

Wake Forest University School of Medicine Clinical and Translational Science Institute Invoicing Guidelines

Guidance Document for period worked January 1, 2025 through December 31, 2025

This document is intended to provide guidance on the invoicing structure for the Wake Forest University School of Medicine Clinical and Translational Science Institute (CTSI). The guidance will review the pricing calculation, pricing grids, and offer clarification on the following terms as it relates to the invoicing of CTSI services:

- a) Researcher Classification,
- b) Extramural Award Investigator Status, and
- c) Funding Source.

CTSI Researcher Classifications

• **Faculty Researchers**

A faculty researcher is defined as an individual with a faculty position:

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

Faculty Researchers may be further classified as **Early-Career** or **Experienced**:

○ **Early-Career Faculty Researchers**

The Principal Investigator (PI) or the Co-Principal Investigator (Co-PI) of the study must meet one of the criteria to be designated as Early-Career:

- Faculty with a rank of Assistant Professor or lower who have never been the PI or Co-PI of an extramural research award exceeding \$100,000 in direct costs per year; OR
- Individuals currently supported by a career development award (e.g. K23, K08); OR
- Active CTSI Translational Research Academy members

○ **Experienced Faculty Researchers**

The Principal Investigator (PI) or the Co-Principal Investigator (Co-PI) of the study is designated as Experienced if they meet the following criteria:

- Faculty with a rank of Assistant Professor or lower, who have been the PI or Co-PI of an extramural research award exceeding \$100,000 in direct costs per year (not currently supported by a career development award (e.g. K23, K08)); OR
- Faculty with a rank of Associate Professor or greater, AND
 - Not currently supported by a career development award (e.g. K23, K08); OR
 - Not an active member of the CTSI Translational Research Academy

• **Non-Faculty Researchers**

Non-faculty researchers are individuals that can be listed as the Project Lead or, more specifically, the Principal Investigator of an IRB protocol, but are not classified as Faculty. A non-faculty researcher is an individual who is in departmental administration or a departmental staff member. Individuals that might meet this definition include:

- Resident
- Fellow
- Physician Assistant
- Nurse Practitioner
- Pharmacist
- Physical Therapist (DPT)
- Nurse Researcher
- Research Associate
- Physician

Extramural Award Investigator Status

- **Principal Investigator**

A Principal Investigator (PI) is defined as the individual who is designated as the lead researcher for a grant. This individual may be a Faculty Researcher or Non-Faculty Researcher and is listed on the IRB protocol. This role is determined at the time of Notice of Award and IRB approval.

- **Co-Principal Investigator**

A Co-Principal Investigator (Co-PI) is defined as an individual who shares responsibility for the grant with the Principal Investigator. This individual may be a Faculty Researcher or Non-Faculty Researcher and is listed on the IRB protocol. This role is determined at the time of Notice of Award and IRB approval.

- **Contact Principal Investigator**

A Contact Principal Investigator is responsible for communication between the PI/Co-PI and the funding source. This role is determined at the time of Notice of Award.

Funding Sources

- **Federal/Foundation/Association**

Projects are investigator-initiated and may be funded by a for-profit, non-profit, state, or federal agency. Examples of funding sources include, but are not limited to:

- Federal – National Institute of Health (NIH), Department of Defense (DoD), PCORI
- Foundation – Anesthesia Patient Foundation, Burroughs Wellcome Fund, Whitehall Foundation, Michael J Fox Foundation
- Association – American Diabetes Association, American Heart Association, American Federation for Aging Research

- **Industry Supported**

Grants and contracts are supported, though the provision of funding, drug, or device, by industry and typically have set costs as agreed through budget negotiations. Examples of industry partners/collaborators include but are not limited to Pfizer, Gilead, and AstraZeneca.

- **Institutional/Unfunded**

Grants are investigator-initiated and supported by institutional or departmental funding.

- **Institutionally-Supported Center Funded Pilot**

Request for Applications (RFAs) are released by Institutionally-Supported Research Centers and Institutes for response by Faculty. The RFAs have a target audience with specific parameters that would support the goals of the Center. Grant funding is supported by institutional or departmental funding through the Institutionally-Supported Research Center.

- **CTSI Funded Pilot**

Request for Applications (RFAs) are released by the Wake Forest CTSI and funding is supported by the CTSA/NCATS grant. The RFAs have a target audience with specific parameters that would support a specific initiative.

Additional Guidance

- Pricing is calculated per project, based on the Principal Investigator or Co-Principal Investigator's researcher classification and source of funding.
- Pricing will be updated each calendar year.
- Rates will no longer be grandfathered based on a previous year's rates.
 - It is encouraged to include a small amount of inflation in the budget to account for a possible increase in service costs each year.
- The Principal Investigator (Co-Principal Investigator, if applicable) is confirmed at the time of the Notice of Award and cannot be amended unless also amended with the extramural funding source and in the IRB protocol.

- If there is a discrepancy between the PI noted on the external funding source and the PI noted in the eIRB system, the default is the external funding source.

Annual Review

The CTSI Operations team will conduct an annual review of the Pricing Model and Invoicing Guidelines based on the timeline detailed below.

Month	Occurrence
August 2025	<ul style="list-style-type: none"> • CTSI will conduct an annual review of the PIs of active studies. Any CTSI Researcher Classification changes will be determined at this time.
October 2025	<ul style="list-style-type: none"> • Communication on CTSI Researcher Classification changes will be communicated to the affected PIs. Pricing changes will go into effect January 1, 2026
November 2025	<ul style="list-style-type: none"> • The CTSI Invoicing Guidelines will be reviewed and updated. CTSI Service Pricing will be recalculated with the Service Line Leaders to be implemented January 1, 2026.
December 2025	<ul style="list-style-type: none"> • The CTSI Invoicing Guidelines and the CTSI Pricing Grid will be published online for the upcoming fiscal year, with an announcement made on the CTSI website.