, with excellence and professional achievement rewarded with academic promotion as detailed in this document.

This policy applies to all faculty with appointments at the WFUSM. Faculty members appointed to the Clinical Faculty Pathway have additional guidance in the Policy on Appointment as Clinical Faculty.

General Requirements

Appointment of Faculty. Faculty at the WFUSM are primarily comprised of physicians and of research professionals who have achieved academic doctoral degrees in areas of expertise that support the broad educational and research missions of our Institution. This includes candidates with earned PhD, MD, DO, and equivalent doctoral degrees. Practice-based clinical doctorates for allied health clinicians may supplement academic doctorates for traditional faculty appointments, and academic departments primarily focused on the administration of degree-granting programs may have unique needs for a limited number of faculty appointments with specialized expertise. Post-doctoral training appropriate for the area of research expertise is expected for non-clinicians. Residency training and/or Fellowship training with associated Board Certification is expected for physician faculty.

Academic Faculty Pathway Appointments. Appointments to the faculty are made to meet specific academic or clinical requirements which strengthen the Institution and/or replace members of the faculty who have retired or resigned, provided institutional need or strategy supports such replacement. All positions are approved by the Dean and, for clinical faculty practicing within Advocate Health, the appropriate clinical employment leader. Faculty may be appointed, reappointed and/or promoted within one of the following academic track designations:

Tenure Eligible

- Tenure Track

Non-Tenure Eligible

- Research Scholar Track
- Educator Scholar Track
- Clinician Scholar Track
- Clinician Expert Track

Appointment Terms

- For appointment as faculty on any of these academic tracks, clinicians typically have a substantial amount of professional effort within the primary academic practice locations of Advocate Health.
• All initial appointments for faculty members with substantial scholarly effort on the Tenure Track (prior to obtaining tenure) or on any of the non-tenure eligible Scholar Tracks have terms of no more than three years, governed as specified in the policy Appendix found in Policy Tech.

• Faculty members with substantial clinical effort on the non-tenure eligible Clinician Expert Track have initial appointments as agreed by the Department Chair, the President of Wake Forest Baptist Health, and the Dean.

• Faculty members on the non-tenure eligible Research Scholar Track have appointments that are determined by the source(s) of funding, the Department Chair, and the Dean.

• After the initial appointment, non-tenured faculty members may be reappointed for one-year terms, which may be renewed annually. There is no right to reappointment at the end of the term.

• Tenured faculty members have appointment terms governed as specified in the policy Appendix found in Policy Tech.

Initial Appointments. All initial academic appointments are proposed by the Academic Department Chair or Center/Institute Director and approved by the Dean after review by the Faculty Executive Council (FEC), advised by a recommendation from the Committee on Promotions and Tenure (P&T Committee) when the rank at appointment is Associate Professor or Professor. The Atrium Health Wake Forest Baptist President approves the clinical effort associated with the appointment of faculty with clinical responsibilities. Policy guidance for rank at the time of initial appointment is provided in the policy Appendix found in Policy Tech.

Clinical Faculty Pathway Appointments. The Clinical Faculty designation is a non-tenure eligible faculty classification for clinicians who primarily contribute to the mission of our integrated health system through medical practice, teaching, and the recurrent direct supervision of patient care provided by medical students, resident physicians, and other healthcare learners. See the separate Policy on Appointment as Clinical Faculty for specific details about this type of faculty appointment.

Academic Faculty Pathway Tracks. WFUSM has multiple tracks for appointment and academic advancement of faculty. All faculty members on one of the following designated tracks are eligible to be considered for promotion. In addition, those on the Tenure Track are eligible to be considered for tenure.

Adjunct and visiting faculty appointments are not eligible for promotion and do not accrue time in rank towards future promotion or tenure. Faculty members on these tracks have standard academic titles, without modifiers.
The Tenure Track is for faculty members whose main professional focus is scholarship in scientific discovery and innovation. As a general guideline, to be appointed on the Tenure Track faculty members in basic science departments and non-clinical faculty members in clinical departments should have at least 75% effort and clinical faculty members should have at least 50% effort devoted to grant-funded scholarship. Scholarly activities may encompass research activities, or education that involves scholarship beyond teaching excellence. With the agreement of the Chair/Division Director and Dean, certain faculty members may be eligible for tenure with lower percentages of scholarly effort but are evaluated for tenure by the P&T Committee using the same standards of scholarship as faculty meeting the 75/50% standards. Granting of tenure is subject to the criteria and procedure detailed in the policy Appendix found in Policy Tech and is typically requested at the time of promotion to Associate Professor. Faculty members on this pathway are expected to have a significant number of peer-reviewed journal articles and scholarship that demonstrate progression of research activity throughout their career and reflect a high degree of productivity within their individual areas of expertise. Past and current success as well as future outlook regarding extramural funding is an important element for a faculty member’s academic advancement on this track.

The Research Scholar Track is a non-tenure eligible track for faculty involved in time-limited research programs with no or minimal teaching or service responsibilities. Such appointments are primarily contingent on continued extramural research funding for full salary support, depending on the appointment details. These faculty members may have independent funding or participate in collaborative funding efforts with evidence of substantial participation in the development of the collaborative grants. Modest participation in the non-research missions as permitted by the individual faculty member’s effort

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The Tenure Track is for faculty members whose main professional focus is scholarship in scientific discovery and innovation. As a general guideline, to be appointed on the Tenure Track faculty members in basic science departments and non-clinical faculty members in clinical departments should have at least 75% effort and clinical faculty members should have at least 50% effort devoted to grant-funded scholarship. Scholarly activities may encompass research activities, or education that involves scholarship beyond teaching excellence. With the agreement of the Chair/Division Director and Dean, certain faculty members may be eligible for tenure with lower percentages of scholarly effort but are evaluated for tenure by the P&T Committee using the same standards of scholarship as faculty meeting the 75/50% standards. Granting of tenure is subject to the criteria and procedure detailed in the policy Appendix found in Policy Tech and is typically requested at the time of promotion to Associate Professor. Faculty members on this pathway are expected to have a significant number of peer-reviewed journal articles and scholarship that demonstrate progression of research activity throughout their career and reflect a high degree of productivity within their individual areas of expertise. Past and current success as well as future outlook regarding extramural funding is an important element for a faculty member’s academic advancement on this track.

The Research Scholar Track is a non-tenure eligible track for faculty involved in time-limited research programs with no or minimal teaching or service responsibilities. Such appointments are primarily contingent on continued extramural research funding for full salary support, depending on the appointment details. These faculty members may have independent funding or participate in collaborative funding efforts with evidence of substantial participation in the development of the collaborative grants. Modest participation in the non-research missions as permitted by the individual faculty member’s effort
allocation is favorably regarded by the P&T Committee. Faculty members on this pathway are expected to have a significant number of peer-reviewed journal articles (or equivalent scholarly dissemination) and scholarship that demonstrate progression of research activity throughout their career and reflect a high degree of productivity within their individual areas of expertise.

The Educator Scholar Track is a non-tenure eligible track for faculty who are not active clinicians and spend a majority of their effort and scholarly work in educational activities, including pedagogy, education practice, educational research, and/or education administration. Faculty members on this track will generally be expected to have academic doctoral degrees in their field (e.g., Ph. D or Ed.D.). Educational scholarship is valued beyond the activities of high-quality teaching generally required of faculty members. Scholarly products include innovative educational models and practices and scholarly publications in highly regarded journals. Faculty members on this pathway are expected to have a significant number of peer-reviewed journal articles (or equivalent scholarly dissemination) and scholarship that demonstrate progression of scholarly education activity throughout their career and reflect a high degree of productivity within their individual areas of expertise.

The Clinician Scholar Track is a non-tenure eligible track for faculty members who contribute to the clinical mission of the Institution and whose scholarly activities and publications directly relate to clinical practice or innovation, clinical research, and/or clinical education. Faculty members on this track have clinical responsibilities, may have extramural grant funding, and have substantial evidence of peer reviewed publications (or equivalent scholarly dissemination). Innovations related to clinical patient care, clinical research, and/or educational scholarship beyond the high-quality teaching that is required of all faculty members is valued.

The Clinician Expert Track is a non-tenure eligible track for faculty members who primarily contribute to the clinical mission of the Institution through independent clinical practice at a primary academic practice location, where the depth and range of involvement in the educational mission of the Institution is woven into the daily fabric of clinical care. Faculty members are eligible for this track when a vast majority of professional effort is allocated to patient care, leadership, and administrative duties that directly support the clinical academic enterprise. Individuals are evaluated based on a record of outstanding patient care, peer-reviewed and non-peer-reviewed publications (or equivalent scholarly dissemination) related to clinical care, participation in teaching activities, committee leadership at the local/regional/national levels, and extended service time to the Institution (generally applying for a potential promotion review after completing more than 10 years in rank). Scholarly products typically relate to areas of clinical expertise. Veterinarians primarily involved in clinical service in support of the research mission of the School of Medicine may be appointed on this track. This track is not available to non-faculty clinicians.

Joint, Visiting, and Adjunct Faculty Appointments

Veterans Administration Employment. Faculty members who are jointly employed by the Veterans Administration and the School of Medicine are eligible for academic titles, promotion and tenure commensurate with these guidelines. Appointment of these faculty members is proposed by the Academic Chair and VA academic director and approved by the Dean after review by the Faculty Executive Council (FEC). Faculty members with clinical appointments at the Veterans Administration and academic appointments at the School of Medicine are eligible for tenure, provided they have appropriate effort assigned to accomplish scholarly excellence. Tenure for these faculty members refers only to the School of Medicine component of the appointment.
Joint Appointments. Faculty members of the Reynolda Campus of Wake Forest University are eligible for joint appointments in the School of Medicine. Similarly, School of Medicine faculty members may be jointly appointed in departments of the School of Medicine, Wake Forest College, or other Schools of the University in which they do not retain a primary appointment. Appointments are proposed by the School of Medicine Academic Department Chair requesting the joint appointment and approved by the Dean of the School of Medicine and the relevant WFU College or School or Academic Department Chair of the School of Medicine, as appropriate. Jointly appointed faculty members are subject to the promotion and tenure policies of the College or School in which they are primarily appointed, but input may be obtained from the Chair of the WFU or WFUSOM Department in which they have the joint appointment. Tenure (if granted by the primary School) does not extend to the secondary portion of the joint appointment. Joint appointments may be terminated if the reason for the joint appointment no longer exists without affecting the tenure status in the School or College in which a faculty member is primarily appointed.

Visiting Faculty. Visiting faculty who hold an academic appointment at another institution are eligible for a temporary appointment as part of an approved faculty visitation, typically one year or less in duration. Such appointments are not tenure eligible, carry no financial obligation of the academic department to the faculty member, are not eligible for promotion, and do not accrue time in rank towards future promotion. Appointments are approved by the Dean at the faculty member’s current rank from their home institution with the title modifier “Visiting” (e.g., Visiting Associate Professor).

Adjunct Appointments at the School of Medicine. Professional employees of Advocate Health institutions may have adjunct appointments at the School of Medicine to facilitate research and scholarly activities. Adjunct faculty appointments are not eligible for promotion or tenure on other tracks, do not accrue time in rank towards future promotion on other tracks, and carry no financial obligation of the academic department to the adjunct faculty member. Some adjunct appointments may have a departmentally administrated progression of titles, as indicated below. Employment by the Medical Center or affiliate supersedes the adjunct appointment and therefore if Medical Center or affiliate employment is terminated, the adjunct appointment automatically terminates. These appointments may be terminated in the discretion of the Dean if the reason for the adjunct appointment no longer exists.

- **Faculty with concurrent appointments at peer schools of medicine** are eligible for adjunct appointments at the same rank as the primary appointment from their home institution with the modifier “Adjunct” (e.g., Adjunct Assistant Professor). Any subsequent changes to professional title will align with academic progression at the primary institution.

- **Ranked adjunct faculty appointments** are available for physicians and doctoral-level research scientists employed by Advocate Health Institutions, and/or identified community physician practices with formal education and research collaborations. Adjunct faculty members with appointments in this category have standard academic titles, with the modifier “Adjunct.” New adjunct faculty are appointed at the level of Adjunct Assistant Professor. New adjunct faculty with prior academic experience are eligible for appointment at a rank equal to their most recent academic rank (e.g., Adjunct Associate Professor). Ranked adjunct faculty appointments do not accrue time in rank towards future promotion on other tracks and are reviewed periodically for renewal.

  - **Progression of ranked adjunct faculty appointments** are managed at the academic department level. Candidates are eligible to be considered for incremental rank advancement when they have completed at least 6 years in their current rank, have
established a regional reputation (for Adjunct Associate Professor) or a national reputation (for Adjunct Professor), and have sufficient academic achievements to meet department-specific criteria for academic advancement in rank.

- **Adjunct clinical faculty members** Adjunct clinical appointments are not eligible for promotion or tenure, do not accrue time in rank towards future promotion, and are not eligible for academic faculty compensation or benefit plans from WFUHS. Adjunct clinical faculty members are expected to participate in the teaching and/or clinical research missions of the school. Clinical faculty members appointed in this category are designated as “Adjunct Clinical Faculty” without rank designations.

- **Adjunct clinical preceptors** Adjunct clinical preceptors are not eligible for promotion or tenure in other tracks, do not accrue time in rank towards future promotion in other tracks, and are not eligible for academic faculty compensation or benefit plans from WFUHS. Adjunct clinical preceptors are expected to participate regularly in the teaching missions of Advocate Health by providing clinical experiences, mentoring, and educational experiences for healthcare learners in the context of patient care encounters. Progression of adjunct clinical preceptors are managed at the academic department level, using the following rank and title nomenclature:
  - “Preceptor” is the initial adjunct faculty title for new clinical preceptors. Expectations include annual renewal of this adjunct faculty title based on continued service and satisfactory evaluations from learners.
  - Faculty are eligible to apply for academic advancement to the adjunct faculty title of “Senior Preceptor” after 6 or more years of continuous service as Preceptor with regular and ongoing teaching activities with evaluations from learners that exceed expectations. Candidates for advancement must also meet or exceed other departmental requirements. Annual assessment is made for continuation of title.
  - Faculty are eligible to apply for academic advancement to the adjunct faculty title of “Principal Senior Preceptor” after six or more years of continuous service as Senior Preceptor with regular and ongoing teaching activities with evaluations from learners that exceed expectations. Candidates for advancement must also meet or exceed other departmental requirements. This title may also be used to designate leadership positions within the clinical learning framework of an academic program. Annual assessment is made for continuation of title.

- **Adjunct faculty lecturers** are not eligible for promotion or tenure in other tracks, do not accrue time in rank towards future promotion in other tracks, and are not eligible for academic faculty compensation or benefit plans from WFUHS. Adjunct faculty lecturers are expected to participate regularly in the teaching missions of Advocate Health by providing didactic instruction, hands-on experiential learning activities, and other regularly occurring educational experiences for healthcare learners in degree-granting programs of WFUSM and/or WFU. Progression of adjunct faculty lecturers are managed at the academic department level, using the following rank and title nomenclature:
  - “Lecturer” is the initial adjunct faculty title for these adjunct faculty. Expectations include annual renewal of this adjunct faculty title based on continued service and satisfactory evaluations from learners.
  - Faculty are eligible to apply for academic advancement to the adjunct faculty title of “Senior Lecturer” after six or more years of continuous service as Lecturer with regular
and ongoing teaching activities with evaluations from learners that exceed expectations. Candidates for advancement must also meet or exceed other departmental requirements. Annual assessment is made for continuation of title.

- Faculty are eligible to apply for academic advancement to the adjunct faculty title of “Principal Senior Lecturer” after six or more years of continuous service as Senior Lecturer with regular and ongoing teaching activities with evaluations from learners that exceed expectations. Candidates for advancement must also meet or exceed other departmental requirements. This title may also be used to designate leadership positions within a formal course structure for a degree-granting academic program. Annual assessment is made for continuation of title.

**Track Changes.** Changes in an individual job description that are deemed to be permanent may require a change of track designation. However, failure of a faculty member to meet performance standards is insufficient reason to request a change of track unless there is a concomitant change in duties and responsibilities. Faculty members are eligible to change from a tenure track to a non-tenure track (or vice-versa) only one time during their appointment, subject to the conditions below:

1. All proposals for track changes, irrespective of the nature of the change, are submitted in writing by the Chair and the faculty member to the Office of Faculty Affairs. Recommendations for track changes must be made by the Chair or Director and approved by the Dean.
2. A request for track change must be submitted well in advance of upcoming promotion application deadlines. Candidates for promotion are evaluated based on current track at time of application to the P&T Committee.
3. Non-tenure track faculty may request a change to the tenure-eligible track, if scholarly excellence, effort, and extramural funding warrant the change.
4. Individuals on the tenure track may be recommended for change to a non-tenure track within seven years of initial appointment, subject to the needs of the Institution and financial resources. (See section on Tenure; Probationary Period to Tenure, below). However, a tenure track faculty member is committed to remain on the Tenure Track once an application for tenure is submitted to the P&T Committee.

**Promotion.** Academic advancement on any of the available academic tracks that are eligible for promotion requires clear demonstration of scholarly activities related to a candidate’s professional activities.

Faculty members who participate meaningfully in scholarly activities follow the principles of scholarship reflected in the criteria proposed by Boyer (Boyer, EL: Scholarship Reconsidered: Priorities of the Professoriate, 1990, The Carnegie Foundation for the Advancement of Teaching). Work becomes scholarship when it is subjected to peer-review and published or disseminated in some form. In addition, scholarly activity should provide a platform for future scholarly activity or application. Four categories of scholarship are recognized:

- Discovery: traditional scholarship involving research.
- Integration: critical analysis and review of knowledge, including creative synthesis of views and insights regarding the original work of others.
- Application: applying knowledge in the solution of problems, such as in the clinical arena.
- Education: the process of education (developing new pedagogical approaches and curriculum design), beyond demonstrating excellence as a teacher.

1. Promotion Process

Each Department, Division or Institute must have a Promotions and Tenure Committee of senior faculty members, advisory to the Chair/Director, to evaluate candidates for promotion and tenure. The Committee must evaluate each candidate for promotion before the Chair/Director proposes the candidate to the School of Medicine’s P&T Committee. Tenured members of the department advise the Chair/Director on the eligibility of candidates for tenure. If the Dean and Chair/Director determine that there are insufficient numbers of tenured faculty in any department to form a committee, the department chair may seek advice from the tenured members of another department. Small departments may elect to create a joint P&T Committee with another department for the purposes of evaluating suitability of candidates for promotion.

The full institutional P&T Committee evaluates candidates for promotion annually. The Dean’s Office and the P&T Committee provide the timeline and deadlines, together with an outline of the process to the Chairs/Directors each academic year. The P&T Committee may recommend approval or denial of requests for promotion and/or tenure. The P&T Committee provides its recommendations to the Dean, who then makes a recommendation to the President of Wake Forest University, who then makes his or her recommendation to the WFU Board of Trustees. Tenure is granted only by action of the Wake Forest University Board of Trustees. The Chair/Director may appeal recommendations for denial of promotions or tenure to the P&T Committee. If, on appeal, the P&T Committee does not recommend promotion/tenure, the Chair/Director or faculty member may then appeal to the Dean. Further appeals may also be available through the Faculty Grievance Committee, pursuant to the rules and definitions of the grievance policy.

2. General Principles and Guidelines for Promotion

a. Experience has demonstrated that fairness and equity in evaluating an individual for promotion are best achieved through the mature judgment of a balanced committee of senior faculty members from the School of Medicine.

b. Promotions are not automatic but are based on merit and professional achievement. The Promotions and Tenure Committee (P&T Committee) has a responsibility to the institution for maintaining a faculty of highest excellence and also a responsibility to the candidate for just recognition and encouragement of achievement, with a reasonable expectation that scholarship and service will continue in the future.

c. The P&T Committee evaluates each candidate with a holistic review of the individual’s record of scholarship, achievement, and leadership. Candidates are also evaluated for their institutional or professional service and administration, for contributions to the overall development and reputation of the medical school through intramural and extramural scholarly and professional activities, and for service to patients and the community.

d. Each faculty member is evaluated individually and with flexibility in how professional accomplishments and scholarship are demonstrated. While some faculty members emphasize scholarship in one category, others may document scholarship in several different areas. Service at the local, regional, and national levels is valued.
e. Faculty members are expected to be role models for students and junior colleagues. Professionalism, integrity, collegiality, mentorship, and support for the careers of colleagues are recognized. Ongoing formal mentorship of junior colleagues is viewed as strong evidence of institutional citizenship and is favorably viewed for promotions to senior faculty ranks.

f. Candidates for promotion will be evaluated based on the guidelines for their currently assigned academic track. Any recommendations made by the P&T Committee for a candidate to consider a change in track can be addressed by the candidate for a future promotions cycle.

g. Factors considered when evaluating candidates for promotion in all tracks are listed in the policy Appendix found in Policy Tech.

h. Required documents and information for promotion candidates are detailed in the policy Appendix found in Policy Tech.

3. Promotion to Assistant Professor

Faculty members appointed at the rank of Instructor are typically recommended for promotion to Assistant Professor after 1 to 2 years. Promotion to Assistant Professor is recommended by the Chair/Director to the Dean based on early evidence of excellence in academic activities appropriate for the assigned track. The P&T Committee is not required to review candidates for promotion to Assistant Professor.

4. Promotion to Associate Professor and Professor

Faculty members being considered for promotion to the rank of Associate Professor or Professor are evaluated by the Promotions and Tenure Committee according to the faculty member’s assigned academic track with guidance of the additional information detailed in the policy Appendix found in Policy Tech. Candidates for promotion may be asked to submit clinical and education portfolios for P&T review that contain the information detailed in the policy Appendix found in Policy Tech.

APPOINTMENT AS CLINICAL FACULTY

Appointment as Clinical Faculty Policy. Wake Forest University School of Medicine (WFUSM) seeks to recruit, retain, and promote faculty clinicians of the highest caliber. All faculty members appointed to the Clinical Faculty Pathway are valued, with excellence and professional achievement rewarded with academic promotion as detailed in this document.

This policy applies to WFUSM faculty members who are designated and appointed to the Clinical Faculty Pathway. This policy is separate from the Appointment, Promotion and Tenure Policy which takes precedence for those faculty members who are appointed to one of the Academic Faculty promotion tracks.

Appointment of Faculty

Appointments to the Clinical Faculty are made to meet specific clinical, educational, and other requirements which strengthen the Institution and/or replace members of the faculty who have retired or resigned, provided institutional need or strategy supports such replacement.

All Clinical Faculty appointments are approved by the Dean or designee.
Faculty members with clinical patient care duties as the major component of professional effort may be considered for appointment, reappointment, and/or promotion as Clinical Faculty (this policy), Academic Faculty (see Appointment, Promotion and Tenure Policy), or may be eligible for appointment as Adjunct Faculty (also see Appointment, Promotion, and Tenure Policy). This determination will depend on an individual's professional activities, effort distribution, employer, eligibility for faculty appointment, and a recommendation by the appropriate Academic Department Chair in consultation with the Dean, or designee.

**Clinical Faculty Appointments**

The Clinical Faculty designation is a non-tenure eligible (fixed term) faculty classification for physicians who primarily contribute to the mission of our integrated health system through independent medical practice, teaching, and the recurrent direct supervision of patient care provided by medical students, resident physicians, and other healthcare learners.

Clinicians who do not hold a regular faculty appointment at another peer institution, and who are otherwise eligible to be designated as Clinical Faculty can be recommended for such an appointment by the appropriate Academic Department Chair in consultation with the Dean or designee.

Within each clinical discipline, the academic department leadership will have flexibility in the use of this appointment type, within the general parameters defining eligibility and academic promotion criteria. Variable factors may include distribution and quantity of clinical effort, geographic location of patient care activities, administrative or teaching responsibilities, academic expectations, and other professional obligations.

Clinicians in a community practice environment who are otherwise eligible to be considered for a Clinical Faculty appointment may be recommended for such an appointment at the discretion of the appropriate Academic Department Chair in consultation with the Dean, or designee. Such faculty members would report to the Academic Department Chair, or designee, for issues related to teaching, supervision of learners across relevant disciplines, academic activities advancing clinical care, and other faculty appointment related issues.

**Professional titles and academic progression for Clinical Faculty**

- Clinical Instructor
- Clinical Assistant Professor
- Clinical Associate Professor
- Clinical Professor

**Appointment Terms**

- For appointment or reappointment as Clinical Faculty, eligible physicians must have a substantial amount of professional effort providing patient care as well as regular and ongoing teaching activities.
- After the initial appointment, Clinical Faculty members may be reappointed for one-year terms, which may be renewed annually. There is no right to reappointment at the end of a term.
- All initial appointments for Clinical Faculty are proposed by the Academic Department Chair in consultation with the Dean, or designee, and approved by the Dean.
• Information regarding rank at the time of initial appointment is provided in the policy Appendix found in Policy Tech.

• Changes Between Academic and Clinical Faculty Designations

  o Changes in job description, expectations, employer, primary site of practice, and/or professional duties that are deemed to be permanent may lead to a change of faculty designation.
  
  o A change between faculty designations is a process separate from applying for a promotion in rank, and such a change must be approved well in advance of any application deadlines for academic advancement reviews.
  
  o Adjunct faculty being proposed for a full faculty appointment in an Academic Faculty track or in the Clinical Faculty Pathway will be considered and evaluated as a new application for a faculty appointment using the applicable policy and guidelines, as the Adjunct designation does not accrue time in rank towards promotion.
  
  o A faculty member with a current WFUSM faculty appointment in good standing is eligible to request a change between Academic Faculty and Clinical Faculty designations as follows:

    ▪ A change from an Academic Faculty Pathway track to the Clinical Faculty Pathway may be requested if the change is recommended by the Academic Department Chair in consultation with the Dean, or designee.
    
