I. Policy Purpose

In furtherance of the Medical Center’s commitment to encourage and assist qualified investigators in their efforts to secure appropriate clinical trial support from commercial entities, the Office of Science & Research and its Office of Clinical Trials are committed to reviewing, negotiating, and executing contracts with clinical trial sponsors as expeditiously as possible. Toward that end, the Medical Center is promulgating this policy to set forth the terms and conditions to be included in clinical trial agreements with commercial entities.

II. Applicability of the Policy

This Policy applies to all Clinical Trials (as defined below) directly or indirectly supported by commercial entities which are conducted at or under the auspices of the Medical Center and all resulting Clinical Trial Agreements (as defined below).

III. Definitions

Clinical Trial\(^1\) refers to any research study conducted at or under the auspices of the Medical Center where:

1. The objective of the study is either:
   a. the testing of drugs, devices, diagnostics, treatments, interventions, or preventive measures including testing for an unapproved indication; or
   b. data collection to increase knowledge that would lead to enhanced safety and efficacy of a specified drug or device; and

2. The study involves contact with humans or retrospective review of medical records, clinical data or specimens obtained from contact with humans.

\(^1\) This definition of “Clinical Trial” is used at the Medical Center to define the commercially-supported, human subjects’ research projects that are administered institutionally for budgetary and contracting purposes by the Office of Clinical Trials. It is understood that many projects defined as Clinical Trials under this definition and subject to this Policy are not ‘clinical trials’ as defined by the FDA or as commonly understood in the clinical trial community.
**Clinical Trial Agreement** refers to the written contract contemplating the conduct of a Clinical Trial by the School of Medicine under the direction of a Principal Investigator. Clinical Trial Agreements include work orders contemplating Clinical Trials under Master Agreements between the School of Medicine and a Sponsor.

**IP Rights** refers to patents and other intellectual property rights in inventions.

**OCT** refers to the Medical Center’s Office of Clinical Trials, the department in the Office of Science & Research responsible for the negotiation and execution of Clinical Trial Agreements.

**Principal Investigator** refers to the School of Medicine faculty member responsible for the conduct of the Clinical Trial at the School of Medicine.

**Sponsor** refers to any commercial entity sponsoring a Clinical Trial or providing funding for a Clinical Trial, or providing without payment a drug, device, material, equipment or other product for use in a Clinical Trial.

**IV. Policy**

**A. Contract.**

(i) **General.** The Medical Center requires a Clinical Trial Agreement for each proposed Clinical Trial receiving support from a Sponsor, whether the support is provided in the form of funding or the provision without payment of investigational drugs or devices, materials, equipment or otherwise. Generally speaking, there should be one Clinical Trial Agreement for each Clinical Trial protocol and Medical Center Trial ID/Research Number (R#). The terms and conditions set forth in this Policy must be contained in each Clinical Trial Agreement.

(ii) **Responsibility.** The OCT has been delegated authority and responsibility to review, negotiate and execute most Clinical Trial Agreements at the Medical Center.

(iii) **Parties.** For studies where support for a Clinical Trial is received directly from a Sponsor, the parties to the Clinical Trial Agreement must be the Sponsor (or a contract research organization representing the Sponsor) and “New York University School of Medicine, an administrative unit of New York University.” For studies where support from a Sponsor is provided for a Clinical Trial initiated and controlled by a non-commercial entity, the non-commercial entity may be a party to the Clinical Trial Agreement instead of the Sponsor. Other units or divisions of the Medical Center may not be parties to Clinical Trial Agreements.

(iv) **PI as Signatory.** The Principal Investigator may not be a party to the Clinical Trial Agreement. The OCT will, however, only agree to the Clinical Trial
Agreement and perform the Clinical Trial if the Principal Investigator signs his or her agreement and acceptance of its terms.

B. Budget and Payment Policy.

(i) **Direct and Indirect Costs.** All direct and indirect costs of each Clinical Trial must be supported by the Clinical Trial budget attached to the Clinical Trial Agreement. The indirect cost, or institutional overhead, rate for commercially-supported Clinical Trials is 30% of all direct costs in the Clinical Trial budget. The only items in the budget that are not subject to the indirect cost rate are IRB fees, OCT fees and pharmacy fees (with the exception of dispensing).

