

November 12, 2021

To Study Sponsors,

Thank you for your interest in opening your clinical research at NYU Langone Health. In the following pages, you will find most of the information typically requested by study sponsors as part of routine feasibility assessment and study start-up. This will include:

- Contact information of central office units: IRB and CRSU
- An overview of internal review process for industry funded studies
 - Information about committee reviews required prior to IRB submission
 - Information about our internal compliance review process
 - IRB submission information and timelines
 - Budget and contract process and timelines
- Commonly referenced fee schedules- **Appendix A**
 - Non-negotiable central office fees (IRB and CRSU)
 - Study team administrative fees
 - NYU Investigational Pharmacy fees
- General information regarding Site Initiation Visits (SIVs) and full Site Activation

For your convenience, we have also included information about our facilities, equipment, and staffing and research capabilities. This includes contact information, addresses and where applicable, detailed information about the following commonly used research resources:

- Clinical Translational Science Institute (CTSI)
- NYU Center for Biospecimen Research and Development (CBRD)
- NYU Investigational Pharmacies
- Radiology facilities
- Laboratory Information

Sincerely,

Clinical Research Support Unit (CRSU)

PLEASE NOTE: It is our policy NOT to duplicate efforts by filling out additional sponsor/CRO forms with the information provided on this form. However, if there is other information requested (not already included on this form), we will be happy to provide that additional information.

NYU Langone Health Systems independent recruitment centers

The NYU Langone Health system is comprised of multiple locations and affiliated hospitals. We can support multi-location research under a single PI, IRB, budget and contract, or with each location functioning as a separate standalone location.

- NYU Langone- Manhattan
- NYU Langone Hospital- Brooklyn (formerly NYU Lutheran Medical Center)
- NYU Langone Long Island (formerly NYU Winthrop Hospital)
- Bellevue Hospital
- VA Hospital

Unit Contacts

General Point of Contact (POC) for study startup-Protocol Implementation

The study team or the assigned study coordinator is the best POC for general questions regarding study start-up processes. For additional information, each units within the Office of Science and Research (OSR), Clinical Research Operations can provide additional details. Contact information for each units provided below:

NYU Grossman School of Medicine's Institutional Review Board (IRB)

Office Hours: 9:00AM–5:00PM

Main Line: 212-263-4110

NYU Langone Hospital—Long Island IRB: 516-663-2552

General Inquiries: irb-info@nyulangone.org

Information About Education and Training: irb-education@nyulangone.org

Information About Single IRB: irb-single@nyulangone.org

Information About External IRB: irb-external@nyulangone.org

Clinical Research Support Unit (CRSU)

NYU Grossman School of Medicine's Clinical Research Support Unit oversees the financial administration of clinical research studies. We provide support services for interventional and non-interventional studies funded from any source. For studies with an industry sponsor, our oversight also includes budget and payment negotiations, coverage analysis, and post-award management.

Office Hours: 9:00AM–5:00PM

Main Line: 646-754-7431

General Inquiries: clinicaltrials@nyulangone.org

Website: [Clinical Research – Resources for Sponsors](#)

Institutional Review Board Operations

1. Pre-IRB review:

- **Scientific Review Committee (SRC)** – A complete, FDA approved final version of the protocol is required in order to start the review process.
- The SRC meets four times a month on Tuesdays and the submission deadline is the Thursday prior to the scheduled meeting. The PI is fully responsible for submitting

the protocol to the SRC. Signed approval letters (or stipulation letters) are issued to the PI within 1 business day.

- ***Interventional Covid Studies only-** SRC approval required before IRB submission.

2. **External IRB Review:**

NYU Langone's IRB Operations Unit can cede review to an external IRB under the following circumstances:

- The study is industry initiated and using one of the following external IRBs:
 - Biomedical Research Alliance of New York Institutional Review Board (BRANY IRB)
 - Western Institutional Review Board (WIRB)
 - Central Institutional Review Board for the National Cancer Institute (NCI CIRB)

OR

- Your study is a federally sponsored, multicenter trial that requires the use of a single IRB (sIRB).