    ▪ Faculty must meet the eligibility requirements for Clinical Faculty Pathway appointment as outlined in this Policy before making such a change request.
    
    ▪ At the time of request approval, the faculty member’s professional title will be changed to include a clinical modifier at the same rank held at the time of the change request. (e.g., “Associate Professor” would be changed to “Clinical Associate Professor”).
    
    ▪ Evaluation for promotion in rank is a separate process (see the policy Appendix found in Policy Tech) and is not performed at the time of this change.
  
  o A change from the Clinical Faculty Pathway category to one of the Academic Faculty Pathway tracks may be requested if the change is recommended by the Academic Department Chair in consultation with the Dean, or designee.

    ▪ Faculty must meet the eligibility requirements for Academic Faculty Pathway as outlined in the separate Appointment, Promotion and Tenure Policy.
    
    ▪ For faculty at the Clinical Associate Professor and Clinical Professor ranks, this change also requires a review by the Committee on Promotions and Tenure to determine the appropriate rank and track after the change for the faculty member. This review will be based on guidelines and standards in place at the time of the request.
    
    ▪ Faculty titles in the Clinical Faculty Pathway category will not automatically align with the same rank in an Academic Faculty track, due to differing expectations and standards for promotion in rank between these faculty designations, and can be recommended at the same or a lower rank at the time of this change. For example, a Clinical Associate Professor requesting such a change may be assigned a new rank of Assistant Professor or Associate Professor based on the outcome of the P&T Committee review process.
    
    ▪ Evaluation for promotion in rank is a separate process (see the policy Appendix found in Policy Tech) and is not performed at the time of this change.
All requests for changes, irrespective of the nature of the change, are submitted in writing by the Academic Department Chair to the Office of Faculty Affairs for review and approval by the Dean.

Promotion

- Academic advancement and promotion in rank for Clinical Faculty requires clear demonstration of excellence in patient care, teaching, and other meaningful professional efforts that contribute to the mission of our Academic Medical Center and Learning Health System.
- Candidates for promotion will have professional activities and achievements that demonstrate a positive reputation outside of our health system:
  - Successful candidates for promotion from Clinical Assistant Professor to Clinical Associate Professor will provide evidence of a favorable regional reputation outside of our integrated health system’s geographic footprint in an area of professional expertise.
  - Successful candidates for promotion from Clinical Associate Professor to Clinical Professor will provide evidence of a favorable national or international reputation in an area of professional expertise.

Promotions Process

- Each Department, Division or Institute will have a committee of senior faculty members, advisory to the Chair, or equivalent, to evaluate candidates for promotion. This committee will evaluate each candidate for promotion before the candidate is presented to the WFUSM review committee.
- An institutional committee designated by the Dean will evaluate candidates for promotion on a regular basis as determined by the Dean’s Office (Faculty Affairs).
- The institutional review committee will advise the Dean with recommendations for approval or denial of promotions based on its current review guidelines and processes.
- The Chair, or equivalent, may appeal recommendations for denial of promotions to the review committee, in writing. If, on appeal, the review committee does not recommend promotion, the Chair, or equivalent, may appeal to the Dean. Further appeals may also be available through the Wake Forest University Grievance Committee, pursuant to the rules and definitions of the grievance policy.

General Principles and Guidelines for Promotion

- Experience has demonstrated that fairness and equity in evaluating an individual for promotion are best achieved through the mature judgment of a balanced committee of senior faculty members from the WFUSM.
- Promotions are not automatic or related only to time in rank but are instead based on merit and professional achievement. The review committee has a responsibility to the institution for maintaining a faculty of highest excellence, and a responsibility to the candidate for recognition of professional achievement with an expectation that excellence in patient care, teaching, and service will continue in the future.
- The review committee will evaluate each candidate with attention to the individual’s record of clinical contributions that meaningfully advance the given specialty,
teaching, achievements, and leadership. Candidates are also evaluated for their institutional and/or professional service.

- Each faculty member is evaluated individually and with flexibility in how professional accomplishments are demonstrated. Service at the local, regional, and national levels is valued, particularly activities that improve patient care through quality and safety initiatives, innovations in healthcare delivery, and excellence in teaching and mentoring.
- Faculty members are expected to be role models for students and junior colleagues. Professionalism, integrity, collegiality, mentorship, and support for the careers of colleagues are recognized.
- Factors considered when evaluating candidates for promotion are listed in the policy Appendix found in Policy Tech.
- Required documents and information for promotion candidates are detailed in the policy Appendix found in Policy Tech.

Promotion to Clinical Assistant Professor. Faculty members appointed at the rank of Clinical Instructor are typically recommended for promotion to Clinical Assistant Professor after 1 to 2 years in rank. Promotion to Clinical Assistant Professor is recommended by the Chair, or equivalent, to the Dean based on early evidence of excellence as a Clinical Faculty member. The review committee is not required to review candidates for promotion to Clinical Assistant Professor.

Promotion to Clinical Associate Professor and Clinical Professor. Faculty members being considered for promotion to the rank of Clinical Associate Professor or Clinical Professor are evaluated by the institutional review committee with guidance and review of the additional information detailed in the policy Appendix found in Policy Tech. Candidates for promotion are required to submit supplemental materials for the committee to review that contain the information detailed in the policy Appendix found in Policy Tech.

PERFORMANCE, PLANNING AND EVALUATION

The annual performance evaluation is a chance for reflection and acknowledgement of faculty performance as well as progress toward goals. Additionally, it is an opportunity to foster a continuous conversation around the well-being and personal/professional development and growth of all faculty members. Faculty members are encouraged to have ongoing conversations with their education and departmental leadership, as well as during the Annual Performance Review process. Please note that faculty members may also be required to participate in performance reviews provided by their employer.

Annual Performance Review

The Annual Performance Review (APR) is intended to promote the discussion of performance and future goals between a faculty member and department leadership. The APR is required for all faculty at the School of Medicine. This policy applies to those with regular and adjunct faculty appointments.

The goal of the APR is to provide a retrospective performance evaluation, an agreement on goals and aspiration for the coming year, and the contribution to the School of Medicine Academic Mission and Atrium Health’s Culture Commitments, and an agreement on shared goals for the future. For faculty involved in supervising learners (e.g., students, house staff, others), the performance review provides
important feedback for continuous improvement and identification of teaching development needs and opportunities. The APR process is intended to benefit the faculty member and the department:

- By documenting a faculty member’s activities and achievements.
- By providing feedback and identifying opportunities as a review of a faculty member’s performance in their assigned roles and on their progress toward academic promotion including but not limited to research and education.
- By defining goals for a faculty member for the upcoming year.
- By identifying and recognizing the faculty member’s contribution to the Academic Mission.
- By identifying and recognizing the faculty member’s contribution to Atrium Health’s Culture Commitments; and
- By defining a plan for academic and professional development. For faculty whose role involves supervision of learners (e.g., students, house staff, others) the performance review is an opportunity to identify, discuss, and develop and action plan for enhancing teaching or assessment skills.

In rare cases, an individual may not concur with their review and may refuse to provide the acknowledgement signature. A signature does not indicate agreement with the assessment. It simply acknowledges that an evaluation conversation has occurred. The faculty member may contact the School of Medicine Vice Dean for Faculty Affairs or the appropriate Human Resources Business Professional if there is a disagreement with the evaluation.

**Adjunct Faculty**

In some cases, Adjunct Faculty members, some of whom who are not employed by the School of Medicine or Atrium Health, are active in teaching or have a substantial commitment to the School of Medicine or Atrium Health Academic Mission. These Adjunct Faculty members are required to receive annual performance reviews under the process outlined below.

Annual Performance Reviews for Adjunct Faculty should be conducted by the School of Medicine Clerkship and/or Course Director in the appropriate discipline/program, or the Department Chair.

For Adjunct Faculty whose role involves supervision of learners (e.g., students, house staff, others) the performance review is an opportunity to identify, discuss, and develop and action plan for addressing teaching or assessment professional development.

In rare cases, an individual may not concur with their review and may refuse to provide the acknowledgement signature. A signature does not indicate agreement with the assessment. It simply acknowledges that an evaluation conversation has occurred. The Adjunct Faculty member may contact the School of Medicine Vice Dean for Faculty Affairs or the appropriate Human Resources Business Professional if there is a disagreement with the evaluation.

**TERMINATION OF APPOINTMENT**

At the discretion of the Dean, the Wake Forest School of Medicine (WFUSM) has a Termination of Appointments Policy in accordance with the procedures listed below.
All faculty with appointments at WFUSM, except this policy shall not apply to the following: (1) tenured faculty (2) adjunct faculty, (3) emeritus faculty, and (4) joint appointments where the initial Wake Forest University appointment is not in the WFUSM.

Guidelines

Appointments may be terminated at any time by voluntary resignation, by expiration of term, by mutual consent, and upon due notice (generally three months). Appointments may be terminated at any time for just cause, such as failure to meet academic requirements, disregard for school policy, physical or mental disability judged incompatible with acceptable standards of academic performance, or moral indiscretion serious enough to affect the reputation of the institution.

The initiation of the process of dismissal for just cause prior to the expiration of a term of appointment rests with the Dean. A Department Chair has the right to lay a charge against a faculty member formally and in writing to the Dean. Any member of the faculty has the right to lay a charge against a faculty member formally and in writing to the Chair of the Department, who must in turn refer the matter to the Dean. The Dean shall have the responsibility for making the decision regarding termination of academic appointment. In arriving at a decision in cases of dismissal for just cause, the Dean shall appoint a committee of senior faculty members to advise on the matter. The accused faculty member has the right to respond formally to the Dean and Chair with respect to the charges and represent her/himself before the committee.

A faculty member whose appointment is terminated prior to the expiration of their term may have additional grievance rights. For additional information about the Faculty Grievance Policy maintained by WFUSM located in this Handbook and in PolicyTech.

EMERITUS FACULTY POLICY

It is the policy of Wake Forest School of Medicine (“WFUSM”), at the discretion of the Dean, to grant Emeritus/Emerita (“Emeritus”) status to retiring faculty at the rank of Full Professor or the rank of Associate Professor, in recognition of distinguished service to WFUSM. Emeritus faculty are encouraged to continue to provide distinguished and productive service to WFUSM. Emeritus Faculty continue to be members of their academic departments and have the right to attend and participate in WFUSM faculty meetings. While retired faculty members who hold emeritus rank may continue to be involved with the WFUSM community and may be employed part-time, as outlined below, emeritus rank in itself does not constitute employment, nor does it confer employment rights or benefits.

General Requirements

- Appointment requirements and guidelines are outlined in the policy Appendix found in Policy Tech.
- Nominations of appointment will be requested by the department leader.

Governance

- Emeritus Academy is managed by Faculty Affairs.
- An appointed body of Emeritus and current faculty make up the Emeritus Faculty Advisory Committee. (policy Appendix found in Policy Tech)
- The EA Director position is appointed, time-limited and voluntary. (policy Appendix found in Policy Tech)
Space and Resources

- Space may be provided upon written request. (policy Appendix found in Policy Tech)
- Office support and resources may be made available upon request.

Emeritus Faculty are encouraged, but not required to:

- Help mobilize and encourage retirees to continue their service to the institution and community.
- Partake in local, national, and international academic activities.
- Participate in internal research.
- Participate in teaching programs (undergraduate, graduate, graduate medical).
- Promote and assist in the establishment of endowments and scholarships for students and student recruitment.
- Mentor faculty and students.
- Serve, as non-voting members, on standing committees of WFUSM in active or ad hoc status.
  - Examples include: The Committee on Undergraduate Medical Education, RB, Risk Management, and the Faculty Representative Council.
  - The Director of Emeritus Academy may participate in the Faculty Executive Council as a non-voting member.
- Attend quarterly academic luncheon meetings with invited speakers; and
- Participate in alumni relations, community outreach and other activities of WFBH.

The following privileges are available to Emeritus faculty:

- Identification badge and email access.
- Parking at WFBMC main Winston-Salem Campus and the Emeritus Academy office.
- Admission to quarterly academic luncheons.
- Access to and inclusion in the Emeritus directory.
- Access to supportive facilities at the same cost as other academic faculty, e.g., Creative Communications.
- Access to Wake Forest University activities, e.g., lectures and sporting events under the same conditions and at the same cost as other academic faculty; and
- Attendance at WFUSM convocation and commencements and participation in processions.

Additional requests may be granted dependent on needs and/or special circumstances. Requests should be sent to the Director of Emeritus Academy and to Faculty Affairs. These benefits include, but are not limited to:

- Inclusion in faculty mailing lists.
- Parking at a WFBH offsite and/or affiliate locations (i.e., Innovation Quarter, Clarkson Campus, etc.); Admittance at WFUSM sponsored postgraduate and educational programs in Forsyth County except for expenses such as meals and materials.
- Invitation to WFUSM functions open to current WFUSM faculty.
- Inclusion as principal investigator on grants with approval of Department Chair and Dean of WFUSM.

VISITING FACULTY POLICY
It is the policy of WFUSM, at the discretion of the Dean, to appoint Visiting Faculty, Visiting Assistant Professors, Visiting Associate Professors, and Visiting Professors (Visiting Faculty) in accordance with the procedures listed below. Visiting Faculty are outstanding scientists, educators, and/or clinicians, who partake in collaborative research and/or contribute to scholarly activities of WFUSM that are on leave from their Primary Academic Institution (Primary Academic Institution) for the time period of the prospective WFUSM appointment (usually for a time period greater than four months and less than one year).

**General Requirements**

- Visiting Faculty must be on leave from their Primary Academic Institution for the time period of the prospective WFUSM appointment (usually for a time period greater than four months and less than one year).
  - Additionally, the appointment from the Primary Academic Institution of the Visiting Faculty must not expire prior to the end date of the WFUSM appointment.
- Visiting Faculty must hold a Comparable Rank at their Primary Academic Institution.
- Visiting Faculty must comply with all policies of Advocate Health and WFUSM.
- Visiting Faculty must use the modifier "visiting" whenever referencing their faculty status.
- Funding for Visiting Faculty generally comes from external or personal sources outside of WFBH and WFUSM.
- Any use of WFUSM funds applicable to the appointment of the Visiting Faculty must be designated by the Dean of WFUSM, after appropriate consultation with the Sponsoring Department Chair.

**Appointment Procedure**

- Visiting Faculty are appointed for renewable terms not to exceed twelve months and with no commitment for appointment to the permanent faculty at WFUSM.
- The Sponsoring Department must assure that candidates for the title of Visiting Faculty meet all criteria listed within this policy.
- The appointment of Visiting Faculty must be conducted in a manner consonant with similar faculty appointments for faculty at WFUSM.
- Candidates for the title of Visiting Faculty must submit to the Sponsoring Department Chair:
  - Two letters of support from individuals with equivalent or higher Academic Rank that understand the candidate's individual academic pursuits.
  - A curriculum vitae.
- The Sponsoring Department Chair must submit to the Dean of WFUSM:
  - The Visiting Candidate's two letters of support; and
  - The Visiting Candidate's curriculum vitae; and
  - Faculty Requests.
- Visiting Faculty candidates must fulfill all onboarding requirements of WFBH Contingent Workforce. See the Non-Employee Access Policy.
- All Visiting Faculty candidates must have documentation of health insurance applicable in the United States, either arranged through WFUSM or acceptable to WFUSM, or from their country of origin and acceptable to WFUSM.
- If the Visiting Faculty candidate will practice medicine while at WFUSM:
  - Accreditation/licensure requirements of the North Carolina Medical Board must be met; and all requirements for Atrium hospital privileges and for billing of professional services must be
met; and proof of liability insurance coverage applicable in North Carolina is required, or the Sponsoring Department Chair shall arrange for coverage to be provided in North Carolina.

- Visiting Faculty will not have benefits provided and/or paid for through Atrium Health. Salary and sources of research funding will not be provided and/or paid for by Atrium Health or WFUSM.
- Visiting Faculty candidates from other countries must have:
  - A valid visa appropriate for their roles at WFUSM and/or Atrium Health.

Appointment Renewal

- Renewal options for appointments of Visiting Faculty will be at the discretion of the Dean of WFUSM and Sponsoring Department Chair.
CHAPTER THREE
GOVERNANCE

SCHOOL OF MEDICINE GOVERNANCE

The source of operating authority for the Wake Forest University School of Medicine (WFUSM) is Wake Forest University (WFU or the University) and its Board of Trustees (BoT).

Dean of the School of Medicine

The Dean of the WFUSM (the Dean) is appointed upon the concurrence of the WFU President, the WFBMC CEO (if different from the CAO) and the CAO (after consultation with the Atrium CEO).

The Dean has authority over the academic programs and activities of the WFUSM including presiding over faculty matters and, subject to the consent of the WFBMC CEO, appointing WFUSM Department Chairs.

The Dean consults with the CAO with respect to budgetary and other financial matters, such as setting medical school tuition and developing and adopting budgets as further addressed elsewhere in the Related Agreements (including any budget approval rights set forth therein). The Dean has such responsibilities and authorities as are customarily associated with the role of medical school Dean and as set forth in her or his WFUSM job description, her or his employment agreement, the policies of WFU and WFUSM, and as required by the LCME.

Department Chairs; Directors of Divisions, Institutes and Centers

- Department Chair: Each department is administered by a Chair, who is appointed by the Dean and for clinical departments, also by a clinical leader. Chairs are appointed for a five-year term and serve at the pleasure of the Dean, and for clinical departments, also at the pleasure of the clinical leadership at their place of employment.

- The reporting structure of Department Chairs varies on location. Department Chairs in Winston-Salem are responsible to the Dean and, among clinical departments, to the President, Atrium Health Wake Forest Baptist for clinical service and related matters. In the Greater Charlotte Region, Department Chairs are responsible to the Dean, and among clinical departments, to the Chief Physician Executive of Atrium Health for clinical service and related matters.

- A Department Chair represents her or his Department before the Dean, making recommendations as to appointments, promotion, faculty development, curriculum, research, budgets, and related matters. For clinical departments, the Chairs in Winston-Salem are responsible to the President, Atrium Health Wake Forest Baptist for clinical service and related matters; the Chairs in the Greater Charlotte Region are responsible to the Chief Physician Executive of Atrium Health. For matters related to graduate medical education, Department Chairs in Winston-Salem are responsible to both the Dean and the President of Atrium Health Wake Forest Baptist; Chairs in the Greater Charlotte Region are responsible to both the Dean and the Chief Physician Executive of Atrium Health.

- Directors of Division: Appointments of Directors of Divisions and department-based centers are made in accordance with the process for appointments of Department Chairs. Responsibilities of Directors
of Divisions and department-based centers are consistent with those of Department Chairs with the exception of graduate medical education.

- Center and Institute Directors are appointed by the Dean and serve at the pleasure of the Dean without term. They are responsible for accomplishing the goals of the Center as developed and directed by the Dean.

**Departments, Divisions, and Institutes**

- Departments are formed and dissolved by the Dean with advice from the Faculty Executive Council (FEC, council is comprised of all Enterprise Academic Department Chairs, Regional Academic Department Chairs and Center Directors) and, for departments with a clinical mission, in consultation with the President, Atrium Health Wake Forest Baptist for Winston-Salem based Departments, and the Chief Physician Executive for the Greater Charlotte Region Departments. Faculty members have primary appointments in a given Department, Division or Institute and may have secondary appointments in other Departments, Divisions, Institutes or Centers.
  - The Departments of the School of Medicine are:
    - Academic Nursing Winston-Salem Campus
    - Anesthesiology Winston-Salem Campus
    - Biochemistry Winston-Salem Campus
    - Biomedical Engineering Winston-Salem Campus
    - Cancer Biology Winston-Salem Campus
    - Cardiothoracic Surgery Charlotte Campus
    - Cardiothoracic Surgery Winston-Salem Campus
    - Dermatology Winston-Salem Campus
    - Emergency Medicine Charlotte Campus
    - Emergency Medicine Winston-Salem Campus
    - Family and Community Medicine Winston-Salem Campus
    - Family Medicine Charlotte Campus
    - Internal Medicine Charlotte Campus
    - Internal Medicine Winston-Salem Campus
    - Microbiology & Immunology Winston-Salem Campus
    - Neurobiology & Anatomy Winston-Salem Campus
    - Neurological Surgery Winston-Salem Campus
    - Neurology Charlotte Campus
    - Neurology Winston-Salem Campus
    - Obstetrics & Gynecology Charlotte Campus
    - Obstetrics & Gynecology Winston-Salem Campus
    - Ophthalmology Winston-Salem Campus
    - Oral Medicine Charlotte Campus
    - Orthopedics Charlotte Campus
    - Orthopedic Surgery Winston-Salem Campus
    - Otolaryngology Winston-Salem Campus
    - Pathology Winston-Salem Campus
    - Pediatrics Charlotte Campus
- Pediatrics Winston-Salem Campus
- Physical Medicine and Rehabilitation Charlotte Campus
- Physician Assistant Studies Winston-Salem Campus
- Physiology & Pharmacology Winston-Salem Campus
- Plastic and Reconstructive Surgery Winston-Salem Campus
- Psychiatry & Behavioral Medicine Charlotte Campus
- Psychiatry & Behavioral Medicine Winston-Salem Campus
- Radiation Oncology Winston-Salem Campus
- Radiologic Sciences Winston-Salem Campus
- Surgery Charlotte Campus
- Surgery Winston-Salem Campus
- Urology Charlotte Campus
- Urology Winston-Salem Campus
- Vascular and Endovascular Surgery Winston-Salem Campus

- The Divisions are:
  - Public Health Sciences
    - Departments within Public Health Sciences
      - Biostatistical Science
      - Epidemiology and Prevention
      - Implementation Science
      - Social Sciences and Health Policy
  - Institutes are:
    - Wake Forest Institute for Regenerative Medicine
    - Wake Forest School of Medicine Clinical and Translational Science Institute

- Research Centers and Cores

Research Centers and Cores are formed by the Dean on recommendation of the Centers and Cores Advisory Committee. Faculty appointments are approved by the Dean upon the recommendation of the Center/Core Director and the Chair/Director of the faculty member’s primary Department/Division/Institute.

STANDING COMMITTEES

WFUSM committees provide leadership and oversight to various segments of the academic mission areas, including education, research regulatory requirements, and faculty shared governance. All committees are advisory to the Dean of WFUSM. Faculty representatives are appointed or peer-selected for committee service.

WFUSM has two types of committees - Standing Committees, which are required by the Wake Forest University Bylaws and charged by such, and Ad-Hoc Committees which are charged by the Dean of WFUSM and the Faculty Executive Council (FEC) for special projects or purposes and for a defined period of time.

The following constitute the Standing Committees of the Faculty of WFUSM:

Governance Committees
• Faculty Executive Council (Appointed)
• Faculty Representative Council (Peer Selected)

**Education Committees**

• Academic Assessment Committee (Appointed)
• Brooks Scholarship Advisory Committee (Peer Selected and Appointed)
• Committee on Admissions (Peer Selected and Appointed)
• Continuing Medical Education Committee (Peer Selected)
• Graduate Medical Education Committee (Appointed)
• Graduate School of Arts and Sciences: Biomedical Sciences Committee (Appointed)
• PA Student Progress Committee (Peer Selected and Appointed)
• Professional/Academic Dismissal: Appeals Committee (Appointed)
• Student Professionalism and Academic Review Committee (Peer Selected)
• Undergraduate Medical Education Curriculum Committee (Peer Selected)

**Operations and Compliance Committees**

• Atrium Health Wake Forest Baptist Title IX and Clery Steering Committee (Appointed)
• Committee on Outside Activity (Appointed)
• Conflict of Interest Review Committee (Appointed)
• Veteran’s Affairs Dean’s Committee (Appointed)

**Faculty Support/Advisory**

• Promotions and Tenure Committee (Peer Selected)
• Women in Medicine and Science Committee (Peer Selected)
• Emeritus Academy Advisory Committee (Peer Selected and Appointed)
• Faculty Development Committee (Peer Selected)
• Faculty Legal Advisory Committee (Appointed)

**Research Committees**

• Animal Research Security Committee (Appointed)
• Chemical Safety Committee (Peer Selected and Appointed)
• Institutional Animal Care and Use Committee (Peer Selected and Appointed)
• Institutional Biosafety Committee (Peer Selected and Appointed)
• Institutional Data and Safety Monitoring Board (Peer Selected and Appointed)
• Institutional Review Board (Peer Selected and Appointed)
• Intramural Research Support Committee (Peer Selected and Appointed)
• Radiation Safety Committee (Appointed)
• Research Advisory Committee (Peer Selected and Appointed)
• Research Operations Committee (Peer Selected and Appointed)

**WFU Committees with WFUSM Representations**

• Academic Freedom and Responsibility Committee (Peer Selected)
• Faculty Grievance Committee (Peer Selected)
• Wake Forest University Senate (Peer Selected)

The charge, membership and other details for each committee can be found on the Standing Committees Intranet Page.

Standing Committee General Requirements

• The Dean of WFUSM shall approve the mission and charge of all Standing Committees.
• All Standing Committees are advisory to the Dean or the Dean’s designated Vice Dean.
• Standing Committee terms begin July 1. Members serve for a three-year term, which may be renewed once. Exceptions include some committees with customized terms specified in the appropriate charter.
• Appointments shall be restricted to members of the faculty. Instructors on Standing Committees must have had at least one year in rank as a faculty member.
• Appointments will take into consideration: academic pillar, special interests, experience, expertise, current administrative workload as well as departmental representation and continuity of committee membership.
• Community representatives who are not members of the faculty may be appointed to Standing Committees when it is a matter of compliance with law or when it is deemed to be in the best interest of the school or university.
• Students in any of the educational programs of WFUSM may be appointed to Standing Committees when it is a matter of compliance with accreditation standards or deemed to be in the best interest of the school or university.
• Standing Committees are given a charge by the Dean for the function of the committee.
• Standing Committees may be comprised of the following members: Appointed, Elected, Ex Officio, Ex Officio without a Vote and Advisory.
• The Standing Committees’ charters and lists of membership will be available to faculty on the WFUSM website.