(ii) **Fair Market Value.** All payment terms set forth in a Clinical Trial budget must represent the fair market value for the services to be rendered and must not be determined in any manner that takes into account the volume or value of any referrals or business otherwise generated between the Medical Center and the Sponsor. The Clinical Trial Agreement should include a mutual representation reflecting this requirement.

(iii) **Patient Care Costs.** In accordance with applicable law and regulation, as well as institutional and insurer policies, all non-routine patient care costs must be supported by the Clinical Trial budget and not charged to the Clinical Trial subjects and their medical insurers. In contrast, routine care is that which is medically reasonable, necessary, ordinarily furnished (absent any research study), and appropriate to the medical condition of the patient. The Clinical Trial Agreement, Clinical Trial protocol or Informed Consent Form will specify who will pay for those routine patient care services that may not be covered by third party health insurance payors due to the patient’s study participation, limits on insurance coverage and/or eligibility exclusions.

(iv) **IRB Costs, OCT Fees, and Site Startup fees.** For commercially-sponsored Clinical Trials, Institutional Review Board (IRB) and OCT fees must be paid by Sponsors. All initial IRB, OCT and site startup fees should be due upon Clinical Trial Agreement execution and should be non-refundable.

(v) **Personal Payments.** Investigators and staff conducting a Clinical Trial must not receive direct personal payments from the Sponsor, other than institutional salary support in the Clinical Trial budget, for their performance of the Clinical Trial.

(vi) **Bonuses/Penalties.** Clinical Trial Agreements must not include financial bonuses or penalties specifically targeted at subject recruitment efforts.

(vii) **Payment Terms.** All Clinical Trial Agreement budgets must have clearly defined payment terms including identification as to whether an invoice is required for payment.
(viii) **Amendments.** Like other Clinical Trial Agreement terms, amendments to the Clinical Trial Agreement budget and payment schedule must be approved in writing by the Sponsor and the OCT.

C. **Sponsor Monitoring and Reporting of Findings.**

(i) **Protocol.** A Clinical Trial must be governed by a protocol reviewed and approved by the Institutional Review Board (IRB). The protocol must explain the monitoring role, if any, that will be taken by the Sponsor.

(ii) **Safety Findings.** For Clinical Trials where the Sponsor is responsible for monitoring, Clinical Trial Agreements should contain a provision stating the Sponsor has a duty to promptly update the Principal Investigator concerning serious or continuing monitoring findings that influence the conduct of the Clinical Trial or affect the safety of subjects.

(iii) **Data and Safety Monitoring Reports.** For Clinical Trials where the Sponsor is responsible for data and safety monitoring, Clinical Trial Agreements should contain a provision – either express or through incorporation of the Clinical Trial protocol – requiring the Sponsor to provide routine data and safety monitoring reports periodically.

(iv) **Post-Study Results.** For Clinical Trials directed by the Sponsor, Clinical Trial Agreements should contain a provision requiring the Sponsor to inform the Principal Investigator of post-study results that directly affect the safety of subjects for an appropriate time period (e.g., two years).

D. **Sponsor’s Confidential Information.** Sponsors may require confidentiality of Sponsor-provided information and study terms and may request that the data generated by the Clinical Trial be treated as confidential information for purposes other than academic publication. Neither the existence of the Clinical Trial Agreement nor the identity of the Sponsor of the Clinical Trial may be confidential. Confidentiality, non-disclosure and non-use restrictions covering the Sponsor’s confidential information should not exceed seven (7) years from the end of the Clinical Trial. The Medical Center should have the right to disclose the Sponsor’s confidential information as needed to review, conduct and oversee the Clinical Trial, to adhere to applicable laws and regulations, and to assure the appropriate medical care and treatment of Clinical Trial subjects.

E. **Publications.**

(i) **General.** Clinical Trial Agreements must provide for the right to publish and present research results.

(ii) **Registration.** For Sponsor-initiated and controlled Clinical Trials, the Sponsor must register the Study if registration is required by applicable law or is required under the guidelines of the International Committee of Medical Journal Editors.
(ICMJE) on trial registrations in order for the Clinical Trial results to be eligible for publication in an ICMJE journal.

(iii) **Final Study Data.** Clinical Trial Agreements should address the Principal Investigator’s access to final study data and analysis for all sites and allow retention of a copy of the Clinical Trial site data to document the research and to permit the Principal Investigator to make a site publication.