* Exceptions are considered on case by case basis. Please reach out to irb-external@nyulangone.org

✓ *Please keep in mind that NYU Local IRB will still conduct an administrative review and require the study team to complete an authorization review, prior to the study team submitting to an external IRB. This will take 3-5 business days for NYU IRB sign-off.*

✓ *Local ancillary reviews will also need to grant approval prior External IRB approval.*

3. **NYU IRB**

For full board submission, the approval process may take up to 50 days. Within this timeframe, the protocol receives a board meeting date and is assigned to a Tuesday board meeting. The study team will have the Tuesday prior in order to answer any queries for their protocol to be assigned to the following Tuesday meeting. IRB decision will be released within 24 hours.

For expedited review, the approval process may take up to 28 days. Expedited reviews are not assigned to an IRB meeting – they are approved in-house by an Expedited IRB specialist.

*[Required IRB documents](#)

4. **Ancillary Reviews**

- **MCIT Review:** Committee meets as needed. Only applicable if protocol uses mobile application or software program that requires IT oversight and approval.
- **Conflicts of Interest Management Unit ([CIMU](#)) Review:** Committee meets based on dollar amount related to Institutional/PI/Study Team member conflict.

- **Radiation Safety Committee (RSC):**
 - Review will be required if the protocol involves radiation over 50 mSv (millisievert) or the use of radio-active materials/pharmaceuticals.
 - This committee meets on an as needed basis.
 - Approval should take approximately 1-2 weeks.

Institutional Biosafety Committee (IBC): For research involving the administration of recombinant or synthetic nucleic acid molecules, IBC approval is required prior to IRB approval. Both committees can work in parallel on the review but the IRB will not approve if the IBC has not granted approval. The IBC meets once a month, usually during the 2nd half of the month.

** Required Institutional Committee Reviews may occur in tandem with IRB submission*

Budget & Contracts Operations

1. Budget negotiation process and timeline

Each industry-supported study is assigned a CRSU operations specialist upon internal CRMS portal submission.

- Negotiation will commence shortly following internal CRMS portal submission. The following items are required for budget development, review and negotiation:
 - Editable contract/work order and payment terms template
 - Editable budget template
 - Final protocol
 - All applicable manuals (clinical laboratory and pathology, imaging, pharmacy, etc.)
 - A screenshot or copy of all CRFs required for patient visits

The goal is to have a final budget within **60-90 days**, depending on study complexity as determined by central office and/or principal investigator for the study. The goal is also dependent on Sponsor/CRO responsiveness and service provider feedback.

- Due to the high volume of studies being reviewed by CRSU, external negotiation portals are highly discouraged.
- Standard fee schedules (**Appendix A**) that may apply to funded research include, but are not limited to:
 - OSR (IRB and CRSU) administrative fees (non-negotiable)
 - Investigational Pharmacy fee schedule (non-negotiable)
 - Administrative (Department) fee schedule
- Facilities and Administration (F&A) is applicable based on type of funding
 - Industry-sponsored studies incur a 35% overhead rate (non-negotiable)

2. Contract negotiation process and timeline

Each study is assigned a contract analyst upon internal CRMS submission and/or completion of study Schedule of Events Build (SOE) in CRMS, as applicable.

- CDA: NYU strives to have a draft out to the sponsor/counterparty within two business days and fully execute an agreement within seven (7) business days.

- CTA/CSA/WO: A typical agreement draft will be returned to the sponsor/counterparty within 5 business days of internal SOE build. NYU strives to complete negotiation of contract language within sixty (60) business days of SOE build.
- Budgets and contracts are negotiated in tandem.
- Budgets and contracts can be finalized prior to IRB approval.
- NYULH accepts electronic DocuSign and Adobe Sign, scanned PDF via email and wet ink signatures on contracts.
- A brief final internal QA review process prior to routing the contract will commence following receipt of acceptable versions of the final executable from the sponsor/counterparty.