Standing Committee Appointments

The WFUSM Dean Standing Committees consist of faculty members who have been peer selected and/or appointed. Standing Committee members who are peer selected will follow the following process:

• Each Standing Committee may update the Committee’s Mission and Charge Document for the upcoming Academic Year. Substantive changes are approved by the Dean or Dean’s designee.
• The Faculty Representative Council-Strategy Subcommittee (FRC-SS) will facilitate the nomination and election process on an annual basis.
• A call for nominations will be issued by the Dean’s Office. Faculty will have a minimum of three weeks to provide nominations for roles on standing committees. Faculty may have the opportunity to self-nominate or to nominate others. Faculty members must identify no more than TWO categories of committees in which they are willing to serve.
  o Education Committees
  o Evaluation & Selection Committees
  o Faculty Governance Committees
  o Research Committees
WFU Committees with WFUSM representation

- Department Chairs will have an opportunity to provide feedback for each of their faculty members nominated for Standing Committee Service. Feedback will include “recommended” or “not recommended” based on the nominee’s special interests, experience, expertise, and current administrative workload. In addition, Chairs provide input on candidates from prior collaborations and experiences.

- Committee members who have not been active are offered the opportunity to withdraw before their term ends, providing the opportunity to backfill the position.

- The FRC-SS will review nominations and candidate bios and propose selection for service based on needs.

- The FRC-SS Chair will vet the peer-selected members with the WFUSM Office of Faculty Affairs (OFA) leadership. Once approved, the Dean Welcome Letter will be sent to all new and renewing members. Candidates will have seven days to decline. In the case of decline response(s), the FRC-SS and OFA will have no more than 10 days to propose substitute candidates.

- Once finalized, the FRC-SS will provide the roster to each Standing Committee Chair.

- OFA will provide communication to candidates not selected for Standing Committee Service.
CHAPTER FOUR

CODE OF CONDUCT

As the academic anchor of Advocate Health, WFUSM is driven to uphold ethical and legal responsibility to act in ways that protect the best interests of our patients and research, including following relevant and applicable laws, rules, and regulations. Adhering to Advocate Health’s Code of Conduct, and in conjunction with WFUSM policies and guidelines, the School is committed to an ethical culture of compliance and integrity by providing faculty with clear expectations and resources needed to provide operational excellence and exceptional education, research, and patient care.

Advocate Health Code of Conduct

EQUAL OPPORTUNITY/NON-DISCRIMINATION

The Wake Forest University School of Medicine complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, religion, national origin, age, sex, sexual orientation, gender identity, gender expression, disability, or veterans status. The Wake Forest University School of Medicine is committed to maintaining an educational and working environment free of discrimination.

To report concerns of discrimination contact:

- Human Resources/Teammate Relations for your employer:
  - Atrium Health Wake Forest Baptist teammates may call the HR Service Center at 336-716-6464 or report concerns through the online portal.
  - Atrium Health Greater Charlotte teammates may call the HR Service Center at 704-631-1500 or report concerns through the online portal.

To report concerns of sex-based discrimination or harassment in education programs and activities contact:

- Wake Forest University Title IX Coordinator: File a report using the online form [cm.maxient.com], which is routed to the Reynolda Campus Title IX Office.
- Kim Caprio, Deputy Title IX Coordinator for AHWFB employees, at kcaprio@wakehealth.edu.

Faculty members may refer to their employer’s policies pertaining to equal opportunity and non-discrimination for additional information.

INFORMATION SECURITY POLICY

The purpose of this policy is to protect the confidentiality, integrity, and availability of sensitive data and assets by implementing administrative, technical, and physical information security controls, processes, and best practices. This policy establishes an information security framework to appropriately secure
access to Atrium Health information resources and services. Adherence to this policy will help to protect Atrium Health, our patients, and our workforce from information security threats, whether internal or external, deliberate or accidental. This policy complements and supports other institutional policies that protect information assets and resources. This policy is intended to prevent inappropriate use and dissemination of sensitive information, including but not limited to Protected Health Information (PHI), and to comply with the requirements of applicable state and federal laws and regulations.

Guidelines

Enterprise Cybersecurity is responsible for the guidance, direction, and authority for information security activities for Atrium Health. It will develop an Information Security Program to implement any requirements outlined within this and other supplemental policies.

Enterprise Cybersecurity will oversee development and ongoing review of subsequent and supplementary security policies and standards; will promote information security awareness; and will monitor the information security program to validate its effectiveness.

• Standards and procedures relating to cybersecurity and technology will be periodically reviewed and updated. Updates may supersede previous standards but will remain consistent with the governing principles of this policy.
• Enterprise Cybersecurity will have authority to issue revisions and new standards as necessary to reflect changes in the technical environment or the regulatory environment.
• Enterprise Cybersecurity will develop and implement policies and standards in accordance to applicable local, state, and federal laws and regulations. This policy is intended to supplement those laws and regulations.
• Enterprise Cybersecurity will maintain a series of supplemental policies and standards. They will have authority to issue revisions and new standards as necessary to reflect changes in the enterprise technical environment or the regulatory environment.

Information collected and/or generated shall be maintained in such a manner that access to sensitive information is restricted to authorized individuals with a need-to-know.

• The use of sensitive information is for authorized business purposes only.
• The handling of sensitive information must be in accordance with Atrium Health’s Acceptable Use Policy and other applicable institutional policies.
• The release of sensitive information is in compliance with applicable state and federal laws and regulations.

Personally owned computers and electronic devices are not allowed to connect to the enterprise network(s) unless they are authorized by Enterprise Cybersecurity based on approved business needs or are within the limits of policies governing the use of personal electronic devices.

Physical and logical security must be maintained throughout the life cycle of sensitive information regardless of:

• The media on which sensitive information is stored (paper, computer/electronic, CD/DVD, USB drives, etc.)
- The information systems which process sensitive information (personal computers, voice mail systems, etc.)
- The methods by which sensitive information is moved (electronic mail, face-to-face conversation, memos, etc.).

All new information systems that will store or have access to sensitive information must meet minimum cybersecurity requirements, as determined by this policy and any supplemental policies, standards, or procedures as a condition of purchase.

- A periodic audit/review may be required for all computer-related platforms and systems containing sensitive information.

Teammates are required to complete cybersecurity training. Teammates must understand and comply with this policy as well as all supplemental cybersecurity policies and standards. The need for adherence to this policy should be continually reinforced by leadership.

Access to information systems audit and monitoring tools shall be protected to prevent any possible misuse or compromise.

The application, server, and/or system owner is responsible for the cybersecurity of their respective system(s) and must ensure compliance with all departmental policies.

Violation or abuse of this policy may be grounds for disciplinary action, up to and including employment or contract termination as well as possible civil and criminal penalties. Violations will be referred to Human Resources, Office of Student Affairs, Faculty Services, Office of Audit and Compliance, or Legal Department as appropriate.

Policy exceptions may be requested for all Enterprise Cybersecurity policies and standards where a business need arises. Requests must have a documented requester, risk assessment, policy in conflict, reason/justification, compensating controls (if possible), and approval from the requester’s management. Exception approvals are granted by the CISO or appointed designee for a maximum period of one year.

**CHARGES, CONVICTIONS, OR SANCTIONS**

The Wake Forest University School of Medicine strives to create an environment where those seeking care, learning, or working here feel safe. If a faculty member receives a criminal charge, conviction, or a sanction, this potentially creates a safety and security issue in the work environment. This may also trigger actions that must be taken by law. For these reasons, faculty members are required to immediately report any criminal charge, conviction, or sanction to their WFUSM leader, Academic Department Chair, the WFUSM Deans Office, the Office of Faculty Affairs, and their employer’s Human Resources/Teammate Relations department.

**CONFLICT OF INTEREST**

**General.** The purpose of this policy is to provide guidelines for establishing principled personal outside relationships with industry and other organizations and to establish rules for personal interactions with Industry, health care industry representatives and other vendors throughout WFUSM defined as Wake Forest University Health Sciences (WFUHS) and North Carolina Baptist Hospital (NCBH) and their controlled affiliates, while remaining in compliance with disclosure, management and approvals. The
Institution supports principled relationships with industry and other organizations in which its faculty, clinical providers and staff collaborate. The Institution has adopted this policy to promote the public’s trust in the Institution’s role in healthcare, research, and education. The policy supports the highest level of patient care, integrity of research, safety of human subjects, objectivity of education and the reputations of faculty, clinical providers, and staff.

Faculty, clinical providers and exempt employees are required to disclose to the Institution any outside interests, including financial relationships with Industry or other outside organizations, that are related to Institutional duties. This includes disclosure of family members’ outside interests with entities that do business with the School. The Conflict of Interest Office will assist Individuals to determine if there is an appearance of conflict of interest, to manage any associated conflicts of interest which might arise in personal outside relationships, and to eliminate those conflicts that cannot be effectively managed.

Conflict of Interest and Disclosure. The institution requires faculty, clinical providers, and exempt employees to disclose both research and non-research related outside interests, regardless of the value or income received. Disclosures are collected upon new hire and each April through an online process and must be completed within 30 days of receipt of the reminder notification from the Conflict of Interest Office. All annual disclosures will be reviewed by the Individual’s Department Chair/Section Head/Director/Manager as defined by HRIS. In the case of Department Chairs, the Dean of the Medical School will perform the review. Please note that leaders are expected to disseminate information about significant conflicts of interest for their direct reports to the appropriate superior leadership.

Upon disclosing outside interests, the Individual will cooperate with the COI Office to mitigate potential conflicts of interest, and the CIRC to manage significant conflicts of interest. Individuals must update their disclosure within 30 days of a substantial change in external relationships or activities.

Additional required disclosures:
- Disclosure of project specific relationships is required with submission of grants, contracts, and regulatory protocols.
- Disclosure of outside relationships is required when submitting requisitions to Institutional procurement committees.
- Significant conflicts of interest in clinical research require disclosure of the conflicting relationship to the human subjects enrolled in the project.
- Public disclosure of outside interests is required for all publications (including news releases), presentations (including posters) and approved media contact related to an Individual’s outside relationship or financial interests.
- Prior to sponsored professional travel, the Individual will disclose the Sponsor’s name, the destination, purpose, and duration of travel by fully completing the Travel Authorization.
- Clinicians with past and/or present financial relationships with Industry (e.g., consulting and speaking agreements, research contracts) should disclose relationships to patients when such a relationship might appear to be a significant conflict of interest.
- Disclosure of all financial interests will be made by standing committee members to their committee(s). Committee members with a financial interest in a sponsor or vendor will recuse themselves from voting on decisions involving the entity in which they have an interest.
**Conflict of Interest in Research.** On behalf of the Conflict of Interest Review Committee (CIRC), the COI Office evaluates all disclosures of outside interests, including a review of related research projects to determine if a significant financial interest (SFI) may be a conflict of interest on sponsored research and if a FCOI exists for PHS-funded research.

- If the COI Office determines that a FCOI exists on PHS-funded research, the CIRC reviews the design, conduct, and reporting of the research to determine and implement the appropriate management process and Federal reporting in accordance with PHS Regulations 42 CFR, Part 50, Subpart F and 45 CFR, Part 94, to protect the credibility and integrity of the Institution and its faculty, clinical providers and staff.

- If the COI Office determines that a SFI exists for non-PHS sponsored research, it reviews the design, conduct and reporting to determine and implement the appropriate management process to protect the credibility and integrity of the Institution and its faculty, clinical providers, and staff.

  - **Human Subject Research:** If a conflict of interest is identified in research involving human subjects, the Institutional Review Board (IRB) and CIRC will conduct their respective reviews in parallel, and the IRB will withhold final approval pending the completion of the CIRC review, resolution of the issues and recommendations for management.

  - **Compliance with PHS Regulation 42 CFR, Part 50, Subpart F and 45 CFR, Part 94.**

Prior to the expenditure of funds and within 60 days of any subsequently identified FCOI on PHS-funded research:

- The Institution shall adhere to its publicly available policy and provide reports regarding identified FCOI to the PHS Awarding Component in accordance with the Institution’s own standards and within the timeframe prescribed by this regulation.

- Designate an Institutional official(s) to solicit and review disclosures of Financial Interests from each Investigator who is planning to participate in, or is participating in, the PHS-funded research. The designated official is responsible for determining if a Significant Financial Interest exists, and whether or not it constitutes a Financial Conflict of Interest per PHS Regulations 42 CFR, Part 50, Subpart F and 45 CFR, Part 94.

- The Institution will ensure that each Investigator is informed of its policy on FCOI, the Investigator’s responsibilities regarding disclosure of SFI’s, and of these regulations. Each Investigator is to complete training regarding FCOI requirements prior to engaging in research related to any PHS-funded contract and at least every four years, and immediately when any of the following circumstances apply:
  - The Institution revises its FCOI policies or procedures in any manner that affects the requirements of Investigators
  - An Investigator is new to the Institution
  - The Institution finds that an Investigator is not in compliance with the Institution’s FCOI policy or management plan.

- If an Investigator carries out PHS-funded research through a subrecipient (e.g., subcontractors, or consortium members), the Institution will take reasonable steps to ensure subrecipient Investigator compliance through:
• A written agreement with the subrecipient that establishes whether the FCOI policy of the awardee Institution or that of the subrecipient will apply to the subrecipient’s Investigators.
• The CIRC will provide FCOI reports to the PHS Awarding Component regarding all FCOI of all subrecipient Investigators consistent with this regulation.

  ▪ If an Investigator’s SFI is related to PHS-funded research:
    • The CIRC determines if the SFI could be affected by the PHS-funded research, or is in an entity whose financial interest could be affected by the research.
    • The CIRC determines if a FCOI exists when the SFI could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.

  ▪ Identification of an FCOI initiates development and implementation of a management plan by the CIRC and, if necessary, a retrospective review and mitigation report pursuant to § 94.5(a).
  ▪ The Institution provides initial and ongoing FCOI reports to the PHS awarding component as required pursuant to § 94.5(b).
  ▪ The Institution maintains records relating to all Investigator disclosures of financial interests, the CIRC’s review of, and response to, such disclosures, and all actions under Institutional policies or retrospective review, if applicable, for at least three years from the date of the final expenditure of funds.
  ▪ The Institution maintains enforcement mechanisms and provides sanctions and other administrative actions to ensure Investigator compliance as appropriate.
  ▪ The Institution ensures public accessibility, via written response to any requestor within five business days of a request, for information concerning any SFI disclosed to the Institution that meets the following three criteria:
    • The SFI was disclosed and is still held by Investigator
    • The Institution determines that the SFI is related to the PHS-funded research
    • The Institution determines that the SFI is a FCOI

  ▪ The information available via written response to any requestor within five business days of a request shall include, at a minimum, the following: Investigator’s name,
    • Investigator’s title and role with respect to the research project,
    • Name of the entity in which the SFI is held,
    • Nature of the SFI, and
    • Approximate dollar value of the SFI, or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

Permitted Outside Employment/External Professional Relationships Requiring Prior Approval
• Outside employment is evaluated primarily by departmental leadership through prior approval requests and in compliance with the Conflict of Commitment Policy (see section 1 – Outside Employment).

• Certified continuing education is either evaluated through the institution’s CME Office or must adhere to their same policies if certified outside the institution (see section 2 – Certified Continuing Education (CCE) Activities).

• Under the guidance of the Conflict of Interest Review Committee (CIRC), the COI Office evaluates
  o Requests for non-certified education funded by Industry (see section 3 – Attending, Organizing or Speaking for Non-Certified Educational (non-CE) Events Sponsored by Industry).
  o Requests for travel funding received by Industry (see section 4 – Receiving Travel Funding from an Industry Sponsor for Special Circumstances).
  o Other reported outside relationships, including equity in faculty start-up companies (see section 5 – Licenses, Royalties, and Equity and Engaging in a Start-up Company).

• For prior approvals the COI Office may grant approval based on guidelines established by the CIRC, or may determine that a request needs additional review by the CIRC.

• Outside Employment. Individuals who wish to undertake outside employment (generally requiring considerable effort, earning equity or income, and/or related to institutional responsibilities), including but not limited to consulting, expert witness activities, personal businesses and advisory boards must consult the Conflict of Commitment Policy, complete an Outside Employment Request for each separate entity, and obtain prior approval from his or her departmental leadership.

Specific requirements for undertaking Outside Employment are found in the Conflict of Commitment Policy. Departmental leadership will review Outside Employment Requests for the appropriateness of the activity, if the activity serves the mission of the Medical Center, and the time to be spent outside of institutional responsibilities. Final review for COI policy compliance is available through the Conflict of Interest Office, at the request of the department leader.

• Certified Continuing Education (CCE) Activities. To ensure that potential for bias is minimized and that CCE programs are not a guise for marketing or off-label promotions, all CCE events receiving Industry support or Industry sponsorship that are hosted, sponsored, or jointly sponsored by the Medical Center must comply with the 2004 Updated Accreditation Council for Continuing Medical Education (ACCME) Standards for Commercial Support of CME: Standards to Ensure the Independence of CME Activities (or other similarly rigorous, applicable standards required by other health professions). All such Industry supported activities must comply with the Wake Forest University School of Medicine (WFUSM) (“WFUSM”) Office of Continuing Medical Education (“CME”) policies. Any such educational activity must be open on equal terms to all interested practitioners, and may not be limited to attendees selected by the company supporter(s).

• Attending, Organizing or Speaking for Non-Certified Educational (non-CE) Events Sponsored by Industry. Unless covered under a contractual agreement previously approved by his/her supervisor, an Individual who wishes to attend, organize or conduct speaking for a non-CE meeting, conference, or other activity that is fully or partially sponsored by Industry must follow
the guidelines for the specific activity found in the policy Appendix found in Policy Tech and complete the appropriate prior approval request documents.

- Receiving Travel Funding from an Industry Sponsor for Special Circumstances. Any Individual who has been offered travel funding from an Industry sponsor to view capital equipment or for specialized training on capital equipment/devices must obtain prior approval from his or her supervisor and the COI Office.

Prior approval is required if the travel meets one of the following circumstances:

- To view capital equipment in situ if the equipment is being considered for purchase by WFBMC; must submit request for prior approval by the Chair/Section Head/VP/Director (Industry-Funded Travel to View Capital Equipment or for Specialized Training).
- To participate in initial and ongoing education necessary to operate or use products and devices which require specialized expertise and are currently being used at the Institution; must submit request for prior approval by the Chair/Section Head/VP/Director (Industry-Funded Travel to View Capital Equipment or for Specialized Training).

Prior approval is not required if the travel meets one of the following requirements:

- For reimbursement for travel to provide contractual services, such as approved consulting that has been approved by Chair/Section Head/VP/Director through an Outside Employment Request.
- To participate in meetings directly related to the initiation of sponsored research or ongoing sponsored research covered under a research agreement.
- Receipt of travel funds from scientific societies, even if Industry is the source of the funds, provided that the society controls the selection of the recipient of the travel support.

- Licenses, Royalties, and Equity and Engaging in a Start-up Company. Individuals must report proposed outside professional relationships with Industry and other entities related to their areas of expertise and professional duties, including start-up companies, in which they expect to receive royalties or equity, regardless of the value, or under which they are or WFBMC or WFUHS is expected to assign, license, or otherwise transfer rights in WFBMC- or WFUHS-owned technology or copyrights, as set forth in the Intellectual Property Policy. These relationships must be reported in advance to the appropriate Department Chair/Section Head/VP/Director for review and approval prior to agreeing to, engaging in, or accepting income for the activities.

Prohibited Personal Professional External Activities with Industry and Other Entities

- Speaker’s Bureaus. Individuals may not participate in promotional speakers’ bureaus or other promotional events for Industry designed to influence purchasing or prescribing decisions (see additional speaking guidelines in the policy Appendix found in Policy Tech). This includes advising on creating promotional and marketing materials for Industry to sell their products or services, and participating in focus groups where the focus is on marketing products for Industry. This section is not intended to prohibit legitimate, principled educational activities that meet the allowable Speaking guidelines.
- Advising for Investment Companies. Individuals are prohibited from advising representatives of investment companies (including but not limited to investment firms, hedge funds, investment bankers, venture capital firms, and brokerage houses) on the status of areas of research and
development, especially non-public information within the realm of the individual’s professional expertise or collaborative knowledge, whether by telephone or email, in meetings, or otherwise. Directly or indirectly disclosing material or confidential information from a clinical trial prior to publication to individuals or companies that trade stock or advise such companies based on such information is prohibited. In addition, individuals must exercise caution in the relationships that are formed through memberships in expert networks (e.g., Gerson Lehman, Primary Global Research, Coleman Research Group, etc.).

Gifts from Industry (including medication samples) – see policy Appendix in Policy Tech

Industry Access to Facilities, Staff and Trainees – see policy Appendix in Policy Tech

Other Considerations for Faculty and Key Officials

- Administrative Actions by Key Officials. Key officials in the Institution include Presidents, Vice Presidents, Officers, Directors, Student Advisors, Deans, Department Chairs, and Section Heads. Because of their leadership roles, authority to make important decisions, fiduciary duty to act in the best interests of the Institution, and positions as role models for other Individuals, key officials are held to an even higher standard of ethics, integrity, professionalism, and objectivity in their decisions and conduct. Key officials might not be permitted to engage in some personal, professional relationships with industry that are allowable for others, when actual or perceived conflicts of commitment or interest would result, or may have restrictions on their ability to make certain decisions. Key officials should always be aware that their decisions may create institutional conflicts of interest in all missions.

- Committee Participation When Members Have Personal External Relationships with Industry. Individuals who serve as voting members on Medical Center committees shall recuse themselves from participation in voting and similar decision-making processes when the decision or discussion may pose a real or perceived conflict of interest. In addition, the Chair of the committee may remove a member from the committee in the event the Chair reasonably determines that the member cannot substantially contribute to and participate in the work on the committee due to the member’s actual or perceived conflict of interest. Additionally, committee members are required to verbally disclose any potentially conflicting relationships in open meeting to be documented in the meeting minutes.

- Faculty Participation in Student Affairs. Identifying and managing potential conflicts of interest involving students and faculty where a personal financial or fiduciary relationship may exist preserves and maintains academic integrity. Matters involving COI in student assessment may be found in the Conflict of Interest Related to Student Assessment Policy. Matters involving COI in appeals of student dismissal, may be found in the Student Appeal of Dismissal Policy. Program specific policies related to COI in admissions or mentoring of students are maintained by the applicable program and/or in the Student Handbook.

Penalties for Breach of Policy. Individuals have an obligation to comply with this policy. Examples of conduct that violates this policy includes, but is not intended to be exhaustive:

- Failure to comply with the annual disclosure process by refusal to respond
- Intentional deception or dishonesty in disclosures
- Omission of industry relationship disclosures
• Failure to remedy conflicts of interest
• Failure to comply with management plan requirements, or,
• Repeated failure to seek prior approval for speaking or for organizing or attending non-certified outside activities funded by Industry.

Reports of suspected violations may be made to any of the Individuals listed below, or anonymously through the Compliance Hotline (1-877-880-7888). Suspected violations will be investigated and referred to leadership in accordance with Definition C – Authority.

Penalties for deliberate violations of this policy will be adjudicated in accordance with applicable disciplinary policies and procedures. Penalties for failure to comply will be commensurate with the breach and may include, but are not limited to:

• Reimbursement to the Institution for misused resources, including salary and/or other forms of institutional compensation and other applicable fines imposed by outside entities
• Written admonition for placement in Individual’s employee file indicating that the individual’s good standing has come into question
• Ineligibility to participate in grant applications, IRB or IACUC applications or on committees
• Ineligibility to work with graduate students
• Dismissal from an educational or training program
• Performance improvement counseling
• Dismissal of employment

If the failure of a research investigator to comply with this policy has, or appears to have, biased the design, conduct, or reporting of PHS-funded research, in accordance with 42 CFR, Part 50, Subpart F, Section 50.606 (a) and 45 CFR, Part 94, the Institution must promptly notify the PHS Awarding Component of the findings and corrective action taken or to be taken. The PHS Awarding Component will consider the situation and may take appropriate action or refer the matter to the Institution for further action, such as determining how to maintain appropriate objectivity in the funded project.

Allegations of research misconduct are addressed in the Research Integrity Policy. If, in the course of investigating allegations of research misconduct, evidence of violations of the Conflict of Commitment Policy and Conflict of Interest Policy is discovered, the Research Integrity Officer conducting the misconduct investigation may consult with the Conflict of Interest Office to determine the need for any additional course of action.

GRIEVANCE

Appendix II of Wake Forest University’s Policy Resolutions contains the University’s Faculty Grievance Policy. This policy is designed to encourage the internal resolution of disputes in a collegial manner. As provided in the University’s Faculty Grievance Policy, the Faculty Grievance Committee is composed of ten regular members from the University Faculty who shall come from separate faculties of the University (College, Business, Law, Medicine, Divinity, Graduate, and Library), with four members coming from the School of Medicine.

Any faculty member of the University who believes that they have been aggrieved by the University or its representatives may, except as provided otherwise by the WFU Board of Trustees, initiate a grievance
proceeding. A grievance proceeding may relate to action taken with regard to a member of the faculty concerning: (a) Promotion, tenure or position; (b) Compensation; or (c) Other conditions of employment.

To be grievable, the action of which a complaint is made must be based upon wrongful conduct. Wrongful conduct includes any decision by the University or its representatives which is not in accordance with the rules, regulations, or other standards of the University, or of an applicable school or department.