(iv) **Sponsor Review.** Submission of proposed multi-site and individual site publications and presentations to the Sponsor for review and comment prior to submission for publication or presentation is appropriate. If the Sponsor during such review (usually within a period of thirty (30) to sixty (60) days) determines that patent filing is needed to protect intellectual property, submission of the proposed publication or presentation may be delayed for a total review and patent filing period not to exceed ninety (90) days from the date of initial submission of the publication to the Sponsor for review. Other than providing for the deletion from any publication or presentation of the Sponsor’s confidential information (other than study results), the Clinical Trial Agreement must not require the Medical Center and the Principal Investigator to yield to the Sponsor’s decisions about whether to publish or present or about the content of such publications or presentations.

(v) **Multicenter Studies.** A Clinical Trial Agreement contemplating a multicenter Clinical Trial may restrict the School of Medicine and the Principal Investigator from making a site publication or presentation before the later of (i) publication or presentation of the entire study results coordinated among the Sponsor and participating sites or (ii) the eighteen (18) month-anniversary of the completion of the Clinical Trial at all sites. Thereafter, the Principal Investigator must be permitted to make a site publication or presentation, subject to the Sponsor’s review rights set forth above and generally-recognized academic standards for clinical trial site publications or presentations.

F. Intellectual Property (IP).

(i) **Ownership.** For Sponsor-initiated Clinical Trials, Sponsors may require the assignment of inventions and other IP Rights directly resulting from the performance of the Clinical Trial where such IP Rights were anticipated by the Sponsor’s protocol or use of the Sponsor’s confidential information or investigational drug or device. Ownership of other patentable inventions arising from the conduct of a Clinical Trial should be determined by inventorship as determined under U.S. Patent Law.

(ii) **Options.** A Sponsor may be provided with a time-limited option (usually no more than ninety (90) days) to negotiate a royalty-bearing license to the School of Medicine’s interests in any sole or joint inventions resulting from the performance of a Clinical Trial.
(iii) **Other IP Rights.** A Clinical Trial Agreement must not grant the Sponsor any right to existing IP Rights owned by New York University or to later arising IP Rights that do not directly result from the performance of the Clinical Trial or from the Sponsor’s provision of its confidential information or its investigational drug or device for the Clinical Trial.

**G. Subject Information.** Clinical Trial Agreements contemplating Clinical Trials where the Sponsor is provided or may access patient identifiers must include the Sponsor’s agreement to: (1) use such information only as permitted in the subject’s HIPAA authorization and in accordance with applicable law, (2) keep such information secure and in confidence, (3) refrain from using such information to contact subjects for additional studies, and (4) refrain from using such information to perform marketing or market research.

**H. Indemnification and Subject Injury.** The following terms must be contained in Clinical Trial Agreements when the Clinical Trial involves an investigational drug or device or where the Clinical Trial data and/or IP Rights may be utilized for such products in the future:

(i) Clinical Trial Agreements for Clinical Trials involving an investigational drug or device that are initiated and controlled by the Sponsor must provide that the Sponsor indemnify, defend and hold harmless the School of Medicine and the affiliated hospital(s) performing the Clinical Trial, including their trustees, directors, officers, employees and agents and the Principal Investigator, from and against all claims arising from the conduct of the Clinical Trial that are not due to the School of Medicine’s negligence or willful misconduct or failure to follow the law, the agreement or the protocol (“Indemnification”). If the Indemnification terms specify types of claims to be covered, the Indemnification must, at a minimum, cover claims arising from (a) subject injury or illness caused by the product, (b) the proper conduct of the protocol, and (c) the Sponsor’s use of Clinical Trial data and of IP Rights granted to the Sponsor.

(ii) Clinical Trial Agreements for Clinical Trials involving an investigational drug or device that are initiated and controlled by the Sponsor must also require the Sponsor to fund medical care costs for any Clinical Trial-related injury or illness. (“Subject Injury”). The Subject Injury terms need not cover injuries or illnesses primarily due to a subject’s underlying medical condition, known risks of routine patient care portions of the protocol, or the School of Medicine’s negligence or willful misconduct or failure to follow the law or the protocol. As a general policy, the Sponsor’s Subject Injury obligation should cover a subject’s medical care costs even if such costs are covered by the subject’s insurance. When an exception to this general policy is made, in order for the Medical Center to be paid and in order to avoid submitting false claims or otherwise violating applicable laws, the Subject Injury provision must provide that the Sponsor’s obligation is primary to Medicare and be interpreted in accordance with applicable laws (including the Medicare Secondary Payer rules).
Sponsors providing product for investigational studies that are initiated and controlled by a School of Medicine-faculty Principal Investigator should provide Indemnification for their responsibilities in the Clinical Trial (i.e., design, manufacture and shipment of the product) and for the Sponsor’s use of the Clinical Trial data and of IP Rights granted to the Sponsor.