Please note that all turnaround times are dependent on priority, complexity, workloads and any applicable approvals by other review committees.

Site Study Activation

Study activation is dependent on Sponsor requirements and study-team/department operation. A fully executed contract and budget, IRB approval, staff training (as applicable), site activation from the sponsor, and all necessary supplies and access are required for full study activation prior to subject enrollment.

Main Research Facility Information Links

Manhattan Location:

[Clinical Translational Science Institute \(CTSI\)](#)

[NYU Center for Biospecimen Research and Development \(CBRD\)](#)

[NYU Langone Radiology- Center for Biomedical Imaging](#)

NYU Investigational Pharmacy (*No Link Available – Please reach out to the study coordinator if you require specific pharmacy information.)

Laura and Isaac Perlmutter Cancer Center at NYU Langone

160 East 34th Street, 6th Floor • New York, NY 10016

NYU CTSI Research Pharmacy

462 First Avenue, C&D Building, 4th Floor, Room 126 • New York, NY 10016

NYU Long Island:

[NYU Langone-Long Island Clinical Research Center](#)

Email: Clinical_trials@nyulangone.org

Main Hospital: 516-663-0333

Clinical Research Center: 516-663-9582

APPENDIX A
Fee Schedules



INVESTIGATIONAL PHARMACY DOCUMENT

NYU Investigational Pharmacy
Laura and Isaac Perlmutter Cancer Center at NYU Langone
160 East 34th Street, 6th Floor • New York, NY 10016
NYU CTSI Research Pharmacy
462 First Avenue, C&D Building, 4th Floor, Room 126 • New York, NY 10016

Investigational Drug Fee Schedule

(Industry Sponsored)

EFFECTIVE: September 17th, 2021

<u>SERVICE ACTIVITY</u>	<u>DESCRIPTION</u>	<u>EEE</u>
Review & Initiation Fee <i>(\$3,250 Charged at initiation)</i>	Review: Evaluation of the following: <i>Safety Data Sheets</i> <i>Pharmacy Manuals</i> <i>Protocol, IB & Blinding Procedures</i> <i>Review of drug Formulation & Auxiliary supplies</i> Communicating with sponsors & Site selection Cost estimate & SOPs submissions Initiation: Site Initiation Visit Study protocol set up in Epic and Vestigo Develop dispensing guidelines Order and/or receive study medication Create and maintain accountability records	\$750 \$2,500
Low Intensity Dispensing Fee <i>(per drug/per dispensation)</i>	No compounding Simple dispensing of tablet/capsule Price per drug/per dispensation	\$50
Moderate Intensity Dispensing Fee <i>(per drug/per dispensation)</i>	Simple preparation of sterile products Price per drug/per dispensation	\$100
High Intensity Dispensing Fee <i>(per drug/per dispensation)</i>	Preparation of biohazardous sterile products or pharmacist performed compounding IVRS randomization Vaccine Studies Price per drug/per dispensation	\$200
Special Compounding Fee	\$50/hour for any compounding requiring (Aliquot, use of a mixer or special filtering) that exceeds one hour time	\$50/hour
Training Fee	Online training modules & updates training: <i>Amendments, protocol versions & pharmacy Manual</i> <i>Updates requiring training & Epic/vestigo build update</i>	\$200