The Faculty Grievance Committee may engage in an informal process of resolving the grievance or proceed with a hearing of the case. The Committee will issue a report and if remedial action is recommended, will bring the report to the attention of the person(s) acting at the lowest supervisory or decision-making level at which remedial action can be taken. If the grievant is not satisfied with this response, the grievant may review the matter with the next supervisory or decision-making level until the matter is satisfactorily resolved or it reaches the decision of the University’s President (or their designee), whose determination is final.

For additional information about the Faculty Grievance Policy, please refer to the “Faculty Grievance Policy” in PolicyTech.

OMBUDS

Wake Forest University maintains a University Ombuds Office, which is a safe place where WFU staff, faculty, and administrators can talk in confidence about any campus issue, problem, or dispute. The University’s Ombuds office supplements, but does not replace, the University’s formal channels for dispute resolution. Use of the Ombuds Office’s services is voluntary and free. Additional information about the Ombuds Office is available at: https://ombuds.wfu.edu/.

Wake Forest University School of Medicine also maintains a separate Ombuds Office. Additional information about the School of Medicine’s Ombuds Office is available at:

COMPLIANCE HOTLINE

The Compliance Office Hotline is an alternative method for reporting suspected violations of laws, regulations, rules, policies, procedures, ethics, or any other information employees feel uncomfortable reporting to their supervisor. Calls will not be traced and no effort will be made to identify the caller. The Hotline operator is not an employee of Wake Forest University and is located off-site. Information gathered from this call will be reported directly to the University Compliance Office. An appropriate response to each call will be available through a later call to the Hotline. The Hotline is available 24 hours a day, seven days a week. To access the Hotline, callers should dial 877-880-7888 (toll free).
CHAPTER FIVE
RESEARCH ADMINISTRATION
REGULATORY POLICIES

Intellectual Property

The mission WFUSM is to improve the health of our region, state, and nation by generating and translating knowledge to prevent, diagnose and treat disease; training leaders in health care and biomedical science; and serving as the premier health system in our region, with specific centers of excellence recognized as national and international care destinations. Stewardship of intellectual property arising at the School is in furtherance of this mission.

Widespread dissemination of ideas and information is fundamental to generating and translating knowledge and training leaders in medicine and science. In certain circumstances, widespread dissemination may be realized by utilizing intellectual property protection to encourage the development of products that are available to the public through established channels of commerce. Appropriate intellectual property protection and commercialization can promote the School’s mission by improving the public health and welfare, encouraging the open dissemination of research results, bringing recognition to the School and individual researchers, and providing a source of revenue to support further research and education at the School.

As integration of Advocate Health, Atrium Health and WFUSM continues, a unified policy around Intellectual Property is being developed that will supplant current policies. As it stands, Advocate Health, Atrium Health and WFUSM have individual Intellectual Property policies and procedures. Faculty of WFUSM are expected to adhere to the relevant and appropriate policy based on their employer.

Wake Forest University School of Medicine Intellectual Property Policy can be found here.
Atrium Health Intellectual Property Policy can be found here.
Advocate Health Confidential & Proprietary Information Policy can be found here.

Authorship Policy

General Principles and Right Conduct

Scientific and scholarly publications, defined as articles, abstracts, presentations at professional meetings and grant applications, provide the main vehicle to disseminate findings, thoughts, and analysis to the
scientific, academic, and lay communities. For academic activities to contribute to the advancement of knowledge, they must be published in sufficient detail and accuracy to enable others to understand and replicate the results. For the authors of such work, successful publication improves opportunities for academic funding and promotion while enhancing scientific and scholarly achievement.

The benefits of authorship are accompanied by a number of responsibilities for the proper planning, conduction, analysis, and reporting of research, and the content and conclusions of scholarly work.

Criteria for Defining Authorship:

An author is generally considered to be an individual who has made substantial intellectual contributions to a scientific investigation. It is expected that authorship will be agreed upon before initiation of the project and submission of the resulting manuscript(s). It is the responsibility of the senior author to ensure compliance that all authors have the opportunity to participate in the preparation of the manuscript and to approve it before submission. All authors should meet the following four (4) criteria:

1. Contribute significantly to the conception, design, execution, and/or in the analysis and interpretation of data
2. Participate in drafting, reviewing, and/or revising the manuscript for intellectual content
3. Approve the version of the manuscript to be published
4. Be able to explain and defend in public or scholarly settings that portions of the study for which he or she was directly responsible.

It is recognized that definitions of authorship differ among the various scientific disciplines and professional journals, as may standards for “substantial” and “scholarly effort.” For example, design/development of research equipment, or collection of a specific data set, may be substantial scholarly effort in certain disciplines. The expectation of this policy is that standards and criteria for authorship in an academic discipline will be widely recognized and consistent across that discipline (including Atrium Health and Wake Forest University Health Sciences), and consistent with the journal (publication) in which the work appears.

Responsible (Lead) Author:

One investigator who meets the criteria for authorships is designated as the Responsible or Lead Author. The Responsible Author assumes overall responsibility for each publication (e.g., primary research report, abstract, review article, book chapter) submitted for WFUSM and Advocate Health is typically the faculty member who leads the study and assumes the responsibility for coordinating and completing the work, drafting of the manuscript, satisfying pertinent rules for submitting the manuscript and any required revisions is not necessarily the principal investigator or project leader and does not necessarily have to be the first author (e.g., often the last author) often serves as the managerial and corresponding author addresses authorship disagreements and ensures that authors meet the criteria listed in this policy, as appropriate should exercise due diligence in ensuring the validity and integrity of the entire manuscript.

Order of Authorship:

The selection of the Responsible (Author, the involvement of collaborator(s) as co-authors, and the order of authorship is ideally determined by the research team as a whole. Plans regarding authorship and its
order are best determined before the study begins and any disputes resolved at that time. It is not possible for Advocate Health or WFUSM to define the order of authorship. A written memo attesting to this determination is valuable documentation if a dispute subsequently arises. Changes in authorship plans, which take place as a study proceeds, should be documented in writing.

The Responsible Author should assure that all collaborators are appropriately recognized and that study collaborators listed as co-authors meet the criteria for authorship described in this policy.

Co-authors. All co-authors of a publication are responsible for providing consent to authorship to the Responsible Author prior to submission. By providing consent to authorship to the responsible author, co-authors are acknowledging that they have reviewed and approved the manuscript, including the validity and integrity of the manuscript.

Students, Fellows, and Research Associates. All persons designated as authors should qualify for authorship as defined in this policy. Faculty should be aware of their responsibility to ensure that students, postdoctoral fellows, and other research associates who participate substantively in the preparation of manuscripts are recognized as authors in publications covering the results of research in which they were active participants.

Acknowledgments. Individuals who have made some contribution to the publication, but who do not meet the criteria for authorship, such as staff, editorial assistants, medical writers, or other individuals can provide a valuable contribution to the writing and editing of publications. Since those contributions do not meet the criteria for authorship under this policy, those individuals should be listed in an acknowledgment and/or contributorship section of the work.

Multi-Authorship/Multi-Center Manuscripts. Team science, which can involve many scientists across many disciplines and many institutions, demands careful use of authorship criteria. Sadly, some such studies have led to publications for which no single author was prepared to take full responsibility.

In studies of this type, the Responsible Author should make reasonable efforts to ensure adequate quality of research overall, and among the reasons for the final list of authors, the order should reflect the level of responsibility for quality assurance.

In large studies where quality assurance is distributed, it is essential that each participating investigator verifies the sections of a manuscript within his or her specialty for accuracy and to assure that the list of co-authors who conducted the work described in these sections is valid and appropriate. All authors should approve the final version of a manuscript and be prepared to take public responsibility for the work, as appropriate.

Unacceptable Authorship. An administrative relationship, acquisition of funding, collection of data, or general supervision of a research group alone does not constitute eligibility for authorship. In addition, the referral of patients included in a clinical study does not in and of itself warrant co-authorship status.

Guest, gift, and ghost authorship are also inconsistent with the definition of authorship in this policy and are unacceptable.

a) Guest (honorary, courtesy, or prestige) authorship is defined as granting authorship out of appreciation or respect for an individual, or in the belief that expert standing of the guest will increase the likelihood of publication, credibility, or status of the work.
b) Gift authorship offered out of a sense of obligation, as tribute, due to dependence, or in the hopes of an anticipated benefit.

c) Ghost authorship is an act of omission, whereby mention of a significant contributor is intentionally absent. Ghostwriters can be an example when the writing itself is of such value that it warrants credit, either as an author or by another form of acknowledgement. Omission might also occur to avoid controversy, notoriety, or to hide the appearance of a conflict of interest. It is unacceptable when the reader would reasonably expect to me made aware at the time of reading in order to understand the work in the proper context.

Detrimental Authorship Practices to Avoid:

a) Salami Publication - the slicing of data collected during a single research study into different pieces that form the basis of individual published manuscripts in the same or different journals. The practice is not appropriate when it increases the number of publications intentionally at the expense of the reader.

b) Premature Public Statements – Publicly announcing research results prior to peer-review runs the risk of misleading the public and undermining the credibility of research institutions and individual scientists when later peer-review finds significant criticism.

c) Duplicate Publication (sometimes called Self-plagiarism) – Republishing parts of your own work, such as previously published data sets or parts of previously written work without properly attributing the prior work.

Disputes over Authorship

In general, authorship issues and related matters should be freely discussed and decided upon early during the research process and prior to writing the manuscript. However, agreements relating to authorship may need to be changed during the collection of data and preparation of the manuscript. Possible disagreements include interpretation of the criteria for authorship, order of authors, editorial control of content and focus of the manuscript, selection of journal or other publication media, and choice of Responsible Author.

Disagreements between or among authors should be resolved in a collegial manner by the Responsible Author in consultation with the other author(s), relevant research personnel, and any other individual who claims authorship. Generally, the Responsible Author has the primary responsibility for making decisions on authorship and other matters related to the publication of manuscripts.

When matters of authorship and related issues cannot be resolved in a satisfactory manner by the Responsible Author, other author(s), research personnel, and other individuals who claim authorship, the Responsible Author and/or other author(s)/research personnel should present their controversy in writing to the Department Chair. The manuscript in question should not be submitted for publication before these issues are resolved. The Departmental Chair should meet with the individuals involved in the dispute, collect, and retain appropriate information, and make a recommendation in writing. When the authorship dispute involves the Chair, or if the dispute involves more than one department, then a neutral mediator will be appointed by the Vice President, Research Administration and Operations, or designee.

In the event that a satisfactory resolution is not achieved by the Departmental Chair or by a neutral mediator, then the Vice President, Research Administration and Operations /designee will appoint three
senior faculty members to investigate the dispute. The review group will not include individuals with personal responsibility for the research but should include faculty members with unique qualifications relative to the dispute in question (i.e., research expertise, training of graduate students, experience with clinical trials, active peer-reviewed research, etc.). In addition, the Research Integrity Officer will serve as an ad hoc member. In the case of disputes involving a faculty member from another school within Atrium Health or Wake Forest University, a member of the review groups should be on the faculty of the affected school. The review group will make a recommendation in writing to the Vice President, Research Administration and Operations and he/she will evaluate this recommendation and render a decision. The decision of the Vice President, Research Administration and Operations is final.

Disputes Over Authorship in Multi-Center Studies

Publication, presentation, and authorship policies should be determined and accepted by all participating investigators at the beginning of any multi-center study. Specifically, it is recommended that a Publication Subcommittee representing all Investigators should be established at the beginning of any multi-center study for the purpose of expediting, coordinating, and monitoring the publication processes. Inherent in these charges is the responsibility to adjudicate disputes over authorship.

If a dispute between investigators from separate centers does arise, the solution to the dispute should arise from within the organizational structure of the multi-center study. If a dispute cannot be resolved, the principle of academic freedom generally indicates that an investigator has the right to present those data for which he/she is contract custodian. However, this right should be tempered by the concept of collegial collaboration. It is unacceptable for an investigator to publish or present study findings before the total group of study investigators has had a reasonable opportunity to do so.

Financial Conflicts of Interest

Authors should fully disclose, in all manuscripts to journals, grant applications, and at professional meetings, all relevant financial interests that could be reviewed as a potential conflict of interest or, as required by Atrium Health, WFUSM and/or journal. All such financial interest must also be reported internally as required by organizational conflict of interest policies.

Scientific Misconduct

Scientific Misconduct defined as fabricating data, falsifying data, and plagiarism (knowingly representing the work of others as one’s own) are serious violations of our mission and the public trust. The policies and procedures for handling allegations of Misconduct in Research are outlined in the Research Integrity Policy.

Violations of the Policy

Knowingly, intentional, or reckless violations of this policy will be referred to the Vice President, Research Administration and Operations/designee. Violations of the policy that rise to the level of research misconduct, as defined by the Policy on Research Integrity, will be referred to the Research Integrity Office. Disputes regarding the order of authorship do not, in and of themselves, constitute a violation of this policy.

Data Classification Policy
Four levels of data classification will be used to classify WFUSM Data. The levels of data classification are:

1. Public: Public data is information that may be disclosed to any person regardless of their affiliation with WFBH. The Public classification is not limited to data that is of public interest or intended to be distributed to the public; the classification applies to data that do not require any level of protection from disclosure. While it may be necessary to protect original (source) documents from unauthorized modification, Public data may be shared with a broad audience both within and outside WFBH and no steps need be taken to prevent its distribution. Examples of Public data include:
   a. Press releases
   b. Directory information (not subject to a Family Educational Rights and Privacy Act (FERPA) block)
   c. Course catalogs
   d. Application and request forms
   e. Protected health information that has been de-identified consistent with the standards set forth under Health Insurance Portability and Accountability Act (HIPAA)
   f. Other general information that is openly shared.

2. Internal: Internal data is information that is potentially sensitive and is not intended to be shared with the public. Internal data generally should not be disclosed outside of WFBH without the permission of the person or group that created the data. It is the responsibility of the data owner to designate information as Internal where appropriate. Examples of Internal data include:
   a. Some memos, correspondence, and meeting minutes
   b. Contact lists that contain information that is not publicly available.
   c. Procedural documentation that should remain private.

3. Confidential: Confidential data is information that, if made available to unauthorized parties, may adversely affect individuals or the business of WFBH. This classification includes a confidentiality agreement with a third party, such as a vendor. This information should be protected against unauthorized disclosure or modification. Confidential data should be used only when necessary for business purposes and should be protected both when it is in use and when it is being stored or transported. Examples of Confidential data include:
   a. Personally identifiable information entrusted to our care that is not otherwise categorized as Restricted Use data, such as information regarding applicants, alumni, donors, and potential donors; and
   b. Individual employment information, including salary, benefits, and performance appraisals for current, former, and prospective employees.
   c. Novel research developments that may have commercialization potential unless classified otherwise by the funding agency.

4. Highly Restricted: Highly Restricted data includes any information that WFBH has a contractual, legal, or regulatory obligation to safeguard in the most stringent manner. In some cases, unauthorized disclosure or loss of this data would require the WFBH to notify the affected individual and state or federal authorities. In some cases, modification of the data would require informing the affected individual. Examples of Highly Restricted data include:
   a. Protected Health Information (PHI) subject to the Health Insurance Portability and Accountability Act (HIPAA);
   b. Information covered by the Family Educational Rights and Privacy Act (FERPA), which requires protection of records for current and former students;
c. Financial account numbers covered by the Payment Card Industry Data Security Standard (PCI-DSS), which controls how credit card information is accepted, used, and stored;

d. Controlled Unclassified Information required to be compliant with NIST 800.171;

e. Data controlled by U.S. Export Control Law;

f. Personally Identifiable Information (PII) that includes an individual’s name plus the individual’s Social Security Number, driver’s license number, or a financial account number;

g. Unencrypted data used to authenticate or authorize individuals to use electronic resources, such as passwords, keys, and other electronic tokens;

h. Information covered by the European Union’s General Data Protection Regulation (GDPR); and

i. Information covered by the Gramm-Leach-Bliley Act (GLB), which requires protection of certain financial records.

Data Handling

1. WFBH Data must be handled in a manner consistent to its regulatory environment, industry best practices, and contractual agreements in order to protect the confidentiality, integrity, and availability of information assets. Use and disclosure should follow applicable Medical Center policies, and should be handled in accordance with the applicable data classification level.

2. Data handling includes the appropriate standards and procedures for the access, use, transmission, storage, declassification, and disposal of information.

3. Reclassification: On a periodic basis, it is important to reevaluate the classification of WFBH Data to ensure the assigned classification is still appropriate based on changes to legal and contractual obligations as well as changes in the use of the data or its value to WFBH. The appropriate Data Steward should conduct this evaluation and recommend reclassification to the Data Governance Committee for approval. Conducting an evaluation on an annual basis is encouraged; however, the Data Steward should determine what frequency is most appropriate based on available resources. If a Data Steward determines that the classification of a certain data set has changed, an analysis of security controls should be performed to determine whether existing controls are consistent with the new classification. If gaps are found in existing security controls, they should be corrected in a timely manner, commensurate with the level of risk presented by the gaps. All configuration changes must follow the appropriate change management procedures.

Enterprise Data Governance Roles Policy

This Data Governance Roles policy grants data-related decisions rights and accountabilities to specific roles to empower the data stewardship community at Advocate Health. These roles are critical for actively managing and governing data as a strategic asset, ensuring high-quality, trusted data and accurate reporting across the Advocate Health enterprise.

Applicability

1. The roles, defined in this policy, apply to teammates selected from across the Advocate Health enterprise to participate in the Data Governance stewardship community.

2. This policy applies to all types of data unless there are explicit exemptions.

3. This policy supplements regulatory and IRB requirements for research data.

Data Governance Roles

1. Data Governance Council
a. Defines the scope and priority of each data domain.
b. Assigns Information Governors and Data Stewards.
c. Sets enterprise priorities and aligns organization resources.
d. Approves policies, processes, and tools.
e. Resolves escalated issues.
f. Defines strategic direction for the enterprise data assets

2. Data Governance Practice Leads (Data Governance Office)
a. Manage and coordinate workstream activities.
b. Provide the Data Governance Council with roadmaps, status, and supporting materials.
c. Provide best practices, education, and process documentation.

3. Information Governors
a. Identify and direct Data Stewards regarding data collection, maintenance, movement, archiving, use, and release for assigned data domains across the enterprise.
b. Prioritize data quality initiatives and manage remediation within assigned data domains.
c. Approve and consolidate data definitions including local and enterprise standards.
d. Define the best source of truth and reference data standards within their assigned domain.
e. Participate in drafting policies and ensure data domains are compliant with Data Governance processes and policies.
f. Identify, resolve, or escalate any data issues.
g. The Principal Investigator for an IRB approved study shall serve as the Information Governor.

4. Data Stewards
a. Provide primary data use expertise for specific business units or data assets as assigned by Information Governor.
b. Investigate, remediate, and monitor data quality issues for their assigned data responsibilities.
c. Create, report, and maintain local and enterprise business terms and data definitions consistent with Enterprise standards, policies, and procedures.
d. Create and maintain master data requirements.
e. Maintain reference codes, mappings across data sources, and rollups consistent with Enterprise standards, policies, and procedures.
f. Participate in drafting policies and procedures for their responsible assets.
g. Ensure business units or data assets are compliant with Enterprise standards, policies, and procedures.
h. Responsible for providing support, training, and education.
i. Identify, resolve, or escalate any data issues to the Information Governor.

5. Application Stewards
a. Application Stewards are assigned in collaboration with IAS Leadership
b. Provide application and data source specific expertise, training, and education.
c. Identify, investigate, remediate, and report data quality issues.
d. Create and maintain application and data source metadata.
e. Participate in master and reference data initiatives
f. Participate in drafting policies and procedures.
g. Ensure applications and data sources are compliant with Data Governance processes and policies.
h. Implement administrative data management policies including Data Access, Data Privacy, Data Security, and Data Release policies.

i. Identify and assist with gaps in data management policies and processes.

j. Ensure access to application systems is provided and maintained in accordance with policies and processes.

6. Analytics Stewards
   a. Analytics Stewards are assigned in collaboration between the Business and IAS Leadership
   b. Represents a team of individuals who create and distribute information.
   c. Create and maintain report, dashboard, and other analytics solution metadata.
   d. Incorporate master data and reference data into analytics solutions in compliance with the Data Governance processes and policies.
   e. Participate in drafting policies as requested.
   f. Ensure analytics solutions are compliant with Data Governance processes and policies.
   g. Responsible for reporting data quality concerns to the appropriate Data Stewards and Information Governors.

Data Ownership Policy

Ownership and Responsibilities

Unless superseded by specific terms of sponsorship and contractual agreement or policy, the Institution owns all research data developed or acquired by the faculty, fellows, students, and employees of WFUHS or Atrium Health through research projects conducted at or under the auspices of the Institution regardless of funding source. Although the Institution, as owner of the research data, must meet the requirements of sponsors for custodians of research data, Principal Investigators (PIs) and other researchers are stewards of research data, and shall retain the principal responsibility for custody of the data.

Access to Research Data

Research data are to be accessible to members of the WFUHS and Atrium Health community, external collaborators, and others as appropriate (e.g., patent applications or journal submissions). The Principal Investigator has primary responsibility for oversight and access to the Research Data generated by the project. Any other faculty, staff, student, or person involved in the creation of Research Data may have the right to review that portion of the Research Data that he or she created. The Institution will have access to the Research Data as necessary for technology transfer, compliance, and other purposes. The Institution also has the option to take custody of the Research Data as determined by the appropriate institutional official. Such option will not be invoked without cause and subsequent notification of the Principal Investigator. In some instances, a research sponsor has a legal right of access or access may be requested through the sponsoring agency under the federal Freedom of Information Act (FOIA). Requests for data access will be coordinated through the CTSI Office of Regulatory Affairs and Research Integrity.

In cases of multi-institutional studies, the institution of the primary study director shall be responsible for arranging appropriate access to, use of, and retention of Research Data unless otherwise specified in the terms of the particular study.
When necessary, to assure needed and appropriate access (e.g., research misconduct investigations), the Institution may take custody of research data in a manner specified by the Research Integrity Policy.

The Institution’s responsibilities with respect to research data include, but are not limited to:

- Complying with the terms of sponsored agreements;
- Ensuring the appropriate use of project resources (e.g., animals, human subjects, recombinant DNA, biological agents, radioactive materials, etc.);
- Protecting the rights of researchers, including but not limited to their rights to access to data from research in which they participated; and
- Maintaining confidentiality of research data, where appropriate and as may be required pursuant to the terms of an applicable sponsored agreement.

The PI’s responsibilities with respect to research data include, but are not limited to:

- Ensuring proper management and retention of data in accordance with this policy;
- Establishing and maintaining appropriate procedures for the protection of research data and other essential records, particularly for long-term research projects;
- Ensuring compliance with sponsor program requirements;
- Maintaining confidentiality of research data, where appropriate and as may be required pursuant to the terms of an applicable sponsored agreement; and
- Complying with applicable state and federal laws and regulations.

Data Retention

It is the responsibility of the PI to preserve, where feasible, all research data generated at the Institution for a minimum period of five (5) years from the date of the last publication or the date of the final report issued upon completion of the project, whichever is later.

In addition, any of the following circumstances may justify longer periods of retention:

- Research data must be kept for as long as may be necessary to protect any intellectual property resulting from the work;
- If litigation or other dispute resolution, claim, financial management review or audit related to the research project is started before the expiration of the five-year period, or commenced after the five year period, the research data and other project records must be retained until all litigation/dispute resolution, claims, financial management review or audit findings involving the records have been resolved and final action taken;
- If any charges regarding the research arise, such as allegation of research misconduct, research data must be retained in a manner consistent with the policy on Research Integrity, or as otherwise instructed by the CTSI’s Office of Research Integrity or Office of General Counsel; and
- When research is funded by an award to or contract that includes specific provisions regarding ownership, retention of and access to technical data, the provisions of that agreement will supersede this Policy;
• If a student or trainee is involved in research, that research data must be retained at least until the degree is awarded to the student, the training is complete, or it is clear that the student has abandoned the work.

Beyond the period of retention specified here, the destruction or permanent de-identification of research data is at the discretion of the PI. Destruction of research data must follow applicable federal regulations, sponsor requirements and other applicable guidelines.

Research data will normally be retained by the unit/Department where they were produced, in accordance with Institutional practices for the secure storage of information.

Transfer in the event a researcher leaves the Institution

When a PI for a research project leaves the employment of the Institution, and the research project will no longer be conducted at the Institution, but instead moved to another institution, ownership of the original data may be eligible for transfer to the PI’s new institution, upon request from the PI. An agreement on the disposition of research data must be negotiated between the PI and his/her department chair, in consultation with the Office of Regulatory Affairs within the CTSI, concerning possession of research data, notebooks, and other data retention materials and unique resources to be transferred to the departing investigator. If the departing faculty member is the department chair, he or she will work directly with the Office of Regulatory Affairs and Research Integrity. To fulfill obligations to funding sources and others, such agreements may provide for the Institution to retain copies of the research data, where feasible.

If research data must remain at the Institution, as mandated by the Institution, by law, or as required by the funding agency or commercial sponsor or other applicable policies, the PI will have the right to access and, where practical, to copy such research data produced by him/her subject to any restrictions set forth in a sponsored agreement.

Upon the death of a PI, the Department Chair shall appoint a researcher to assume stewardship of the research data.

When individuals other than the PI, such as collaborating investigators, fellows, students or other trainees, leave the Institution, they may take copies of research data for projects on which they have worked or have the right to reasonable access to such data, subject to relevant confidentiality restrictions and/or restrictions set forth in a sponsored agreement.