School of Medicine-faculty Principal Investigator-initiated and controlled Clinical Trials do not require provision of Subject Injury for Clinical Trial-related injury or illness.

Non-commercial entities initiating, sponsoring and/or controlling a Clinical Trial and/or providing investigational products for a Clinical Trial are not always required to provide Indemnification or Subject Injury. Sponsors providing product for such Clinical Trials should provide Indemnification for the design, manufacture and shipment of the investigational product.

Sponsors of non-investigational Clinical Trials should provide Indemnification for their use of the Clinical Trial data and of IP Rights granted to the Sponsor.

A Sponsor’s Indemnification and Subject Injury obligations must not be capped or subject to unreasonable conditions or exceptions.

All Indemnification and Subject Injury obligations must survive expiration or early termination of the Clinical Trial Agreement.

In accordance with School of Medicine policy, the School of Medicine does not indemnify Sponsors in Clinical Trial Agreements.

I. Insurance. Sponsors are expected to maintain, through the Clinical Trial and for a reasonable period thereafter, sufficient insurance, including general liability insurance in the amount of $2 million per incident and $4 million in the annual aggregate, to cover their obligations under the Clinical Trial Agreement.

J. Use of Name. Clinical Trial Agreements must provide that the Sponsor refrain from using the name, symbol or marks of New York University, the School of Medicine, NYU Hospitals Center, NYU Langone Medical Center or other affiliated institutions and/or faculty and staff in press releases, marketing and other promotional documents without the prior review and written approval of the Medical Center.

K. Other Research. A Clinical Trial Agreement must not contain provisions that unduly restrict the School of Medicine or any of its faculty members or employees (including the Principal Investigator) from engaging in other research at the Medical Center or any Clinical Trial subjects from participating in other research at the Medical Center. For example, a Clinical Trial Agreement should not prohibit the Medical Center from collecting, retaining and using tissue specimens from Clinical Trial subjects for research unrelated to the Clinical Trial and the investigational drug or device being tested.
L. Miscellaneous. A Clinical Trial Agreement must not contain any language requiring the School of Medicine or the Principal Investigator to use “best efforts” in the conduct of the Clinical Trial, to guarantee Clinical Trial results, to be in contract breach if a deviation is necessary to protect subject safety, to make representations or warranties related to NYU personnel not engaged in the Clinical Trial and without access to Clinical Trial information, or to adhere to any laws, regulations or guidelines not generally applicable to the conduct of clinical trials in New York at the Medical Center. A Clinical Trial Agreement also must not provide for a governing law other than New York law or a jurisdiction for a dispute other than the courts in New York, or provide for any mandatory or automatic remedies in the event of a breach of the Clinical Trial Agreement.

M. Informed Consent Language.

(i) **General.** As a general policy, Clinical Trial Agreements should not specify language or terms to be included in the informed consent form to be used for the Clinical Trial.

(ii) **OCT/IRB Collaboration.** Clinical Trial Agreements that propose to include specific language or terms in the Informed Consent Form and/or that include terms which may affect statements contained in a protocol-specific Informed Consent Form must be agreed to by the Medical Center’s IRB. The OCT will notify the Principal Investigator and the IRB of such terms, and the Principal Investigator, IRB and OCT will work together to ensure that the Clinical Trial Agreement and Informed Consent Form contain appropriate and consistent language.

(iii) **Timing.** The IRB’s review of a Clinical Trial and the OCT’s negotiation of a Clinical Trial Agreement are usually conducted simultaneously. In the event the IRB’s review and approval of the Clinical Trial occurs before full execution of the Clinical Trial Agreement, the IRB will not release its approval to the Principal Investigator until the OCT notifies it that the Clinical Trial Agreement has been fully-executed. In the event the Clinical Trial Agreement is fully executed before the IRB approves the Clinical Trial, the conduct of the Clinical Trial may not commence until IRB approval is made.

V. Questions.

Any questions relating to this Policy should be directed to the Office of Clinical Trials at 212-263-4210 or clinicaltrials@nyumc.org.