Annual Maintenance Fee	Drug storage (including refrigerator, freezer) Maintain dispensing records Protocol updates Maintain records of returned drugs Monitoring visits <i>(Per protocol per year for first drug +\$250 for each additional drug)</i>	\$1000
Principle Investigator	One-time fee	\$500
Self-Storage Site	Study drug stored off-site	
Inspection Fee <i>(Per protocol)</i>	Inspected by Investigational Pharmacist Will meet State, Federal and Study requirements for drug storage <i>(+\$150 every 3 months for high volume studies and every 6 months for low volume)</i>	
Coordinating Center Services	Preparation of shipments including: Accountability adjustment & Chain of custody forms Drug inspection Temperature logger report NYU Manhattan Sites NYU Other sites	\$50 \$100
	<i>(per shipment + any other additional transporting vendor fees)</i>	
Drugs Procurement	Contacting drug suppliers and procurement Providing drug quote, invoicing set up & account reconciliation	GPO/WAC Price + 8% processing fee
Destruction Fee <i>(Per protocol at study closure)</i>	Destruction of drugs: Oncology studies Non-oncology studies	\$500 \$250
Closure Fee <i>(per protocol)</i>	Reconcile inventories Return drugs Close out protocol	\$600

December 1, 2020

To: All Clinical Researchers

From: James Holahan, Director, Clinical Research Support Unit (CRSU) *James Holahan*
 Helen Panageas, Director, Institutional Review Board (IRB) *Helen Panageas*

Re: OSR Administrative Fees – Industry Supported Projects

The NYU Langone Health retains Institutional Review Boards (IRB) and an IRB operational team to support the function of the IRB’s. The IRB’s function include the initial and ongoing review of research studies to assess the safety, efficacy, benefits, adverse reactions, other outcomes of drugs, devices, diagnostics, treatments, procedures, medical evaluations, monitoring or preventive measures and ensures the research is in compliance with federal regulations and institutional policies and procedures. IRB Operations facilitates the review process of human subjects research at NYU Langone and our affiliates. The IRB Operations team provides professional guidance to the research community and supports researchers in submitting to an IRB. The IRB Operations Unit includes the External Review Unit which facilitates the institutional clearance process for all human subjects research that is undergoing external IRB review, ensuring compliance with NYU Langone policies.

The Clinical Research Support Unit (CRSU) provides centralized guidance and support to the entire NYU Langone Health clinical research community. The Unit charges a standard benchmarked rate per study for start-up, amendment, and close-out activities to all Industry Sponsors and Commercial Agencies for all clinical research studies. The fees collected are to strictly cover the administrative cost for activities leading to the activation and ongoing operational support of the clinical research study on behalf of the Institution. The CRSU fee does not encompass any compliance inquiries or other work performed by the office and is not shared with the investigator.

Specific activities performed by CRSU include, but are not limited, site feasibility, protocol review, reimbursement analysis, internal budget development and approval, CTMS study set-up, administrative data auditing and monitoring, research billing compliance and support, sponsor invoicing, financial account reconciliation and medical center technical & professional service centers, response to sponsor inquires, CMS device submissions, portfolio activity analysis, subject recruitment feasibility, referral and registration guidance, study staff orientation, system/process training, procedure development and support.

Office of Science and Research Fee table:

Start up Fees	Amendment Fees	Annual Fees	Closure Fees
All industry-funded clinical research budgets are assessed a non-refundable Office of Science and Research fee of \$8,500.00 at study start-up. This covers the central office operations at study start-up: <ul style="list-style-type: none"> Initial NYU (local) IRB Review (\$3,500) Clinical Research Support Unit (CRSU) Administrative Start-up management (\$5,000) 	IRB Amendment Reviews (\$1,500) CRSU Amendment (For Sponsor Initiated Amendments) (\$1,000)	IRB Continuation Reviews (\$1,500) CRSU Annual Financial Administrative Fee (\$1,000)	IRB Closure Review (\$500) CRSU Closure (For Study Reconciliation) (\$1,500)
Other as applicable: <ul style="list-style-type: none"> External IRB (central IRB) one time administrative fee (\$2,500) CRSU Centers for Medicare & Medicaid Services (CMS) Device Approval Submission Process (\$2,000) CRSU Commercial Vendor & Service Provider Arrangements (Per Arrangement) (\$500) Data & Material Use Project Start-up (\$500) Subsite Engagement & Start-up per site (\$1,000) 			