Research Data Ownership Policy Oversight and Dispute Resolution

The Office of Regulatory Affairs and Research Integrity within the CTSI, under the direction of the Vice Dean and Vice President, Wake Forest University School of Medicine Administration & Operations, has responsibility for oversight of, and resolution of, disputes resulting from this policy. In an investigator wishes to contest the decision of the Vice Dean and Vice President, Wake Forest University School of Medicine Administration & Operations, the investigator may file a written appeal to be reviewed by a committee of researchers, appointed by the Office of Regulatory Affairs and Research Integrity.

Research Honest Broker Policy

General Requirements
• Investigators are responsible for designing and conducting research studies that protect, to the fullest extent possible, both the privacy of the individuals who are potential or actual research subjects and the confidentiality of the information about such individuals. Investigators who plan to use or disclose PHI or other Confidential Information for research purposes shall follow requirements of this standard, WFBH system policies on privacy, and state and federal law governing the privacy of health information.

• WFBH Research Administration and/or the WFBH Institutional Review Board ensures that applicable requirements of WFBH’s system policy on privacy, and federal and state law governing the privacy of health information, are met when reviewing and approving human subject research.

• The IRB is responsible for assessing the degree to which a research project involving PHI subjects has been designed to address subject privacy and confidentiality of subject information. Where necessary or appropriate, the IRB will require that the investigator modify the design of the research project or the recruitment process and enrollment procedures to satisfy inadequacies identified by the IRB in relation to the protection of the privacy of research subjects and the confidentiality of sensitive or individually identifiable health care information of potential or actual research subjects.

• An employee Honest Broker’s failure to abide by this policy may result in disciplinary action pursuant to WFBH policies, up to and including termination. Other non-employee Workforce members may be sanctioned in accordance with applicable WFBH procedures. An Honest Broker’s failure to abide by this policy may result in immediate termination of his or her WFBH certification to serve as an approved Honest Broker. Questions regarding this policy should be directed to the IT Program Director, CTSI or WFBH Privacy Officer.

Honest Broker Certification Procedure

For an individual to serve as an Honest Broker for WFBH, the proposed Honest Broker must be certified pursuant to the following procedure:

1. The Honest Broker must be initially sponsored by investigator(s) within a department or unit who are in good standing (i.e., no revoked research privileges) with a WFBH -recognized Institutional Review Board (IRB) of record AND who intend to use the honest broker’s services.
2. Honest Brokers must have written documentation of the processes and/or systems that they use to develop both fully De-Identified health information data sets and Limited Data Sets, for both electronic and paper-based records.
3. Honest brokers must have written documentation of policies, procedures, and controls necessary for:
   a. Compliance with the HIPAA Privacy Rule, the Federal Policy regulations for human subject protections (45 CFR 46) and WFBH BAA Policy.
   b. Security and management of all PHI in the Honest Broker’s possession during the performance of Honest Broker functions
   c. Audits and/or quality checks related to determining the efficacy of De-Identification mechanisms.
   d. Security and management of re-identification keys.
   e. Documentation/maintenance/retention of all work performed (for whom, what was provided, IRB approval info, etc.).
4. Honest Brokers must submit a written statement assuring that they will abide by all relevant WFBH and IRB guidelines, policies, and procedures, including continuing adherence to the WFBH honest broker certification criteria section of this policy, the duties, and other requirements section (see section that follows) and the terms and conditions of WFBH BAA (if applicable).

5. Honest brokers must complete the following training:
   a. CITI Training: Basic Human Subject Protection training course and Health Information Privacy & Security Course (HIPS) including HITECH
   b. Annual Privacy and Security Training provided by Privacy Office
   c. i2b2 Training

6. Honest brokers must submit an application to become a WFBH- and IRB- certified honest broker. The Honest Broker certification application and training are available at https://ctsi.wakehealth.edu or https://redcap.link/z7f4ymby. The application is to be submitted by the sponsoring department or unit to the IRB (of record) staff member that is designated to receive these applications (e.g., expedited reviewer). Once the IRB has approved the Honest Broker application, the application will then be forwarded to the WFBH ITS Security for review.

7. The WFBH ITS Security, in conjunction with Privacy Office, will evaluate the application and related documentation to determine that the honest broker has presented satisfactory evidence to meet or exceed the criteria outlined above.

Honest Broker Duties and Other Requirements

In order for a certified honest broker to work on behalf of investigators to De-identify or provide PHI that is owned/held by WFBH, the honest broker must perform the following WFBH-defined duties and adhere to the following WFBH defined requirements:

1. Individuals serving as an Honest Broker must have legitimate access to the data requested by the investigator and they must be completely independent of the research team.

2. Honest Brokers who are neither WFBH employees nor members of the WFBH Workforce must execute an Honest Broker Services Agreement along with a Business Associate Agreement with WFBH, the terms of which will specify the continuing confidentiality requirements, duties, and other expectations WFBH has of an honest broker service. Master Services Agreement will be customized by WFBH to reflect the specific duties and other requirements WFBH specifies for honest broker services.

3. A certified Honest Broker must ensure that approval of the IRB of record has been obtained for a research study whereby the honest broker receives a request for De-identified PHI or a Limited Data Set.

4. A certified Honest Broker must adhere to all of the terms and conditions specified by the IRB for any research study for which the Honest Broker will perform De-identification services.

5. The WFBH Honest Broker providing the data extract shall record the date the extract was provided to the requesting party and shall maintain a copy of the request for a minimum of six years from the date of the request.

6. If a Limited Data Set is to be disclosed outside WFBH, a Data Use Agreement must be entered with the recipient of the Limited Data Set information. In such instances, the Honest Broker must obtain (and retain) evidence of an appropriately executed Data Use Agreement.
7. To identify eligible patients for recruitment in clinical trials: The Honest Broker may provide the investigator a data list of eligible patients based on defined search criteria. Presence or absence of direct identifiers will be determined by the IRB documentation.

8. The IRB may also require evidence of a completed Data Use Agreement for a Limited Data Set as part of its application process for approval of the proposed research. The Data Use Agreement will include a list of WFBH-required disclosures (honest broker data set specifications) relative to:
   a. Where the PHI is located (i.e., what WFBH entity)
   b. What HIPAA-defined limited data set elements are requested for the research;
   c. The purpose of the limited data set request (i.e., detailed uses pertinent to the limited data set).
   d. Who (names, titles, addresses) will access, use, and disclose the limited data set information other than the principal investigator.

9. If an investigator requires data from two or more Honest Brokers for the same project, the IRB application must indicate each Honest Brokers involved. This will allow independent Honest Brokers to share linkage codes with one another.

10. An individual serving as an Honest Broker should notify the CTSI if he or she terminates his/her position with WFBH or his/her standing with the WFBH IRB is in jeopardy.

11. When providing data to an approved study team, an Honest Broker must assure the study team is receiving the minimum amount of data necessary to accomplish the goals and that only data elements approved by IRB are provided to study teams.

Institutional Oversight of Animal Research and Teaching Policy

It is the policy of Wake Forest University (WFU), Atrium Health, Wake Forest University Health Sciences (WFUHS), and their respective affiliated entities, to meet all applicable laws and regulations for the use of animals in research and education. Wake Forest has established an Institutional Animal Care and Use Committee (IACUC) and Animal Welfare Program to provide Enterprise-wide oversight regarding compliance with regulation, adequacy of facilities, animal husbandry and health care, and the appropriate use of animals in education programs and research. Wake Forest applies the guidance of the United States Department of Agriculture (USDA), the Office of Laboratory Animal Welfare (OLAW) and the accrediting organization, the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC).

This policy applies to faculty, staff, students, trainees, and other individuals engaged in teaching and/or research activities using animals conducted at WFU, Atrium Health, WFUHS, and their respective affiliated entities.

Guidelines

- Wake Forest University has a written Animal Welfare Assurance Statement of Compliance on file with OLAW, which is required to receive federal sponsorship under Public Health Services’ jurisdiction, such as the National Institutes of Health, and obligates it to adhere to the Public Health Services Policy on the Humane Care and Use of Laboratory Animals and the U.S. Government Principles on the Utilization and Care of Vertebrate Animals in Testing, Research and Training. The assurance has been signed by the Institutional Official (IO) with the legal authority to represent the institution. The IO establishes an institutional culture of respect for animal subjects; ensure effective institution-wide communication
and guidance on animal research issues; ensures that investigations fulfill their responsibilities; facilitates participation in animal research education activities; serves as a knowledgeable point of contact; establishes an IACUC with necessary resources; and supports the authority and decisions of the IACUC.

- Wake Forest University maintains a registration of facilities and license to sell certain animals as required by the USDA.

- The WFU IACUC responsibilities consist of review and approval of all activities involving the care and use of animals at WFU, Atrium Health, WFUHS, and their respective affiliated entities, including the suspension of activities that are not conducted properly, at least semi-annual inspection of all Enterprise animal facilities and review of the Animal Welfare Program, from humane care and use, recommendations to the IO regarding the program, facilities and training of personnel, and reporting of activities to outside agencies with oversight authority.

- Oversight by the WFU IACUC encompasses the use of animals for research, education, and all other activities which in part involve animals, regardless of sponsorship, and must be reviewed and approved by the WFU IACUC. Activities involving animals must be reviewed by the WFU IACUC when: employees or agents of WFU, Atrium Health, WFUHS, and/or their respective affiliated entities, in connection with their institutional responsibilities, use animals for research, education, or other activities; the activity is conducted under the direction of employees or agents of WFU, Atrium Health, WFUHS, and/or their respective affiliated entities; the activity involves the use of any property or services of WFU, Atrium Health and/or WFUHS; WFU, Atrium Health and/or WFUHS receives a direct award to conduct the activity, even where all activities involving animals are carried out by a subcontractor or collaborator; and/or the activity is sponsored by WFU, Atrium Health and/or WFUHS. Employees include individuals employed by WFU, Atrium Health, WFBMC, WFUHS, NCBH, and all on-site subsidiaries as well as those off-site governed by WFU, Atrium Health, WFBMC, or WFUHS policies and procedures. Agents include all individuals performing institutionally designated activities or exercising institutionally delegated authority or responsibility for WFU, Atrium Health and/or WFUHS or its subsidiaries or governed sites. Agents include students and other trainees enrolled at Wake Forest or at Atrium Health educational programs performing activities in connection with their roles and responsibilities as students or trainees.

- The Attending Veterinarian is responsible for the well-being and clinical management of live vertebrate animals used in research and teaching. The Director of the Animal Resources Program is responsible for the maintenance and upkeep of centralized housing and support facilities.

- The Director of the IACUC and Animal Welfare Program ensures that resources allocated to the IACUC are utilized to support the IACUC mission and that Animal Welfare Program administrative processes facilitate the successful fulfillment of IACUC responsibilities.

- United States Department of Veterans Affairs: The Institution employs faculty with a joint appointment at a VA Medical Center, which obligates portions of the animal welfare program to adhere to VA Handbook 1200.07, “Use of Animals in Research.”

- United States Department of Defense: The Institution may perform animal-based research and education sponsored by any of the military branches, which obligates portions of the program to comply with Army Regulation 40–33 (aka, SECNAVINST 3900.38C, AFMAN 40–401(I), DARPAINST 18, USUHSINST 3203) enforced by the Animal Care and Use Review Office under the United States Army Medical Research and Material Command.
AAALAC International: WFU maintains an official accreditation for the Animal Welfare Program. AAALAC International assesses programs for compliance with the Public Health Services policy and The Guide of Care and Use of Laboratory Animals and other key guiding documents.

Institutional Oversight of Human Research Policy

It is the policy of Atrium Health, Wake Forest University Health Sciences (WFUHS), and their respective affiliated entities and representatives to ensure that the safety, rights, and welfare of individual research subjects, in the conduct of human research at Atrium Health and WFUHS, are considered above any interest of science and society. To this end, Atrium Health and WFUHS are guided by the ethical principles for the protection of human research participants as set forth in the Belmont Report and the Declaration of Helsinki. The research enterprise assures, through a Federal wide Assurance (FWA) under WFUHS, that whenever human research is conducted or support by any federal department or agency that has adopted the Federal Policy for the Protection of Human Subjects, known as the Common Rule, the Institution will comply with the terms set forth in the Code of Federal Regulations at 45 CFR 46 (including all applicable Subparts), unless the research is otherwise exempt from these requirements, or the department of agency conducting or supporting the research has determined that the research shall be covered by a separate assurance. For clinical investigations regulated by FDA under section 505(i) or 520(g) of the Federal Food, Drug, and Cosmetic Act (21 U. S. 6. 355(i)), Atrium Health and WFUHS will apply FDA regulations human subjects regulations. These regulations include, but are not limited to, Protections of Human Subjects (21 CFR 50), Institutional Review Boards (21 CFR 56), Investigational Drugs (21 CFR 312), Investigational Devices (21 CFR 812), and Application for FDA Approval to Market a New Drug (21 CFR 314). For all other human research Atrium Health and WFUHS applies the Code of Federal Regulations at 45 CFR 46 and the ICH Good Clinical Practice Consolidated Guidance (1996) when applicable.

This procedure applies to all faculty, staff, students, trainees, and other individuals conducting of human research at Atrium Health, Wake Forest University Health Sciences, and their respective affiliated entities and representatives.

Guidelines

WFUHS designates one or more IRBs for review of human research under the WFUHS FWA. A Human subject is defined as stated in the IRB SOPs. IRBs designated under the WFUHS FWA “shall review and have authority to approve, required modifications in (to secure approval), or disapprove all research activities” subject to the regulations [45 CFR 46.109(a)][21 CFR 56.109(a)]. Further, the designated IRBs “shall conduct continuing review of research” annually or more often when appropriate [45 CFR 46.109(e)][21 CFR 56.109(f)]. The designated IRBs also have the authority “to suspend or terminate approval of research that is not being conducted in accordance with the IRB’s requirements or that has been associated with unexpected serious harm to subjects” [45 CFR 46.113][21 CFR 56.113]. The IRB may make determinations regarding the appropriateness of measures to correct non-compliance and may require specific corrective measures in order for research to continue if non-compliance has been identified. The disposition of human research data, which has been collected without IRB approval or in a manner non-compliant with IRB SOPs, falls under the IRB’s authority to protect the rights and welfare of human subjects. No change to an approved human research protocol can be implemented until approval of the change has been granted by the IRB. Operation of the IRB shall follow the IRB SOPs approved by the Institutional Official (an individual with the legal authority to represent the institution) or a designee.
The HRPP/IRB Director and staff are part of the Clinical Translational Science Institute and report to the Associate Vice President & Assistant Dean for Regulatory Affairs and Research Integrity.

The Director of the HRPP/IRB, in conjunction with staff who have appropriate expertise in research regulation and application, ensure that appropriate conduct of the review, approval and oversight of human research. WFUHS HRPP components which operate outside the CTSI are accountable to the Institutional Official for carrying out the human research-related duties according to the policies, procedures, and standards set forth by the Institutional Official. The HRPP/IRB is charged with overseeing the efforts of persons conducting human research, overseeing the research related activities of all HRPP components, and ensuring that all portions of the human research program at WFUHS are in compliance with the directives communicated by the Institutional Official.

In order to comply with federal regulations, state and local laws, and institutional policies, Atrium Health and WFUHS investigators must follow the policies and procedures detailed in the IRB SOP document. The HRPP/IRB office provides education, guidance material, and study specific consultation in order to assist investigators. Investigators should consider consulting the HRPP/IRB prior to initiating or modifying human research activities.

**Quality Conduct of Clinical Research Policy**

It is the policy of Atrium Health, Wake Forest University Health Sciences, and their respective affiliated entities, to ensure there is appropriate review of research, sufficient/appropriate monitoring (internal and external) and a quality assurance plan to conduct research in accordance with all internal and external policies, procedures, and regulations governing research. This Policy is guided by the ethical principles set forth in the Belmont Report and Declaration of Helsinki, regulations found in 45 Code of Federal Regulations Part 46, the regulatory requirements of the Food and Drug Administration, policies of the National Institutes of Health, and other applicable laws, regulations, local standards, and ordinances that pertain to human subjects research in which Atrium Health is engaged. The purpose of this policy is to set forth the requirements and processes to ensure clinical research is conducted in a quality and compliant manner.

This policy applies to faculty, staff, students, trainees, and other individuals engaged in research activities conducted at Atrium Health, Wake Forest University Health Sciences, and their respective affiliated entities.

**Guidelines**

Atrium Health Research Administration and The Office of Regulatory Affairs and Research Integrity within the Clinical and Translational Science Institute (CTSI) at Wake Forest School of Medicine are responsible for setting forth and maintaining requirements, policies, and procedures to foster a consistent approach to the human subjects research, yielding conduct and results of the highest quality and integrity.

Principle Investigators are responsible for ensuring all study personnel are appropriately trained to conduct the research, that there is a clear monitoring plan in place, and that a process for ensuring data integrity is followed. The following standard operating procedures are implemented to provide guidance to investigators and study staff on proper procedure at Atrium Health.

- **Standard Operating Procedures**
  - Data Retention and Destruction of Human Subjects Data/Records
b. External Audits of Human Subjects Research

c. Internal Post-approval Monitoring of Human Subjects Research

d. Sponsor Monitoring of Human Subjects Research

e. Training of Human Subjects Research Coordinators

f. Investigational Medical Devices used in Human Subjects Research

Research Security Program Policy

Guidelines

Cybersecurity

Atrium Health, Wake Forest University Health Sciences, and their respective affiliated entities and representatives apply the following safeguarding protocols and procedures through a combination of cybersecurity standard operating procedures and Information Technology and Services (ITS) policies:

- Provide regular cybersecurity awareness training for authorized users of information systems, including in recognizing and responding to social engineering threats and cyber breaches.
- Limit information system access to authorized users, processes acting on behalf of authorized users, or devices (including other information systems).
- Limit information system access to the types of transactions and functions that authorized users are permitted to execute.
- Verify and control/limit connections to and use of external information systems.
- Control any non-public information posted or processed on publicly accessible information systems.
- Identify information system users, processes acting on behalf of users, or devices.
- Authenticate (or verify) the identities of those users, processes, or devices, as a prerequisite to allowing access to organizational information systems.
- Monitor, control, and protect organizational communications (i.e., information transmitted or received by organizational information systems) at the external boundaries and key internal boundaries of the information systems.
- Implement subnetworks for publicly accessible system components that are physically or logically separated from internal networks.
- Provide protection of scientific data from ransomware and other data integrity attack mechanisms.
- Identify, report, and correct information and information system flaws in a timely manner.
- Provide protection from malicious code at appropriate locations within organizational information systems.
- Update malicious code protection mechanisms when new releases are available.
- Perform periodic scans of the information system and real-time scans of files from external sources as files are downloaded, opened, or executed.

These protocols are implemented via operational practice and policy including the Access Control Policy, Anti-Virus Policy, Authorization and Acceptable Use Policy, Computer Equipment and Media Disposal and Reuse Policy, Data and System Integrity Policy, Data Governance Policy, Encryption Policy, FISMA General Policy, Incident Response Policy, Information Security Policy, Information System Activity Review Policy, ITS...

Additionally, in accordance with the Information Security Policy, every workforce member at Atrium Health and Wake Forest University Health Sciences are required to complete training related to Information Security and the policy associated with required practices.

Foreign Travel

The following activities related to international travel are reportable export activities:

- Travel to any Office of Foreign Assets Control (OFAC) sanctioned or embargoed country
- Travel to destinations outside the U.S. for work related purposes (even if the work is not directly funded by Atrium Health, Wake Forest University Health Sciences, and their respective affiliated entities and representatives)
- Providing a lecture or presentation at a foreign university, conference, or event (both in person or via videoconferencing)
- All foreign travel booked through Concur will be automatically reviewed by the International Research Compliance Office. Faculty and staff are required to report all work related foreign travel booked outside of Concur by emailing exports@wakehealth.edu. The International Research Compliance Office will provide pre-travel security briefings when appropriate. These security briefings will include information related to U.S. State Department security concerns, export control considerations, electronic device security, and WFHS executive security services insurance (when applicable).

Research Security Training

The training module entitled “DoD Mandatory Controlled Unclassified Information (CUI) Training” is required for all faculty, staff, and students who will be handling or have access to Controlled Unclassified Information (CUI) related to a federally funded project. Additional training may be assigned to ensure appropriate coverage of topics such as: insider threats, reporting security incidents, proper handling of CUI, and physical storage of CUI. It is the responsibility of the Principle Investigator (PI) associated with projects involving CUI to notify the International Research Compliance Office regarding personnel assigned to such projects. After award of a CUI project, the PI must make initial personnel notifications by emailing exports@wakehealth.edu. Any changes to personnel assigned to a CUI project must also be reported. Additionally, the training module may be assigned to faculty and staff as a mandatory training requirement as deemed appropriate by the International Research Compliance Office.

Export Control Training

Relevant personnel may be assigned the U.S. Export Controls training module in HealthStream. The U.S. Export Controls module consists of information related to export control regulations, license exceptions/exclusions, international travel, penalties for noncompliance, and compliance responsibilities. All faculty, staff, and students who will be handling or have access to CUI will be required to complete the U.S. Export Controls training module. Certificates of completion for the U.S. Export Controls training and the DoD Mandatory Controlled Unclassified Information (CUI) Training module must be emailed to exports@wakehealth.edu prior to participation in a CUI project.
Use of Care Everywhere in Research Policy

To clarify that when a national epidemic is officially declared a public health emergency, such as was done for COVID-19, research staff who are associated with an active research study related directly to the public health emergency may query for and request outside records for patients in Epic who are actively enrolled in the study, with the explicit consent of the research participant. Research staff can use the information for research related to treatment, testing, and vaccines that are directly related to the public health emergency. Information may be gathered from Care Everywhere in accordance with the Epic “Rules of the Road,” organizational policy and processes, and applicable regulations. The Secretary of the Department of Health and Human Services (HHS) issues declarations of public health emergencies.

Guidelines

IRB in collaboration with Privacy Office will review each study request to determine if it meets criteria for use. Enter request into the electronic Institutional Review Board (eIRB) application for routing and approval.

The following criteria must will be met:

- The study has IRB approval and is active in WakeOne.
- Care Everywhere requests cannot be made to initially identify or recruit patients for a research study.
- If the queried organization is not participating in research request, it will not be available for query.
- The patient has given consent for and is actively enrolled in a research study related to treatment, testing, or vaccines for certain public health emergencies. The research study must be approved by WFBH Institutional Review Board.
- Informed consent and authorization must be signed or otherwise authenticated by the participant. It must clearly indicate to the participant that the research staff intend to request their information from the other healthcare organizations for research purposes.

User requirements:

- User must be listed on the study team in eIRB.
- Must be listed in one of the following roles on the study Provider’s form in WakeOne Study Coordinator
  - Research Contract
  - Provider Investigator
  - Other Provider
  - Nurse
- User with Dual Roles should not query for research purposes. For example, if you normally request records in CE for treatment, research queries must be assigned to a study team member who has been assigned the research purpose of use by security class.

Following approval, the IRB, Study team member must attach IRB documentation of “approval for use of Care Everywhere in research” in ServiceNow for initiation of access.

Research Integrity Policy

It is the policy of Atrium Health and AHWFB (each as defined below, and collectively referred to herein as the “Institution”) to inquire into and, if necessary, to investigate and resolve in a timely and fair manner
all instances of alleged research misconduct. In carrying out its research mission, all persons engaged in research are expected to adhere to the highest standards of research integrity to protect the accuracy and reliability of the research record and published results.

The purpose of this policy is to promote the Institution’s compliance with federal regulations and best practices for dealing with research misconduct and to protect the integrity and reputation of the Institution and its scholars from false or unproven allegations of research misconduct.

This policy applies to all research and scholarship activities conducted within the Institution, irrespective of the funding source, if any. Individuals accused of research misconduct are presumed innocent of any allegations until the contrary has been established by a final decision reached under this policy.

Guidelines

This policy does not address, and specifically excludes, fiscal improprieties and issues concerning the ethical treatment of human or animal subjects, authorship disputes, sexual harassment or discrimination, general matters not within the definition of scientific misconduct, and criminal matters.

In addition, because of the inherent unfairness and the difficulties presented by any attempt to assess stale evidence, allegations of misconduct based on events that occurred six or more years ago will not be subject to review under this policy unless clear and convincing mitigating circumstances are present, as determined by the Research Integrity Officer.

General Requirements:

- **Responsibility to Report Research Misconduct**
  Allegations of research misconduct may be filed by anyone, whether associated with the Institution or not. All persons associated with the Institution should report promptly, any concerns regarding possible research misconduct. If an individual is uncertain about whether the concern qualifies as research misconduct, they may contact the Research Integrity Officer to discuss the concern informally and confidentially. If the circumstances described by the individual do not meet the definition of research misconduct, the RIO may refer the individual or allegation to other offices with responsibility for resolving the concern as necessary and appropriate.
  Reports can be made on an informal (oral) or formal (written) basis. Formal allegations should be submitted in sufficient detail to permit a preliminary assessment into whether an inquiry is warranted. Reasonable efforts will be made to review and resolve informal reports of alleged misconduct; however, such reports will not be processed through the procedures set out below unless they are submitted in writing or confirmed separately through available evidence.

- **Requirements for Findings of Research Misconduct**
  A finding of research misconduct requires that:
  - There be a significant departure from accepted practices of the relevant research community; and
  - The research misconduct be committed intentionally, knowingly, or recklessly; and
  - The allegation be proven by a preponderance of evidence.

- **Cooperation with Inquiries and Investigations**
  Individuals covered under this policy must cooperate with the RIO and other Institutional officials in the review of allegations and during inquiries and investigations. Such individuals also have an
obligation to provide relevant information to the RIO or other Institutional officials about research misconduct allegations. Moreover, individuals covered under this policy shall cooperate fully and on a continuing basis with ORI during its oversight reviews of the Institution and its research misconduct proceedings and during the process under which the respondent may contest ORI findings of research misconduct and proposed HHS administrative actions. Failure to cooperate is a violation of this policy and may result in disciplinary action.

- Protection and Restoration of Reputations
  
  Respondents
  
  Inquiries and investigations are conducted in a manner that ensures fair treatment to the respondent and confidentiality to the extent possible, without compromising public health and safety or thoroughly carrying out the needs of an inquiry and/or investigation.

  In proceedings where the respondent is not found to have committed research misconduct, the Institution may, to the extent possible, work with the respondent to rectify any injury done to the reputation of respondent, including providing a letter of the results of the investigation.

  Complainants
  
  Institutional officials who receive or learn of a report of research misconduct will treat the complainant with fairness and respect and, when the report has been made in good faith, will take reasonable steps to protect and restore the position and reputation of any complainant, witness, or committee member and to counter potential or actual retaliation against those complainants, witnesses and committee members. Any alleged or apparent retaliation should be reported to the RIO or other Institutional official. The Institution will not tolerate retaliation in any form against any individual who participates in a research misconduct proceeding. Retaliation is a serious violation that can subject the offender to disciplinary action under appropriate rules or policies.

- Interim Protective Actions
  
  At any time during a research misconduct proceeding, the Institution shall take appropriate interim actions to protect public health, federal funds and equipment, and the integrity of PHS supported research process. The necessary actions will vary according to the circumstance of each case, but actions that may be necessary which include delaying the publication of research results, providing for closer supervision of one or more researchers, requiring approvals for actions relating to the research that did not previously require approval, auditing pertinent records, or taking steps to contact other institutions that may be affected by an allegation of research misconduct. Such administrative actions will not be deemed disciplinary in nature.

- Confidentiality
  
  Efforts will be taken to ensure confidentiality is maintained. Disclosure of the identity of respondents and complainants in research misconduct proceedings is limited, to the extent possible, to those who need to know, consistent with a thorough, competent, objective, and fair research misconduct proceeding, and as allowed by law. The applicable laws and regulations may require the Institution to disclose the identity of respondents and complainants to federal oversight agencies pursuant to the agency’s review of Institutional research misconduct proceedings.

Examples of when a release of information may occur include, but are not limited to, the following circumstances:
As required by the rules of, or contract with, a funding entity;
As required by the need to inform the research community of the conclusions reached in order to protect the integrity of the research involved;
As part of a disciplinary sanction imposed;
As deemed necessary by the RIO and DO to protect the legitimate interest of human subjects involved in the research;
As deemed necessary by the RIO and DO, whether or not proceedings external to the Institution (investigations or oversight review) are ongoing;
At the request of the respondent; or
As required by law.

The RIO, in consultation with the DO, is responsible for determining when a release of information is necessary or appropriate. During the course of the research misconduct proceedings, if release of information outside the Institution is deemed necessary, the respondent may be informed of the release.

The goal of maintaining confidentiality does not prohibit Institutional officials from consulting, on a confidential basis and to the extent necessary, with persons within or outside the Institution with relevant experience or expertise to thoroughly investigate the allegations. Nor does it prohibit Institutional officials from disclosing information, on a need-to-know basis, to individuals responsible for oversight of the respondent’s research activities or to other Institutional officials involved in the questioned research, such as department chairs or deans.

If information concerning the alleged research misconduct is disclosed in accordance with law (for example, by the respondent or government agency), Institutional officials may comment publicly in connection with such disclosure.

Except as may otherwise be prescribed by applicable law, confidentiality must be maintained for any records or evidence from which research subjects might be identified. Disclosure is limited to those who have a need to know to carry out a research misconduct proceeding.

Legal Counsel

The presence of legal counsel at the proceedings of the inquiry and investigation committees shall be at the sole discretion of the committees. The respondent(s) will be informed that the Institution’s Legal Department serves as an advisor to the Institution and cannot render advice to the respondent(s), but that the respondent(s) may obtain their own legal advisor at any time during the proceedings established by this policy. The respondent(s) will be informed that any person, including other Institutional personnel, can act as an advisor as long as that person’s Institutional position does not have any formal role in the process.

Prevention of Research Misconduct

The Institution strives to provide an open and stimulating environment for creativity and individual thought where faculty and staff members will develop independently and productively. It is intended that this climate will promote high ethical standards and enhance the research process.
The Institution will provide training to faculty, staff and other individuals involved in research to promote the responsible conduct of research and discourage research misconduct.

○ Deadlines
Due to the sensitive nature of allegations of research misconduct, each complaint will be resolved as expeditiously as possible. The nature of some complaints may render normal deadlines difficult to meet. If a procedural deadline set forth in this policy cannot be met during the research misconduct proceeding, the RIO will review and approve, where appropriate, requests for additional time.

If a regulatory deadline set forth in this policy cannot be met, the RIO will file written notice with the oversight agency or funding entity and the DO, setting out the reasons why the deadline cannot be met. The term “day” as used in this policy means “calendar day.” If the last day of a designated time period falls on a weekend or a day on which the Institution is closed, the time period will expire at the close of business on the next succeeding business day.

○ Termination of Institutional Affiliation
If a respondent terminates affiliation with the Institution before a research misconduct matter is resolved, the proceedings under this policy will continue, to the extent possible, until a final determination is reached.

○ Correction of the Research Record
As set forth in 42 CFR §93.313(4), the Institution has the responsibility to identify whether correction or retraction of published or submitted work is required to ensure the integrity of the scientific record is maintained. If research misconduct is found under this policy and falsified, fabricated, or plagiarized research has been published or submitted, including within grant proposals, the respondent must work with the RIO and any other Institutional officials or publishers to correct, retract, or withdraw the research record.

If research misconduct is not found under this policy, but falsified, fabricated, or plagiarized research has been published or submitted, including within grant proposals, due to honest error or for any other reason, the RIO working with the researchers involved will seek to correct, retract, or withdraw the research record.

The Institution may request correction or retraction of the published work at any time during the research misconduct proceedings or during a resolution with the respondent(s) when there is clear evidence of falsified, fabricated, or plagiarized research. The correction or retraction may occur before a final determination of research misconduct against a respondent has been made or if the Institution finds there are no research records available to support the published or submitted research.

○ Reopened Complaints
Any complaint that has been closed with a determination that research misconduct did not occur may be reopened only if, in the opinion of the RIO in consultation with the DO, new and potentially significant information of research misconduct, not previously considered, has been presented.

○ Conflicts of Interest
Throughout the process the Institution will take precautions to ensure that the response to allegations is conducted in a thorough, competent, objective, and fair manner, including precautions to ensure that individuals responsible for carrying out any part of the research misconduct proceeding do not have
unresolved personal, professional, or financial conflicts of interest with the complainant, respondent, or witnesses.

**Retention and Destruction of Human Subjects Research Data Records**

It is the policy of Atrium Health, Wake Forest University Health Sciences (WFUHS), and their respective affiliated entities to collect, store, and properly disposing of all study-related documents for each research study in a manner and timeframe compliant with federal, state and sponsor requirements.

**Guidelines**

General Requirements: The Principal Investigator is responsible and accountable for collecting, filing, storing, and properly disposing of all study-related documents for each research study as required by federal and state law and institutional policy. The PI may delegate the task of maintaining accurate and complete records to another qualified study team member, but s/he may not delegate accountability. Access to research records should be controlled to prevent unauthorized use, disclosure, removal, or destruction of the records. Research records must be stored in a manner that ensures confidentiality, security, and accessibility.

- Research records existing on paper or in portable electronic media must be stored in a locked room and/or a locked cabinet when not in use. Access to the records must be restricted to authorized staff only.
- For electronic records, proper storage, access controls, and transfer provisions must be utilized, including encryption and password protection in accordance with Atrium Health Policies.
- Research data and records should be quickly accessible to authorized staff members when needed for regulatory review or other reasons consistent with Atrium Health policies.

After the study is completed, records must continue to be stored in accordance with all organizational policies to assure the confidentiality of the research subjects and other proprietary information.

**Offsite storage of hard-copy information** must occur at a secure facility that is contracted with Atrium Health and/or Advocate Health to meet regulatory standards for protected health information. When preparing the research records for storage, the study team must be able to easily identify the contents of each storage box in the event that individual research files need to be pulled for an auditor or for data query. Investigators should include the cost of long-term storage of study related-records in their budget. The contents of stored containers must be recorded by the department from which it originated since that department is ultimately responsible for the disposition of the stored information.

**How Long Should Research Records be Kept?**

The PI is responsible for following the study records retention guidelines as required by federal regulations, the study sponsor, and the institution. The requirements for the retention of research records may vary depending on the government agency/study sponsor. The tables below indicate the minimum retention requirements for consent forms and study data by agency. Note that the completion of the research is defined as the point at which the study application is closed with the IRB, not the completion of participant activity.
Once the required retention period has been met, the study team can either destroy the data and records according to the procedures required under Atrium Health and/or Atrium Health AH WFB policy or ensure that data and records are de-identified or coded. De-identified means that ALL of the 18 HIPAA identifiers are removed from the data and link to identifiers is destroyed, thereby preventing the possibility of re-identification. Coded data means that only a linkage file, stored separately from the data, would associate the identities of individuals with the data.

Physical destruction of Health Records (including on and offsite) shall be in accordance with Atrium Health and/or AH WFB Information Security Policy. IT Security can assist with “cleaning/sanitizing” electronic equipment that contains confidential information before it is redeployed. Special processes may be necessary to minimize the likelihood that data could be restored and accessed, so it is important to consult with IT Security to determine the type of data destruction procedure your equipment needs. If electronic equipment containing confidential information is broken or otherwise no longer useable it should be destroyed according to Atrium Health and/or AH WFB requirements. An Equipment/Asset Disposal eForm is available to request the removal/ destruction of electronic devices that have reached the end of their useful life.

Destruction of paper records should be carried out using the confidential shred process in place at Atrium Health and/or Advocate Health. Compact disks can also be placed individually in the confidential shred containers for destruction. If paper records are stored off-site at a facility contracted to Atrium Health and/or AH WFB for the protection of confidential information, the facility may have destruction services that provide disposal of records eligible for destruction. The Privacy Office can provide guidance if there are any questions about the best way to destroy paper records.

Export Controls Policy

The purpose of this procedure is to provide information on proper procedures to follow when shipping or carrying material, technology, or information abroad; sharing technology with foreign collaborators abroad and in the United States; and collaborating with non-U.S persons.

This procedure applies to all individuals conducting research under the auspices of Atrium Health, Wake Forest University Health Sciences, and their respective affiliated entities and representatives.

Guidelines

What is Export Control?

The U.S. government regulates the transfer of information, commodities, technology, and software considered to be strategically important to the U.S. in the interest of national security, economic and/or foreign policy concerns. A complex network of federal agencies and inter-related regulations govern exports collectively referred to as “Export Controls.” Export Controls regulate the shipment or transfer, by whatever means, of controlled items such as software, technology, or services out of U.S. (termed an “Export”). The government also restricts the release of certain information to foreign nationals here in the U.S. (referred to as a “Deemed Export”).

Export Controls have the potential to constrict research opportunities of Medical Center faculty, students and staff, as well as to prevent international collaboration in certain research areas if the export control policy is not followed. Non-compliance with export controls can result in severe monetary and criminal
penalties against both an individual as well as the institution, and can result in the loss of research contracts, governmental funding, and the ability to export items.

Faculty and staff are prohibited from collaborating or engaging in business relationships with any foreign persons – including businesses, research institutions, government and private organizations, individuals, or other types of legal persons – that are listed on the U.S. Department of Commerce Entity List or other lists contained within the U.S. Consolidated Screening List (CSL), without the explicit authorization of the International Research Compliance Office.

1. What Kinds of Activities Might Trigger Export Control Issues?
   a. In order to ensure compliance with export controls, it is critically important for employees to identify when their activities may trigger export controls. When export controls apply, individuals must take the appropriate steps to obtain any required government licenses, monitor and control access to restricted information, and safeguard all controlled materials, including:
      i. Military or Defense Articles and Services
      ii. Select Agents & Toxins (see Select Agent/Toxin list)
      iii. High Performance Computing
      iv. Dual Use Technologies (technologies with both a military and commercial application)
      v. Encryption Technology
      vi. Missiles & Missile Technology
      vii. Chemical/Biological Weapons
      viii. Nuclear Technology
      ix. Space Technology & Satellites
      x. Medical Lasers

2. Traveling overseas with high tech equipment, confidential, unpublished, or proprietary information or data.
   a. Traveling with certain types of high-tech equipment including but not limited to advanced GPS units, scientific equipment, or with controlled, proprietary or unpublished data in any format may require an export license depending on your travel destination.
   b. Traveling with laptop computers, web-enabled cell phones, and other personal equipment. Laptop computers, web-enabled cell phones, and other electronics containing encryption hardware or software and/or proprietary software can require an export license to certain destinations. In general, an export license will be required to take any items to or through any U.S. sanctioned country (e.g., Iran, Syria, Cuba, Sudan, and North Korea).
   c. Use of 3rd party export-controlled technology or information. Activities involving the use of export-controlled information, items, or technology received from outside Atrium Health are not protected under the Fundamental Research Exclusion and all research involving the use of export restricted technology is subject to all export controls.
   d. Sponsored research containing contractual restrictions on publication or dissemination.

The vast majority of research done at the Atrium Health is shielded from export controls under the Fundamental Research Exclusion. However, this protection is lost whenever Atrium Health, or the
researcher, agrees to allow any restrictions on the publication, dissemination, or access to the research by foreign nationals.

3. Shipping or taking items overseas.
   a. Activities that involve the transfer of project information, equipment, materials, or technology out of the U.S. by whatever means will be subject to export controls and may require export license(s) depending on the item, destination, recipient, and end-use.

4. Providing financial support/international financial transactions.
   a. Activities that involve the international payment of funds to non-U.S. persons abroad need to be verified to ensure that the medical center is not inadvertently providing financial assistance to a blocked or sanctioned entity. Examples include providing support via a subcontract to a non-U.S. academic institution or providing payments to research subjects in other countries. Contact brsa@wakehealth.edu if your activity involves payment to persons or organizations outside the U.S.

5. International collaborations and presentations.
   a. Activities that involve foreign national faculty, students, staff, visiting foreign scientists or collaborator(s), or other foreign entities (e.g., non-U.S. company, university or other organization) or research that will include travel to international conferences to present unpublished results may be subject to export controls especially if any of the foreign nationals are from embargoed or sanctioned countries.

6. International field work.
   a. Research projects where any part of the research will take place outside the U.S. (e.g., field work outside the U.S.) may not qualify under the Fundamental Research Exclusion and may be subject to export controls.

   a. Providing professional consulting services overseas, especially to embargoed or sanctioned countries (e.g., Iran, Syria, Cuba, Sudan, and North Korea) is, in most cases, strictly prohibited.

8. What is the Fundamental Research Exclusion (FRE)?
   a. Fundamental Research is defined by the National Security Decision Directive 189 (NSDD189) as “any basic or applied research in science and engineering, the results of which are ordinarily published and shared broadly within the scientific community...” In order to qualify as Fundamental Research, the research must be basic and applied research conducted free of any publication restrictions and without any access or dissemination restrictions. Research that qualifies as Fundamental Research is not subject to export controls as provided for under the federal regulations (15 CFR§734.8). It is critical to note that the Fundamental Research Exclusion will be lost if a researcher agrees to any “side-deals” allowing sponsors the ability to review and approve publications or to control access to the project or project results. Loss of the Fundamental Research Exclusion can quickly put your research in jeopardy of non-compliance with export controls.

**Guidelines for International Travel:**
General Requirements: When traveling abroad there are basic questions that personnel need to consider when determining if export controls apply to their travel:

1. Where are you going?
   a. In general, travel to most countries is not a problem with the exception of countries that are comprehensively sanctioned by OFAC. In almost all cases, travel to these countries requires a license from OFAC. If your travel plans include transit to or through an OFAC comprehensively sanctioned country, contact exports@wakehealth.edu for assistance in determining if government authorization is required.

2. What are you taking abroad?
   a. Items & Equipment
      i. When taking items abroad (including scientific equipment, computers, cell phones, and GPS units) you need to verify that the items are not export restricted based on your travel destination(s). For most low-tech, commercially-obtained items, an export license will not be required unless you are traveling to or through a comprehensively sanctioned country (i.e., Cuba, Iran, Syria, Sudan, and North Korea) in which case an export license will almost certainly be required – even for everyday items such as cell phones and laptop computers.
   b. Research Data & Information
      i. When traveling abroad, you are free to take and openly share or discuss any data or information resulting from Fundamental Research or that qualifies under the Educational or Public Information Exclusions. However, you cannot take or share data or information that is in any way export-restricted (e.g., related to export controlled technologies, proprietary information, or is information resulting from a project not protected under the Fundamental Research Exclusion). All controlled or restricted data or information should be completely removed from laptops, phones, PDAs, or other portable storage devices (e.g., flash drives) before you leave the U.S.

3. What will you be doing and who will you be interacting with?
   a. It is important to ensure that you do not accidentally export restricted information or provide any type of assistance or benefit to a sanctioned or blocked entity. The following are a few things to keep in mind as you plan your travel activities:
      i. Presentations
         1. When presenting data/information in an international setting (including in the U.S. where the audience may include foreign nationals), you need to ensure that you limit your presentation to only information or data that is published, or is publicly available, or that qualifies as Fundamental Research. Be careful not to include or discuss any proprietary, unpublished, or export-restricted data or information as that may constitute an unauthorized export.
      ii. Interactions with foreign colleagues
         1. As noted above, you are free to openly discuss any published or publicly available information or information generated as the result of Fundamental Research as long as the recipient is not a sanctioned or specially designated entity. It is important to remember that while the
results/information resulting from Fundamental Research are not subject to export controls and can be shared without a license, any items, technology, or software generated under that Fundamental Research would be subject to export controls and may require an export license.

iii. Field work
1. Any research activity done outside the U.S. may not qualify for the Fundamental Research Exclusion and would therefore not be protected from export controls until the work is published or otherwise made publicly available. Before disclosing or sharing information or data resulting from international field work it is important to ensure that the information is not export restricted.

iv. Provision of financial assistance
1. In order to ensure compliance with OFAC regulations prohibiting the provision of material or financial assistance to any blocked or sanctioned individual or entity, any activity that involves payment to a non-U.S. person, business, or organization (e.g., international subcontracts, purchase of items from international vendors, or payments to research participants) must be verified against all appropriate sanctioned party and entity lists.

Reportable Activities:

If you are participating in an activity that involves an export/deemed export, that activity must be reported to the International Research Compliance Office by emailing information related to the activity to exports@wakehealth.edu. Although many activities will qualify for an exclusion or exception, it is important that AH WFB document the facts and analysis associated with each export. While it is vital for all faculty to have knowledge of export laws and regulations, the export analysis must be completed by an authorized individual within the International Research Compliance Office. Export analysis must be completed prior to participation in an activity involving an export or prior to establishing an agreement that involves an export. Additionally, it is important to understand that export analysis can be a lengthy process and often requires coordination with U.S. government organizations. If a license is required, the license application process normally requires 30-60 days to complete. If a commodity classification request is required, this process typically requires 2-4 weeks for results. When an export activity is reported, AH WFB reserves the right to deny the activity or decide not to pursue an export license for the activity when there is insufficient time to obtain a license or complete an analysis, the activity is deemed inappropriate, or the activity is associated with increased risk to the institution. Below are “reportable activities” that require coordination with the International Research Compliance Office:

a. Participation in research that involves items controlled under ITAR.
b. Collaborations or non-disclosure agreements (NDAs) with a third party that make reference to “export controls” or “controlled technology”.
c. Requests to abide by a restrictive trade practice imposed by another country.
d. Planned travel to any OFAC sanctioned or embargoed countries.
e. Planned travel to destinations outside the U.S. for work related purposes (even if the work is not directly funded by AH WFB).
f. Shipping tangible items or commodities internationally using an AH WFB account.
g. Emailing or otherwise electronically transferring export-controlled technology to a foreign person.
h. Providing a lecture or presentation at a foreign university, conference, or event (both in person or via videoconferencing).
i. Hosting a foreign person for a visit to any AH WFB facility.
j. Adding a foreign researcher to a project that involves export-controlled items or research with restrictions on the outcome.
k. Becoming party to a research agreement with restrictions on the outcome of the research.
l. Verbally, visually, or otherwise transferring export-controlled technology to a foreign person.

If you need any further help related to export control issues or if you are unsure if you have followed the correct procedures, please contact exports@wakehealth.edu.

Clinical Research

Billing Compliance for Human Subjects Research

This policy will set forth the requirements for determining the appropriate, responsible party for patient care costs incurred as part of human subjects research conducted at WFUSM. The policy will also define the requirements and standards for budgeting and billing research-related patient care costs; address the need to adhere to coverage analysis for the purpose of accurate budgeting and billing practices; clarify the role of the institution in assuring compliance with the Centers for Medicare and Medicaid Services (CMS) National Coverage Decision 310.1; and clarify the responsibilities related to research claims review and charge allocation at WFBMC.

Guidelines

Coverage Analysis (see SOP for details)

- All human subjects research initiated and performed at WFBMC that involves patient care expenses intended to be the financial responsibility of the patient and/or their insurance must undergo a Coverage Analysis performed by the Office of Clinical Research Study Administration team.
- No WFBMC research participant may be enrolled in a WFBMC human subjects research study that may involve billing third-party payers or the patient for clinical services conducted as part of that research study until:
  a. It has been determined which clinical services performed during the course of the subject's enrollment in the research are “routine” and can be billed to third-party payers or the patient through the completion of a Coverage Analysis (CA);
     AND
  b. A billing grid for the research-related costs for the study has been developed in WISER to allow appropriate assignment of charges;
     AND
  c. The study has been activated in WakeOne with a completed RSH record and a published billing grid in WakeOne by the Office of Clinical Research (OCR) Study Administration team.
- Similarly, no WFBMC research participant may be enrolled in a WFBMC human subjects research study involving an investigational/conditionally approved medical device being studied under an
Invesigational Drug Exemption (IDE) or Humanitarian Device Exemption (HDE) that may involve billing third-party payers or the patient for clinical services conducted as part of that research study until:

a. The Medicare Administrative Contractor (MAC) has approved the proposed clinical research study for invoicing and individual patient circumstance if the device is a Humanitarian Use Device, as applicable; OR

b. An alternate funding source has been identified for expenses related to the clinical research project. Refer to Medical Center Policy-MC 31-Invesigational/FDA Conditionally Approved Medical Devices for more detail; AND

c. It has been determined which clinical services performed during the course of the subject's enrollment in the research are “routine” and can be billed to third-party payers or the patient through the completion of a Coverage Analysis (CA); AND

d. A billing grid for the research-related costs for the study has been developed in WISER to allow appropriate assignment of charges; AND

e. The study has been activated in WakeOne with a completed RSH record by the Office of Clinical Research Study Administration team.

The Office of Clinical Research Study Administration team will follow the CMS National Coverage Decision 310.1 and associated CMS policies as the foundation for the Coverage Analysis work. Details of the Coverage Analysis process are outlined in the standard operating procedure titled “Coverage Analysis for Human Subjects Research (OCR-S-02-01)”

Order Entry in WakeOne (see SOP for details)

- Upon activation of the study in WISER and WakeOne, the study team will begin enrollment and link all research participants in WakeOne, per the Documentation in the Medical Record for Human Subjects Research policy.
- All clinical procedures ordered in WakeOne and any visits scheduled in WakeOne (i.e., labs, scans, office visits) that are related to the study, regardless of payer, must be linked to the study in WakeOne so that the Special Billing Team in the Office of Clinical Research can review the charges related to that order or visit for proper allocation (sponsor vs. insurance/patient).
- Details of the order entry process are outlined in the standard operating procedure titled “Revenue Cycle and Order Entry for Human Subjects Research (OCR-S-02-02)”

Research Charge Segregation and Claims Processing (see SOP for details)

- Financial Services will bill all patient care charges related to the study in WakeOne that are allocated to insurance/patient following WFBMC billing practices.
- OCR Special Billing will bill all patient care charges related to the study in WakeOne that are allocated to the study sponsor via invoice to the study chartfield.
OCR Study Administration will bill all study charges (patient care and non-patient care) in WISER that are the responsibility of the research sponsor via invoice to the study sponsor and work with Financial Services to apply received revenue to the study chartfield.

<table>
<thead>
<tr>
<th>WFBMC</th>
<th>Study Initiation Process</th>
<th>Study Conduct</th>
<th>Study Closeout</th>
</tr>
</thead>
<tbody>
<tr>
<td>Principal Investigator/Designee</td>
<td>☐ Perform InfoEd and WISER submission and approval.</td>
<td>☐ Order clinical procedures as required by study protocol. Perform charge capture in WakeOne.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>☐ Log completed visits and invoiceable items in WISER.</td>
<td>☐ Perform financial reconciliation of study chartfield.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>☐ Review and edit charge allocation, based on finalized billing grid.</td>
<td>☐ Review WakeOne to ensure all patient care costs have been appropriately addressed.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>☐ Append modifiers on third-party payer charges, as needed.</td>
<td>☐ Closeout of study in WISER and WakeOne</td>
</tr>
<tr>
<td>Office of Clinical Research (OCR)</td>
<td>☐ Perform coverage analysis, develop billing grid, and build budget in WISER.</td>
<td>☐ Invoice research sponsor based on WISER activity.</td>
<td>☐ Closeout of study chartfield once financial reconciliation is complete.</td>
</tr>
<tr>
<td></td>
<td>☐ Set-up study account in WakeOne.</td>
<td>☐ Review and edit charge allocation, based on finalized billing grid.</td>
<td>☐ Assist in financial reconciliation of study chartfield.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>☐ Append modifiers on third-party payer charges, as needed.</td>
<td>☐ Ensure all outstanding patient care charges for the study in WakeOne are resolved.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>☐ Invoice research sponsor based on WISER activity.</td>
<td>☐ Closeout of study in WISER and WakeOne</td>
</tr>
<tr>
<td>Office of Sponsored Programs (OSP)</td>
<td>☐ Set up study chartfield in PeopleSoft, based on InfoEd submission.</td>
<td>☐ N/A</td>
<td>☐ Closeout of study chartfield once financial reconciliation is complete.</td>
</tr>
<tr>
<td>Financial Services</td>
<td>☐ Maintenance and rollout of research Chargemaster</td>
<td>☐ Submit appropriate research charges to third-party payers with appropriate modifiers.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>☐ Contact Office of Clinical Research to review and address any denials received from an insurer for research-related charges.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>☐ Apply received revenue from research sponsor</td>
<td>N/A</td>
</tr>
</tbody>
</table>
Review/Revision/Implementation

This policy shall be reviewed at least every three (3) years from the effective date.

Related Policies and Standard Operating Procedures

- Coverage Analysis for Human Subjects Research (OCR-S-02-01)
- Revenue Cycle and Order Entry for Human Subjects Research (OCR-S-02-02)
- Review Segregation and Processing of Claims for Human Subjects Research (OCR-S-02-03)
- Investigational/FDA Conditionally Approved Medical Devices (PPB-MC-31)

Regulations

- Medicare Clinical Trial Policies: [https://www.cms.gov/Medicare/Coverage/ClinicalTrialPolicies](https://www.cms.gov/Medicare/Coverage/ClinicalTrialPolicies)
  - 42 CFR 405.201-405.215
  - 42 CFR 411.15
  - 42 CFR 411.406
  - 21 CFR sec 405.201

Compliance in the Conduct of FDA Regulated Human Research Policy

It is the policy of Atrium Health, Wake Forest University Health Sciences, and their respective affiliated entities, that all investigators and study staff members conduct human subjects research in accordance with FDA guidance and regulation.

This policy applies to faculty, staff, students, trainees, and other individuals engaged in FDA regulated research activities conducted at Atrium Health, Wake Forest University Health Sciences, and their respective affiliated entities.

Guidelines

It is the goal of the institution to conduct safe, compliant, and meaningful research. In order to do so, it is of paramount importance that clinical investigations be conducted in accordance with the investigational plan that has been submitted and approved by the institutional review board. Deviations and violations
from the investigational plan may have a negative impact on the safety of participants and be cited by monitors, auditors, or inspectors for regulatory non-compliance. The following sections are example of situations that violate the investigational plan. The examples listed in this document are not intended to be an exhaustive list.

**Informed Consent (21CFR 50.20)**

With limited exceptions, permitted under the regulations, no investigation may involve a human being as a subject in research unless the investigator has obtained the legally effective informed consent of the subject or the subject's legal representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

Practices should not be implemented that jeopardize the informed consent process. For example, orders for research tests and procedures should not be finalized until after informed consent has been obtained, in order to avoid the potential for conducting research prior to obtaining consent.

**Eligibility Criteria**

To ensure the safety of participants and the integrity of data collected in research, protocols are required to list the criteria for participant selection and for exclusion of participants. The inclusion/exclusion criteria are based on previous experience with the study procedures or interventions and are in place to mitigate risks to study participants. The inclusion/exclusion criteria should be strictly followed. Willful violation of inclusion/exclusion criteria exposes participants to drugs, procedures, devices, etc., that they would have not otherwise encountered. Appropriate steps should be taken to assess, verify, and document all inclusion/exclusion criteria before a participant is enrolled on study. Similarly, requirements with respect to tests, procedures etc. specified in the investigational plan should be strictly followed.

All deviations and violations must be reported to the Institutional Review Board according to institutional policies. Submission should include a corrective and preventative action plan to remedy the current situation and prevent similar future events. Repeated, willful, or blatant violations of the regulations on obtaining informed consent or following the investigational Compliance in the Conduct of FDA Regulated Human Research Printed copies are for reference only. Please refer to the electronic copy for the latest version. Page 4 of 4 plan may be considered serious or continuing non-compliance. Such determinations result in reports to sponsors, funding agencies, regulatory oversight agencies, and may include actions up to and including suspension or termination of study activities.

**Documentation in the Medical Record for Human Subjects Research**

It is the policy of WFUSM to document in the medical record activities related to any FDA-regulated human subjects research and/or clinical trial that are clinically relevant to the care and treatment of a clinical research participant. Such activities include services, procedures, devices, and medications received as part of the study at a facility affiliated with WFUSM.
All WFBMC employees, faculty and staff involved with human subjects research/clinical trials are responsible for complying with this policy.

Guidelines:

General Requirements:

- Clinical research studies that enroll WFBMC patients are required to be entered into and managed within the WFBMC enterprise Clinical Research Management System (WISER) and WakeOne.
- If a clinical research participant will receive clinical services related to a study at any WFBMC facility, the participant must have or receive a WakeOne MRN.
- Each patient should be linked to the study in WakeOne and the consent form must be uploaded in WakeOne.

Special requirements for studies involving drugs/devices:

- If a clinical research participant will receive any drug(s) or device(s) as part of the study at any WFBMC facility, that drug/device must be properly documented in WakeOne.

Entry of Research Study Documentation into the Electronic Medical Record (WakeOne):

- The Principal Investigator or appropriate designee will be responsible for ensuring that Clinically Relevant research study information/documentation is uploaded and maintained in WakeOne. Examples of clinically relevant documents/documentation may include:
  - Serial/EAP numbers of investigational or FDA-approved significant risk devices
  - Results of lumbar punctures and biopsies
  - Results of Diagnostic tests, labs, ancillary studies, clinical flow sheets
  - Visit notes, progress notes, phone notes, device use
  - Reports and image files from imaging studies performed on WFBMC clinical scanners
- Exceptions to the requirement for EMR documentation are made for the following:
  - Any documentation or information that the Principal Investigator or appropriate designee has deemed as not clinically relevant, as defined by this policy
  - Results of any procedures performed on research scanners
  - Blood draws that are send-out labs
  - Consent forms from subjects who have failed study screening following initial consent and who will not be continuing in the study, provided that the tests and procedures used in the screening process are not potentially billable.
  - Sensitive information, as defined above
  - Demographic information already existing in WakeOne
  - Screening checklists, flow sheets, and other study documents not relevant to the subject’s healthcare
  - Case report forms
  - Results from elective genetic testing that are not routinely used in clinical practice
  - Other non-clinical test data
- It is important to note that information entered into WakeOne must be properly linked to the study so that billing compliance is maintained, and that all data entry into the WakeOne must be performed in accordance with Health Information Management (HIM) requirements.
What is required to be in the Medical Record? | What is not required to be in the Medical Record?
---|---
Study demographics within the EPIC RSH Record with no consent form or Certificate of Confidentiality limitations | Study information limited by an executed Clinical Trial Agreement with a sponsor
Name of Investigational Drug/Device within the EPIC RSH Record | Certificate of Confidentiality studies with no consent form explanation
WFBMC patient link to each study to support both clinical knowledge of study and compliant research billing | Procedures performed on/resulted from Research Imaging Scanners
WFBMC Patient Signed Consent Forms (CMS requirement) | Non-WFBMC external lab/procedural results done for research purposes
Any research procedures that are clinically relevant | Case Report Form data submitted to study sponsor

**Quality Conduct of Clinical Research Policy**

It is the policy of Atrium Health, Wake Forest University Health Sciences, and their respective affiliated entities, to ensure there is appropriate review of research, sufficient/appropriate monitoring (internal and external) and a quality assurance plan to conduct research in accordance with all internal and external policies, procedures, and regulations governing research. This Policy is guided by the ethical principles set forth in the Belmont Report and Declaration of Helsinki, regulations found in 45 Code of Federal Regulations Part 46, the regulatory requirements of the Food and Drug Administration, policies of the National Institutes of Health, and other applicable laws, regulations, local standards, and ordinances that pertain to human subjects research in which Atrium Health is engaged. The purpose of this policy is to set forth the requirements and processes to ensure clinical research is conducted in a quality and compliant manner.

**Guidelines**

Atrium Health Research Administration and The Office of Regulatory Affairs and Research Integrity within the Clinical and Translational Science Institute (CTSI) at Wake Forest School of Medicine are responsible for setting forth and maintaining requirements, policies, and procedures to foster a consistent approach to the human subjects research, yielding conduct and results of the highest quality and integrity.

Principle Investigators are responsible for ensuring all study personnel are appropriately trained to conduct the research, that there is a clear monitoring plan in place, and that a process for ensuring data integrity is followed. The following standard operating procedures are implemented to provide guidance to investigators and study staff on proper procedure at Atrium Health.

**Standard Operating Procedures**

- Data Retention and Destruction of Human Subjects Data/Records
- External Audits of Human Subjects Research
- Internal Post-approval Monitoring of Human Subjects Research
- Sponsor Monitoring of Human Subjects Research
Intake, Review, and Approval of Industry-Sponsored Human Subjects Research Policy

This purpose of this policy is to ensure that all required reviews and approvals related to the regulatory, operational, and financial aspects of industry-sponsored human subjects research are obtained prior to study activation at Atrium Health and Advocate Health.

All Advocate Health employees, faculty and staff involved with industry-sponsored human subjects research are responsible for complying with this policy.

Guidelines

1. Feasibility of Industry-Sponsored Human Subjects Research
   a. All industry-sponsored human subjects research anticipated to be performed at Atrium Health should be evaluated for feasibility by the Principal Investigator or Designee before the study is submitted for review by the Office of Clinical Research. See the SOP titled “Study Feasibility for Industry-Sponsored Human Subjects Research” for more details.

2. All Confidential Disclosure Agreements (CDAs) received from industry sponsors/clinical research organizations must be submitted through Huron for review by the OCR Contracts team for review, negotiation, and execution.

3. Intake of Industry-Sponsored Human Subjects Research after site selection
   a. All industry-sponsored human subjects research to be performed at Atrium Health and WFBMC must be submitted for review in the following three (3) systems and in this order:
      i. OnCore: For development of the study calendar, coverage analysis, and budget by the Office of Clinical Research Study Administration team.
      ii. eIRB: For review of all regulatory items by the WFUHS Institutional Review Board.
      iii. Huron: For review of the agreement by the OCR Contracts team.

4. Review of Industry-Sponsored Human Subjects Research
   a. The Office of Clinical Research (OCR) will negotiate all terms and conditions for all Agreements related to Atrium Health industry-sponsored human subjects research.
   b. The Office of Clinical Research (OCR) will develop the study calendar, coverage analysis, and budget for all Atrium Health industry-sponsored human subjects research in OnCore. The budget developed in OnCore will provide appropriate procedural and institutional costs that should be negotiated into the sponsor budget by the Principal Investigator or Designee or OCR Study Administration team. The Principal Investigator or Designee is responsible for review and approval of the study calendar, coverage analysis and budget build in OnCore by the OCR Study Administration team.
   c. The WFUHS Institutional Review Board (IRB) will review each human subjects research study to ensure that it meets the regulatory criteria for approval.

5. Approval of Industry-Sponsored Human Subjects Research
   a. Once all regulatory-related concerns are addressed, the WFUHS IRB will provide a letter documenting IRB Approval.
   b. Upon completion of the negotiation of the agreement, and confirmation that the financial exhibit in the agreement aligns to the OnCore budget and there is assurance that all study
costs will be covered, OCR will secure full execution of the agreement and work to complete the process of creating a study award/project number.

c. Once the agreement is fully executed and the IRB has approved the study, the OCR will work to activate the study in OnCore and generate the RSH record for the study in EPIC (when applicable).

d. The study team is responsible for opening the study to accrual in OnCore.

Participant Compensation and Reimbursement for Human Subjects Research Policy

Wake Forest University Health Sciences (WFUHS) engages in research projects with a variety of sponsors. The study sponsor may provide funding in order for WFUHS to issue research-related payments to research participants.

Research participants may be compensated for time and participation in a research study, with the payments being made in the form of cash or non-cash. Compensation is primarily used to offset expenses related to travel, meals, time and/or lost revenue and such compensation should be commensurate with the requirements a participant is asked to adhere to as part of the research. Excessive compensation may be viewed as inducement and can place unnecessary pressure on the research participant to participate/remain in the research study.

This policy is effective for any new eIRB submissions that are considered human subjects research as of October 01, 2019.

When WFUHS has determined that it is necessary to include human subjects in research activities; WFUHS must ensure appropriate regulatory processes are in place. This policy and its corresponding SOP are limited to the participant compensation and reimbursement process.

Guidelines

The following research participant compensation payment methods are approved and acceptable at WFBMC (each has different requirements, which are spelled out in the SOP):

- Payment via ClinCard (preferred method)
- Payment via Check (all checks must be issued by WFBMC Accounts Payable Department)
- Payment via Cash (Change Funds)
- Payment via Gift Cards, including e-gift card options

Study teams should choose one participant compensation method from the list above for each study and should refrain from using multiple options per study.

WFUHS encourages all study teams to utilize ClinCard as the preferred methodology of paying participants on clinical research studies as this is the most efficient and time-saving methodology.

Study teams will be required to obtain a W-9 (or W-8BEN for foreign individuals) from all participants receiving compensation on their studies, unless their study meets one of the following exclusion criteria:
No participant within the study will receive more than $200 in any calendar year for participating in the study. This will require an attestation from the Principal Investigator or an appropriate designee in WISER.

No participant will receive more than $600 in total in any calendar year in a given study, and one of the following additional situations is true:

- The research study is being conducted offsite and has no study visits at a Advocate Health or Atrium Health facility (e.g., survey studies performed online). This will require an attestation from the Principal Investigator or an appropriate designee in WISER.
- The research study primarily involves vulnerable populations, in which a collection of a W-9 (or W-8BEN for foreign individuals) would significantly reduce the number of participants recruited, thus resulting in negative effects to the study results. This will require an attestation from the Principal Investigator or an appropriate designee in WISER.

Study teams can contact the Office of Clinical Research (ocr@wakehealth.edu) for any clarifications needed regarding the exclusion criteria.

Study teams using ClinCard as the payment methodology for their study must obtain W-9s from all participants (or W-8BEN for foreign individuals) unless the Principal Investigator / appropriate designee provides attestation that their study meets the exclusion criteria noted above. Gift cards and cash will remain as primary options for studies that meet the W-9 (or W-8BEN for foreign individuals) exclusion criteria noted above.

Study teams should only use gift cards (including e-gift cards) as the payment methodology if their study meets the W-9 (or W-8BEN for foreign individuals) exclusion criteria above. If gift cards (including e-gift cards) will be used, payment logs of gift cards and e-gift cards issued should be maintained within the study team’s Department and should be audited periodically by the Department to ensure study participant numbers and visits coincide with issuance of cards/e-gift cards.

Study teams should only use cash as the payment methodology if their study meets the W-9 (or W-8BEN for foreign individuals) exclusion criteria above. If cash payments will be used, payment logs of cash disbursed should be maintained within the study team’s Department and will be audited periodically by the Department to ensure study participant numbers and visits coincide with issuance of cash. Cash payments will require receipts to be submitted along with the RFP to replenish cash supplies and should also be audited periodically by the study team.

All records related to disbursement of participant compensation must be kept for a minimum of 7 years. The Department must keep copies of the disbursements to support tax reporting requirements and other legal matters. If ClinCard is used as the payment method, the ClinCard system will house the necessary documentation.

A Standard Operating Procedure (SOP) has been established to provide guidance on how to effectively generate payments for research participants in WFBMC clinical research studies.

Sponsored Programs

**Managing Subawards Under Sponsored Research Projects Policy**

Guidelines
WFUHS utilizes the Federal Demonstration Partnership (FDP) templates that are widely accepted at most institutions as acceptable terms and conditions for the majority of our subawards issued to other institutions. There are times when a non-federal sponsor or a particular mechanism funds our prime award that this template cannot be used and will be examined on a case by case basis at the time of issuance. WFUHS developed a subaward tool in 2016 which will be encouraged to be used to assist in preparation of subawards and evaluated at a later point in time for mandatory usage.

- When a new award is received and a subaward is required, the department is responsible for providing a scope of work, budget and contact person at the receiving institution. This can be done either by utilizing the tool or as part of the package sent to the Office of Sponsored Programs (OSP) upon receipt of an award notice.

- When a continuation award is received and a revised subaward is needed, the department is responsible for providing an updated scope of work (if applicable), a budget for the new period being issued and a contact person at the receiving institution. This can be done either by utilizing the tool and creating an amendment or as part of the package sent to OSP upon receipt of an award notice/amendment for the continuation period.

- Subawards to other entities may only be signed by designated personnel, typically within the OSP.

- Invoicing and reporting terms are specified within the subaward documents. Invoices are to be sent to OSP as indicated within the subaward template.
  - When invoices arrive the OSP Administrator will verify that the invoice falls within the subaward period of performance, follows the prior invoice received (i.e. verifies no months are missing) and complies with approved budget overall amounts. The invoice will then be forwarded to the PI/department for review and submission for payment.

- The PI/department is responsible for reviewing the invoices to ensure the charges are reasonable for the scope of work for the period and overall satisfaction with the subawardee’s work to date. If there are concerns with work or the invoices, this should be addressed by the PI/Department with a courtesy copy or email to OSP to alert of the concerns being raised. Otherwise, the invoice should be submitted for payment via the electronic Financial System. Please note, submission for payment is certification that the charges are reasonable and valid.

- For final invoices, PI/departments should also have the final technical report, and any other information they need to complete their research, prior to submitting the invoice for payment via the electronic Financial System.

- Departments are responsible for ensuring all costs are appropriately allocated to sponsored projects. All subawards require a final invoice. In order for these final costs to be included in required financial report, these must be received within the specified time period or risk not being paid. Departments should review work completed by subrecipients and follow up for any final invoices not received. Once a final financial report has been submitted, late invoices cannot be paid. Invoices must be posted in the electronic financial system to be included in any reports. If a department desires to pay late invoices, they will be paid from department unrestricted funds.

**Timeline for Establishing New Chartfields for Newly Sponsored Awards**

**Guidelines**
When a newly awarded federal grant is received in the Office of Sponsored Programs, staff will review the award and send an email to the PI and departmental contact indicating that the award was received and insert information about the proposed budget and any special terms and conditions of the award (see exhibit 1 for example of email language). The PI/departmental contact may choose to either allow the award to be set up within 5 business days with the budget reductions applied across the entire budget or they may provide a new budget within 5 business days. The intent of the 5-day window is to ensure timely set up chartfields related to sponsored projects that will allow HR actions and other charges to be applied both timely and appropriately to sponsored activities.

Review/Revision/Implementation:

- Review Cycle: This policy shall be reviewed by the Office of Sponsored Programs at least every three years from the effective date.
- Office of Record: After authorization, Office of Sponsored Programs shall house this policy in a policy database and shall be the office of record for this policy.

For examples and templates, refer to the policy via PolicyTech.

Residual Funds Policy

The purpose of this policy is to establish the criteria for disposition and use of residual funds from for-profit sponsored research projects. This policy is designed to assure that residual funds are used to advance the mission of the Institution, avoid potential conflicts of interests for investigators, provide timely and appropriate utilization of residual revenue earned on sponsored accounts, ensure expenditures and obligations of sponsored accounts have been met prior to approving access to residual dollars.

It is important that sponsored accounts only be charged for the reasonable cost of performing the research project and not expenses unrelated to the performance of the sponsored research project. Also, all applicable Facilities & Administrative (F&A) costs and appropriate levels of effort for the sponsored project must be assessed prior to any distribution of residual funds.

It is not the intention of the Institution to participate in any sponsored research project, including clinical trials, for the purpose of generating residual funds.

This policy applies to faculty, staff, students, and other individuals engaged in Sponsored Research activities conducted at WFBMC or its affiliates which are sponsored by or supported by for-profit entities.

Guidelines

Close-Out

Sponsored accounts should be closed out at completion of the sponsored research project and any residual balance transferred to a residual account. The close-out process must be initiated immediately upon termination and/or completion of the project to allow sufficient time to complete the close out activities within ninety (90) days of the termination or expiration of the contract and/or completion of the project. In some circumstances, the completion of the close-out process may vary due to (a) completion of all invoicing and receipt of payments (if a clinical trial) or (b) a pending audit and time for adjustments (see post audit review).
Close-outs are an important piece to completion of project and contract requirements and are required to be done in a timely manner. Departments not taking an active role in providing required information to complete the close-out, will be at risk of losing residual balances. Funds in this case will be transferred back to the institution. The Principal Investigator (PI) is responsible for ensuring that all expenses have been appropriately charged to the project and that all funds due have been received before the sponsored account close-out occurs. In the event a waiver of any part of F&A costs had been applied to the active sponsored account, the waived F&A will be earned on behalf of Wake Forest prior to the transfer of the unrestricted residual balance to a residual account.

Once the close-out process has been initiated, no further charges can be applied to the account being closed out, unless errors are identified during the close-out review and/or reconciliation. If the account has a residual balance greater than 25% of the amount received, the PI will be required to provide an explanation and justification. If additional payments are received after a close out occurs, the account may need to be reactivated to create a correct audit trail.

**Deficits**

If the sponsored account being closed has a deficit, the PI and/or department will be responsible for the account deficit.

If there is a deficit(s) in another of the PI’s closed sponsored project account(s), any residual balance must be used to satisfy such deficit(s) prior to distribution to a residual account.

**Internal Audit Review**

All for-profit contracts or sponsored awards with significant residual cash balances will be subject to internal audit reviews. During the process, the PI may be requested to provide information that may explain and justify the reason for significant residual balances. The purpose of the internal audit is to review and determine whether appropriate charging occurred during the conduct of the study, and in the case of clinical trials, may include a review to determine that billing to third parties, i.e., Medicare, Medicaid, insurance, or research subject where appropriate.

**Departmental Budgeting of Residual Funds**

After completion of the close out and internal audit review (if required) residual funds will be transferred to an unrestricted account (115-DEPTID-PRGID-000000) for access by the PI or department Chair/Division Chief according to departmental policy.

The PI/department will be required to prepare a budget during the annual budgeting process in order to access and utilize residual funds each fiscal year if the funds are not going to be spent within the fiscal year where the close-out was finalized. For example, if a residual balance is obtained in January and will be spent prior to June 30th, it is not necessary to budget these funds. However, residual funds that remain after June 30th, will need to be budgeted during the annual budget process to allow for spending in the next fiscal year.

Residual dollars are available for budgeting, however any net deficit or fund balance spend down will be required to be approved during the development/approval process of the annual budget. It is recognized that residuals earned late in the fiscal year are often frozen until the following budget process, but the
goal is to put these dollars towards future research efforts. Special circumstances can be examined on a case by case basis if funds are needed prior to the budget process with the Dean’s Office.

All funds approved for transfer to a residual balance account are under the signature authority of the PI or Department Chair/Division Chief of the project being closed out. In the event a PI resigns, retires, or is separated from the Institution for any other reason, then any unrestricted residual balance will be transferred to the Department or Division and will be under the management of the Department Chair/Division Chief.

Proposal Submission Deadline Policy

It is the policy of WFUSM that all application to external sponsors for funding to be reviewed by the Office of Sponsored Programs (OSP). All application materials are to be uploaded and routed via Huron Research Suite (HRS), the institution’s electronic proposal and award management system.

The purpose of this policy is to provide quality service to the Research Administration community by ensuring that applications for external funding are reviewed for compliance with all relevant policies of the institution and the policies and guidelines of the sponsoring agency.

Guidelines

- Proposal submissions for grants and subcontracts must comply with the internal proposal deadline requirements outlined in the following table. This detailed two step Proposal Submission Deadline Policy is intended to incorporate a sufficient time period for review of the administrative components of the application (3 Business Days prior to the deadline) and allow appropriate time for Principal Investigator’s (PI's) to continue work on the technical component of the application, prior to the final submission to the sponsor (10:00 am the day of the deadline).

- Proposals routed to OSP on or before three (3) business days will be considered “on time” if all administrative aspects of the proposal are complete. The technical component can be saved as draft and still be routed to allow for final edits to the science; however any changes to the technical document should not impact any of the administrative components outlined below. To be considered complete, the proposal must include the following to meet the three (3) business day deadline:
  - All Administrative Sections of the Proposal must be in a Final Form. Drafts and placeholders of any part of the administrative components of the application will not be accepted. The administrative components required in final format for the three (3) business day deadline are:
    - The budget/budget forms with complete budget justification.
    - Indirect Costs (IDC) must be calculated with either the federally negotiated rate or the rate specified by the sponsor in written policy or program guideline documentation.
    - Completed and signed subrecipient commitment form(s) or letters of intent for each subrecipient, with all applicable attachments.
    - Properly documented cost sharing or matching (if applicable).
    - Any special administrative documents required by the Sponsor.
    - NOTE: The PI/Department will be informed of any changes that are necessary with the administrative sections noted above during the proposal review process. It is an expectation that administrative review
changes will be completed by the department as OSP will not be re-reviewing administrative items. A response from OSP regarding a proposal for review will be made within 24 hours or endorsement by the department/section head, which routes the proposal to OSP. Do note that complex mechanisms will take longer than 24 hours to review and should be routed early enough for sufficient review, especially during large volume deadlines.

- Day of Sponsor Deadline (10:00 am)
  - Electronic Submissions: Delivery of the Final Package to the Office of Sponsored Programs (OSP) for Submission to the Sponsor.
    - The PI/Department must release the complete proposal to the OSP no later than 10:00 am the day of the Sponsor deadline for electronic submission to the sponsor. This allows time to address possible technological glitches and for the PI/Department to make corrections in response to system errors indicated by Grants.gov or other Federal systems. Proposals listed in the queue in the order received and submitted to the sponsor as quickly as possible.
    - Per NIH guidance: error free submission must be accepted by Grants.gov by the 5:00 pm deadline. NIH’s late policy does not allow for error corrections after the deadline. The NIH policy that you have 48 hours to correct any errors does not extend the deadline the 5:00 pm due date; therefore, submission 48 hours prior to the deadline is best practice.
    - Administrative sections of the proposal reviewed at the three (3) business day deadline will not be re-reviewed the day of the deadline.
  - NOTE: Proposals routed after 10:00 am, the day of the sponsor deadline cannot be processed in time to meet outlined requirements and will not be submitted to the sponsor.

- Deadlines are necessary because proposals that are electronically submitted through Grants.gov systems and other sponsor systems can contain issues that could prevent the proposal from being fully validated with the sponsor prior to the sponsor deadline. With the proper lead time, it provides an opportunity to review and correct any items that the electronic systems marks either warnings or errors.

- Proposals will be reviewed and submitted in the order they are received. Proposals routed to OSP earlier than the internal deadlines will take review and submission precedence.

- It is critically important that once you route your proposal to the OSP that the PI/Department is readily available to respond to questions and to make any necessary proposal fixes necessary for OSP to submit the proposal.

Effort Certification Policy

Guidelines

Wake Forest University Health Sciences receives federal funding and is therefore subject to the requirements established by the Office of Management and Budget within the Uniform Guidance (2 CFR Chapter I, Chapter II, Part 200, et al., Uniform Administrative Requirements, Cost Principles and Audit Requirements for Federal Awards). To receive federal funding, the Uniform Guidance requires that
Institutions maintain a system of internal control which provides reasonable assurance that charges to federally sponsored projects are accurate, allowable, and properly allocated. The effort reporting process is a primary component of this system of internal control and provides evidence to support the reasonable approximation of employee effort devoted to sponsored projects and/or other WFUHS activities (e.g., instruction, patient care, department administration, etc.).

WFUHS effort certifications are legally binding documents and are reviewed by External and Internal auditors, as well as Sponsors, when requested.

Federal guidelines recognize that research, instruction, patient care, and department administration activities within an academic/medical center environment are often “inextricably intermingled.” The Uniform Guidance provides for “a degree of tolerance” in the preciseness of effort reporting. WFUHS has deemed an acceptable level of tolerance to be +/- five percentage points. In cases where effort certification and salary distribution vary by more than the 5 percentage points tolerance, an explanation is required.

- Semi-annual effort certification is required for all individuals who work on sponsored award activities or have the potential to work on sponsored award activities based on their departmental assignment.
- Completed effort certifications must total 100%. Effort must be certified in whole numbers only.
- With certain exceptions (e.g., equipment and instrumentation grants, doctoral dissertation grants, student augmentation grants, and institutional or individual training grants from faculty mentors) faculty and staff are expected to apply some level of effort (greater than 0%) to sponsored projects on which they are listed as the PI or as key personnel and have committed effort.
- Once the designated effort certification period has ended, completed certifications may not be recertified without explicit permission from the department Chair, Dean, and a designated official in the Office of Sponsored Programs.
  - Retroactive payroll expense transfers involving sponsored projects may not be made for any prior pay period after the effort has been certified. Accordingly, it is very important that effort data is carefully reviewed prior to certification.
    - The only exception to this is for instances where an employee has completed the effort certification and the payroll expense transfer is to align the salary with the completed certification. That is, adding or removing salary to ensure the salary distribution is aligned with the effort certified is permitted. Changing the salary distribution and then requesting a change to the effort certification to match is prohibited.

Establishing Clinical Trials Accounts

It is the policy of WFUSM that documents for industry sponsored clinical trial accounts be submitted, reviewed, and approved concurrently by central office stakeholders prior to study initiation and study spending.

The purpose of this policy is to confirm the appropriate steps to initiate and open a chartfield account to allow for work and spending on industry sponsored clinical trials.

Guidelines
The Institution handles industry-sponsored clinical trials differently from other types of sponsored projects for several reasons. The sponsor negotiates the amount they will reimburse the institution for each subject in the study. This rate is often governed by industry norms rather than time-based costs of doing the research or clinical charges for a procedure. In addition, the actual number of dollars received from the sponsor may vary greatly from the proposed amount because the number of participants recruited for a given study could vary markedly from the original estimate.

All proposed industry-sponsored clinical trial contracts must be processed through established procedures, which include fulfilling all compliance requirements, completing an electronic proposal submission, and obtaining departmental and central office approvals. The Principal Investigator (PI) and study team may not enroll subjects until the contract is executed, the budget is approved, and IRB approval has been obtained.

- Upon execution of the contract, budget approval, and IRB approval, the PI may start the Clinical Trial. While not a party to the contract, as an employee of the institution the PI should abide by all clauses of the contract and will be responsible for the performance of the scientific, safety, technical and administrative duties normally associated with the clinical trial including the submission of reports as required by the sponsor and the IRB. The PI will also be responsible for administering the trial in accordance with the signed contract terms and conditions and the approved clinical research protocol, as well as compliance with broader (i.e. not protocol-specific) institutional policies, including but not limited to general oversight of the study and study staff.

Account Setup for Clinical Trials - Industry sponsored clinical trial accounts are released to the study team upon final execution of the contract and after (IRB) approval. The account is set up for a period of time consistent with the term of the contract.

- Industry sponsored clinical trial budgets are generally based on a per subject reimbursement rate. As such, the account limit is set up as a best guess estimate based on the information provided to the Office of Sponsored Programs because the final amount will depend upon how many subjects are enrolled. The internal budget process with the Office of Clinical Research is important not only to identify costs but also to help PIs and departments appropriately manage expenses and revenue.
  - Invoicing - The first costs that might be billed to a clinical trial project account are start-up costs. These might include IRB fees, administrative set up, pharmacy fees, Medical Coverage Analysis fees, etc. The Office of Clinical Research sends out the first invoice to the sponsor for the study related start-up costs. The Office of Clinical Research will continue to invoice and follow up with the sponsor (as appropriate) for the remainder of the study. Some study visits are paid automatically upon completion of CRFs, in which case invoicing may not be required. All checks received by the Institution for an industry-sponsored clinical trial study must be submitted to the Office of Clinical Research, to be processed and deposited into the correct account.
  - Budget Expenditures - The budget included in a clinical trial agreement is part of the contract; therefore, PIs are required to adhere to the budget for costs needed for the performance of the trial. The PI is responsible for clinical trial expenditures ensuring compliance with the budget ceiling and line items defined in the contract. The PI is responsible for ensuring that all expenses have been appropriately charged to the project,
i.e., faculty and staff effort, (see effort policy) and that all funds due have been received before study close-out occurs.

- PIs and Departments are responsible for managing the financial aspects of the project which includes reviewing and monitoring expenses and income on the project account financial statements on a monthly basis at a minimum. Deficits on clinical trial accounts should be identified and rectified as soon as possible, moving the costs to the appropriate account. Care should be taken to ensure the costs are identified and moved in a timely manner.

Closeout - Clinical trials accounts should be closed out at completion of the project. PIs and Departments are responsible for reviewing the account to verify outstanding invoices, outstanding payments, payroll posting, etc. Any residual funds remaining will be transferred to the department per the residual policy. Any fees related to the closed sponsored research project such as external audits or documentation storage fees will be the responsibility of the Department and should be anticipated before moving residual funds to an unrestricted account (See Residual Funds Policy).

- Deficits and Audit Disallowances - It is the policy of the Institution that the PI/department/center/institute is financially accountable for all deficits and audit disallowances related to a clinical trial or other sponsored award. The PI/department/center/institute is responsible for finding a suitable source of funds to cover overdrafts or audit disallowances. These funds may come from other unrestricted funds available to the PI, department/center/institute, but not from other active sponsored fund accounts.
  - Deficit spending on a clinical trial occurs when expenses are greater than invoice/income. It is understood that Clinical Trials may run a deficit balance from time to time, since activity and charges may occur prior to actual receipt of payment from the sponsor. PIs and Departments should monitor project accounts monthly and review for expenses that should not be there, incorrect amounts, omitted expenses and overdue payments. Corrections should be made in a timely manner as they are identified.
    - If a deficit balance occurs on a project where spending has exceeded the funded amount for the entire project, the PI/department will have a 3-month grace period to reconcile the account and transfer the deficit balance to an appropriate fund. Financial Services has the authority to move deficits to department/institute/center accounts if not resolved in a timely manner.
    - A deficit balance may also occur due to uncollectable invoices either due to the sponsor no longer having the financial means to honor the payment, or due to the sponsor's dissatisfaction with the work or end product. The Office of Clinical Research and the Office of Sponsored Programs will pursue payment for uncollectable invoices from the sponsor in conjunction with the Legal department until written acknowledgment is received from the sponsor indicating the payment is declined. If no response from the sponsor is received, the PI will be sent an email from the Office of Clinical Research listing all outstanding invoices with an overdue date of greater than 365 days. Any attempts to collect payment for the invoices listed will also be documented within the email notification. After 7 days from the email being sent to the PI, a request will be sent to the Dean’s Office asking permission to write off any outstanding and unpaid invoices.
• PIs and departments that have residual and/or other R&D accounts may be required to offset uncollectable invoices using those funds.

Sub-Content Audit disallowances or unallowable costs occur when it is determined that expenses charged to sponsored accounts are not in compliance with the sponsor spending/costing principles. Unallowable expenses must be transferred from the clinical trials account to an unrestricted account in a timely manner as they are identified and may not be transferred to another sponsored funded account.

Financial Management of Activities Related to Research

Guidelines

It is the responsibility of all who may expense charges to a research project to understand the costing principles to a sponsored project. The generally accepted principles are as follows:

○ Is it Reasonable? A prudent person would have purchased this item and paid this price.

○ Is it Allocable? Expenses can be allocated to the government activity based on benefit derived, cause and effect, or other equitable relationship.

○ Is it Consistently Treated? Like expenses must be treated the same in like circumstances. Treatments of expenditures are disclosed in our DS2 statement. Each institution may classify expenses to meet their business needs, so an expense may be treated differently than a prior institution that you may have experienced before.

○ Is it Allowable? Allowable for reimbursement as specified by the sponsor or government regulations.

Charges should only be incurred on projects by team members who understand the purpose of the activity and as such are able to certify that the expense meets the above criteria federal guidelines such as Uniform guidance, agency guidelines such as the NIH policy manual and all award specific guidance found in the notice of award or contract. An explanation of business purpose must be documented and should contain sufficient information so the approver, reviewer and/or auditor will clearly understand how the expense benefits the project being charged.

One of the elements most critical to successful financial management of research activity is the assignment of appropriate accounts to budget line items and expense transactions. The principal investigator and/or grant administrator should be familiar with the account structure and with the accounts available for use each project. When projects are set up, stakeholders are encouraged to review the codes available in accordance with the project budget and scope of work being performed. Proper coding of items ensures appropriate assessment of indirect costs, proper recording of equipment and capital expenditures; reporting requirements and audit compliance.

Expenses are reviewed by central office staff as an audit control to ensure rules and regulations are being followed and documentation standards are upheld at the departmental level.

Monthly statement should be reviewed by departmental staff familiar with a project to ensure all charges accurately reflect known expenditures. This review should include but is not limited to:

○ Payroll
○ Patient charges such as MRIs or lab tests
○ Patient incentive payments
Travel
Supply orders, returns and appropriate allocations if multiple awards used for a bulk order

Payments received from sponsors also should be reviewed by departmental staff familiar with a project to ensure all monies due are received timely and overpayments or incorrect credits are identified.

It is the responsibility of the department and PI to ensure that staff members are appropriately trained to understand the cost principles associated with sponsored activities if they are approving charges on research projects. Training on Uniform Guidance, institutional policies, systems (Wiser, InfoEd, PeopleSoft, EIRB, IACUC etc.) national conferences, research certification and training through the Office of Sponsored Programs is highly encouraged.

PI's and department staff are responsible for maintaining records of financial data in accordance with WF BMC record retention policy; typically 7 years after the final report is accepted or submitted.

Financial Management of awards requires in depth knowledge of policies, processes, and procedures. Staff are responsible for understanding and complying with all of the related polices and SOP's listed within this policy.

Graduate Student Tuition on Sponsored Projects

The purpose of this policy is to define a process by which the Wake Forest School of Medicine applies stipends and tuition as direct costs to sponsored programs or other appropriate funding sources for Wake Forest biomedical graduate students who work on funded projects, including, but not limited to, sponsored programs.

This policy applies to Wake Forest University Graduate School of Arts and Sciences, Biomedical Program Students.

Guidelines

Sponsored program sources

Stipends
  - Under the Uniform Guidance, stipend payments are not compensation for services rendered and, therefore, are not allowable on federal research awards unless prior approval is obtained by the Federal awarding agency.
  - Stipend expenses are allowable on sponsored projects intended to support training or research training as clearly stated in the agency program announcement. Examples of these awards include NIH “T” and “F” awards, and most non-NIH awards.
  - On non-“T” and “F” grant awards, stipends are paid in the form of a salary expense; this does not confer an employer-employee relationship. Examples of these awards include NIH “R,” “P,” “U,” and other NIH research awards.

Tuition
  - Tuition Charges are allowable on sponsored projects provided that:
    - The individual is conducting activities necessary to the Federal award;
• Tuition remission or other support is provided in accordance with established policy and consistently provided in a like manner to students in return for similar activities conducted under Federal awards as well as other activities;
• During the academic period, the student is enrolled in an advanced degree program and the activities of the student in relation to the Federal award are related to the degree program;
• The tuition remission or other support is reasonable compensation for the work performed and is conditioned explicitly upon the performance of necessary work; and
• It is the practice of the institution to similarly compensate students under Federal awards as well as other activities.
  o A Tuition charge will be budgeted on every new or competing renewal sponsored project proposal on which a Wake Forest biomedical graduate student, who is enrolled in an advanced degree program, performs activities, unless specifically disallowed by the sponsor.
  o A tuition charge will also be budgeted on every award where student stipends are budgeted, unless disallowed by the sponsor.
• Non-sponsored funding sources
  o Stipends
    o Stipend expenses are allowable on endowments, startup funds, retention funds, departmental funds, contracts, and other sources.
  o Tuition
    o Tuition may be drawn from all allowable sources, including endowments, startup funds, retention funds, departmental funds, contracts, and other sources.
    o Junior faculty, at the Assistant Professor level, and with no grant support are exempted from the obligation to provide a source for tuition.

Cost Sharing on Grants and Contracts Policy

It is the policy of WFBMC to engage in research activities sponsored by various funding agencies. At times, in order to obtain these funds a commitment of cost sharing is required. Cost Share is a real cost requiring a commitment by WFBMC to provide resources to a sponsored project. WFBMC will generally commit resources to a project when required to do so by the sponsor or when it is demonstrably in its best interest to do so. Requests for Cost Share are vetted at Institutional leadership levels to ensure alignment with budgets, areas of focus and strategic planning.

This policy applies to all WFBMC employees, faculty and staff who are applying for external funding and committing internal resources to leverage these funds.

Guidelines

Commitment to provide cost share or matching funds must be made prior to the submission of the grant proposal. A cost share approval form (located on the CTSI internal website) must be completed and included with the routing form and grant proposal at the time of proposal submission to OSP for review, approval, and submission.
Mandatory Cost Share:

- If Mandatory Cost Sharing is part of a grant solicitation, the Principal Investigator should request support by submitting the completed Cost Share Request form, signed by the Department Chair and submit to the Office of Sponsored Programs for review and approval, which typically requires additional vetting amongst leadership. It is strongly suggested to initiate this process a minimum of 2 weeks prior to proposal submission dates. Due to limited institutional resources not all requests will be honored.

Voluntary Committed Cost Share:

- If Voluntary Committed Cost Sharing is requested, a strong case must be made that such cost share will make a significant difference in the competitiveness of a proposal; then a completed Cost Share Request form containing a significant justification for the proposed cost share must be submitted with grant proposal to the Office of Sponsored Programs.

- Proposals containing Voluntary Committed Cost Share must be routed to the Office of Sponsored Programs five business days prior to the grant submission deadline for review and approval.

- The OSP and/or the Dean’s Office reserve the right to decline requests for voluntary committed cost share especially when institutional resources are being committed.

Voluntary Uncommitted Cost Share:

- This type of cost share is not included in a proposal. It is simply something the department may mention in a routing form or an email, but is not disclosed in the proposal or committed as part of the scope of work. As this is not auditable, no form is required and no tracking is completed on this type of cost sharing.

- Often Voluntary Uncommitted Cost Share occurs near the end of a project when no more funds are available to complete the work but PI effort is still required to finish publication(s). As effort is still required but no funds are available, this is cost sharing but it was neither proposed nor committed.

Leveraged Funds:

- Leveraged Funds may be mentioned in a proposal submission as long as it is clearly indicated that these are funds related to the project and are independent of this funding.

Tracking Cost Share Commitments: If any proposal is awarded in which either Mandatory or Committed cost sharing was made, it is the responsibility of the Institution to track these commitments. The central offices (OSP and Financial Services) and the PI/Departmental Administrator are partners in the tracking and documentation of cost share. In all cases, a plan should be established to ensure that all parties understand their responsibilities in tracking to ensure proper documentation is available for audit.

Cost Transfer Policy

The purpose of this policy is to ensure compliance with federal policies and guidelines related to the transfer of expenses to federally funded sponsored projects. As a recipient of federal funding, Wake Forest University Health Sciences (WFUHS) is responsible for establishing policies that ensure compliance with the requirements of Office of Management and Budget’s Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (OMB Uniform Guidance) and the terms and conditions of federal sponsors.
Although Wake Forest University Health Sciences engages in research projects with a variety of sponsors, it is our policy to apply the federal guidelines on cost transfers to all sponsored projects unless a specific sponsor guideline has a more restrictive policy.

**Guidelines**

WFUHS is required to follow the OMB Uniform Guidance which states, “Any cost allocable to a particular Federal award under the principles provided for in this Part may not be charged to other Federal awards to overcome fund deficiencies, to avoid restrictions imposed by Federal statutes, regulations, or terms and conditions of the Federal awards, or for other reasons.” In order to meet allowability and allocability requirements of OMB Uniform Guidance, timeliness and completeness of justification is required.

In addition, National Institutes of Health (NIH) Grants Policy Statement states, “Cost transfers to NIH grants by grantees...should be accomplished within 90 days... transfers must be supported by documentation that fully explains how the error occurred and a certification of the correctness of the new charge by a responsible organizational official of the grantee... An explanation merely stating that the transfer was made “to correct error” or “to transfer to correct project” is not sufficient. Transfers of costs from one project... to the next solely to cover cost overruns are not allowable.

Grantees must maintain documentation of cost transfers, pursuant to 45 CFR 74.53 or 92.42, and must make it available for audit or other review. The grantee should have systems in place to detect such errors within a reasonable time frame; untimely discovery of errors could be an indication of poor internal controls. Frequent errors in recording costs may indicate the need for accounting system improvements, enhanced internal controls, or both.”

This policy addresses the reallocation of salary expenses and transfer of other direct costs.

Principal Investigator (PI): Responsible for reviewing and monitoring sponsored projects on a regular basis to ensure expenditures are charged appropriately. If a transfer is required the PI or designee will process the necessary documentation in a timely manner.

Office of Sponsored Programs (OSP): Available to assist in interpretation of federal requirements and the WFIHS Cost Transfer Policy. OSP reviews all transfers to sponsored projects and will review, approve, and process Cost Transfer Forms. Cost Transfer Forms and associated backup documentation are stored within the ERP system for audit purposes.

**Tobacco Research Funding Policy**

It is the policy and commitment of Wake Forest University School of Medicine and the Atrium Health (including all affiliated campuses and locations) Enterprise to promote a culture of integrity and transparency for our research mission and will not endorse or support research related to the tobacco industry. WFWFUSM does not endorse the production or sale of any tobacco related products or approve of the use of funding directly resulting from the production or sale of tobacco products.

As such, the Wake Forest University School of Medicine will not accept research funding support from tobacco companies or any directly affiliated organizations producing or distributing tobacco or tobacco related products. This policy pertains to all levels of faculty involved in sponsored research activities at the Enterprise, including full or part-time appointments of instructor, assistant, associate, and full professor levels as well as faculty with adjunct appointments from external organizations.
Guidelines

For the purpose of this policy, the tobacco industry is defined as “companies or corporate divisions that directly produce or purchase tobacco for production of tobacco products, along with their research and lobbying groups.” Examples include:

1. Funds from a company that is engaged in or has affiliates engaged in the manufacture of tobacco produced for human use;
2. Funds in the name of a tobacco brand whether or not the brand name is used solely for tobacco goods;
3. Funds from a body set up by the tobacco industry or by one or more companies engaged in the manufacture of tobacco goods.

The following does not constitute tobacco industry funding for the purposes of this policy as:

1. Legacies from tobacco industry investments (unless the names of a tobacco company or cigarette brand are associated with them).
2. Funding from a trust or foundation initially established with assets related to the tobacco industry but no longer having any connection with the tobacco industry, even though it may bear a name that for historical reasons is associated with the tobacco industry. Funding from an affiliate of a tobacco industry company involved in the manufacture of products having nothing whatsoever to do with tobacco that supports research and that is completely unrelated to tobacco or smoking.
3. Money from government organizations that have fined tobacco companies or received funding from tobacco settlements.

Interdisciplinary

Service Center Policy

The purpose of this policy is to establish WFUSM policies and procedures for the financial management of Service Centers (research Cores and Shared Resources).

This policy applies to faculty, staff, students, and other affiliated individuals engaged in research activities. This policy specifies guidelines that must be followed by Core Directors, Administrators, and Financial Managers overseeing work in Service Centers (referred to as Cores in this policy).

Guidelines

- Billing rates for Cores should be designed to include all allowable direct costs of providing the service (e.g. labor, materials, supplies, services, and similar costs) for the year and to recover only the actual aggregate costs of the services. No costs other than the direct costs incurred in providing the services should be included in the billing rates.
- Billing rates should not include expenditures for capital equipment purchases or reserve factors for capital equipment replacement.
- Billing rates should not include unallowable costs (as defined by 2 CFR § 200.420) (e.g. entertainment, fines & penalties, etc.); duplicate costs (e.g. capital equipment costs and equipment depreciation); or improperly classified costs (e.g. costs of long-term inventory).
- Billing rates should be net of applicable credits.
Billing rates should be computed annually and be based on a reasonable estimate of the costs of providing the service for the year and the projected number of billing units for the year.

Where a Core provides different types of services to users, separate billing rates should generally be established for each service that represents a significant activity of the Core.

Actual costs and revenues for each service should be compared annually. Billing rates should be adjusted to account for over/under applied costs (surpluses or deficits) for the service for the prior period. (Surpluses may not be used to purchase capital equipment, fund losses of other Cores or fund salary increases.)

Amounts charged to users should be based on an established set of billing rates (i.e. a documented billing rate schedule). (See Record Keeping.)

Amounts charged to users should be reflective of the actual services performed.

All users of the service should be billed in a consistent manner (same rate for same service). Rates can be split billed and charged to an institutional Center or Department to subsidize selected services to allow a lower rate to be billed to the Investigator’s grant by paying the balance on an institutional fund. The total cost billed is still the same to all customers for the same service.

All Core charges should be processed (billed) to users in a timely manner. Charges should not be processed in advance of the service completion.

Billing rates for ‘Specialized Service Facilities’ may also include appropriate indirect costs (facilities and administrative costs) as applicable per 2 CFR § 200.414 and/or the Cost Analysis and Rate Setting Manual for Animal Research Facilities (CARS). These amounts are determined by Research Administration’s Director for Interdisciplinary Research.

Typically, one set of billing rates for the same service is applied to all University customers (Federal or non-Federal). However, if special circumstances warrant the need for varied rates for the same service, federally sponsored programs must always be charged at the lowest billing rate. (Note varied billing rates for the same services should only be done with prior approval by Research Administration’s Director for Interdisciplinary Research.)

Additional Information Regarding Rate Setting for External Customers

Internal Customers include all Advocate Health and/or Atrium staff, and WFUSM faculty that use the core facilities to support their research.

Affiliated Internal Customers include all Wake Forest University Reynolda Campus faculty and Atrium Health Enterprise-wide faculty and staff that use the core facilities to support their research, as these entities fall under the Affiliated Entity Agreement.

External Customers are defined as users of the Cores who are from entities outside of Advocate Health and/or Atrium Health and the Affiliated Entity Agreement. These can be other academic institutions or industry partners.

Separate billing rates can be established for customers external to the University. Since the intent of establishing these rates would be to recover all costs of the service (i.e. not limited by Cost Principles of 2 CFR § 200.400 - 200.476 for equipment replacement, unallowable costs, indirect costs, etc.), these rates can be higher.

Note that charges to external users are a possible source of Unrelated Business Income Tax (UBIT) for the University.
The WFUHS Research Administration’s Director for Interdisciplinary Research should be contacted for guidance prior to the establishment of billing rates for users external to the University.

**Record Keeping**

- Cost and income data necessary to appropriately set billing rate structures based on actual costs and to analyze variances must be maintained by the Core Director or other individual responsible for the process. This includes the establishment and use of a separate and distinct project number for the Core.
- The annual billing rate review and rate adjustment process should occur in a timely manner such that newly published billing rates are available for Core users for use in the next budget cycle. This process should be documented and available for audit if requested.
- Detailed records which support all charges billed to users must be maintained and be available for audit if requested.
- All capital equipment utilized in support of the Core should be reviewed as per the WFUHS Property Control manual.

**Space Utilized by Service Centers**

- All physical space (rooms and partial rooms) used by all types of Cores should be specifically identified during a Space Study being conducted for purposes of an F&A Rate Proposal. The departmental administrator responsible for completing the Space Study would code (functionalize) this space as SC (Service Center).