NYU Langone Health	**Policy on Individual and Institutional Conflicts of Interest in Research and Other Sponsored Projects**
Issuing Department: **Conflict of Interest Management Unit**	*Effective Date:* **July 1, 2026**

I. POLICY STATEMENT AND PURPOSE

NYU Langone Health is committed to operating in an ethical manner and in compliance with all applicable legal and regulatory requirements in the conduct of Research and Other Sponsored Projects. Even the appearance of a Conflict of Interest, including an Institutional Conflict of Interest, in Research and Other Sponsored Projects may affect or appear to affect the design, conduct, reporting, review, or oversight of a research project and can be damaging to the reputation of Investigators and NYU Langone Health. Investigators have a duty to comply with all NYU Langone Health policies, sponsor requirements, and guidelines, including federal guidelines where applicable, to disclose all Financial Interests and Outside Activities that reasonably appear to be related to the Investigator's responsibilities in the conduct of Research and Other Sponsored Projects, and to comply with all training requirements prior to engaging in sponsored research.

NYU Langone Health, through the Conflicts of Interest Management Unit, reviews and evaluates research disclosures and Institutional Financial Interests, determines if a conflict of interest exists, and, in consultation with the COI Committee where applicable, determines whether such conflict can be managed or must be eliminated in order to permit the Investigator to engage in the Research or Other Sponsored Project. No research shall be considered authorized and approved to proceed unless all relevant Investigator and Institutional financial interests and activities have been disclosed and evaluated under this Policy, and a COI Plan has been implemented where necessary.

II. APPLICABILITY

This Policy applies to all Investigators engaging in Research and Other Sponsored Projects conducted at or under the auspices of NYU Langone Health.

III. RESEARCH AND OTHER SPONSORED PROJECTS

1. **Generally**:

A. As used in this Policy, a Research Conflict of Interest means any situation where an Investigator's Outside Activities or Financial Interest could affect, be affected by, or appear to affect or be affected by the design, conduct, or reporting of their Research or Other Sponsored Project. Certain Research Conflicts of Interest are too significant to manage and must be eliminated.

B. NYU Langone Health will not engage in any transaction or activity or otherwise authorize Investigators to engage in Research or Other Sponsored Projects unless all Outside Activities and Financial Interests are disclosed, evaluated, managed, or eliminated pursuant to this Policy.

2. **Research and Other Sponsored Project Disclosures:**

A. Conflicts of Interest Management Unit (CIMU): CIMU is the administrative unit authorized to receive, review, and manage Research Conflicts of Interest disclosures, develop, issue, and monitor Research Conflict Management Plans, and act as liaison to the COI Committee and COI Review Committee as appropriate and necessary.

B. Duty to Disclose: Investigators are required to disclose and ensure that all personnel who perform activities on Research and Other Sponsored Projects under their direction disclose their and/or their Related Individuals' Outside Activities and Financial Interests in order to permit the evaluation and determination of actual or potential Research Conflicts of Interest as set forth in this Policy. The duty to disclose is ongoing; where an Investigator is not initially aware of a Research Conflict of Interest but becomes aware of it later, they should disclose the Research Conflict of Interest promptly upon learning of it. CIMU will maintain NYU Langone Health's electronic conflicts disclosure system. Disclosures will be kept confidential, provided that information may be disclosed as necessary in order for NYU Langone Health to undertake its responsibilities under this Policy, and as may be required by applicable law, research contracts and grants, and NYU Langone Health policies.

i. A new proposal or continuation submission for Research or Other Sponsored Project will not be considered complete, and NYU Langone Health will not proceed with such project or submit a proposal to a research sponsor, unless all Investigators participating in the Research or Other Sponsored Project have both (a) completed and submitted an annual disclosure within the previous twelve (12) months and (b) completed and submitted a disclosure for the Research or Other Sponsored Project as required by this Policy. Failure to make timely submissions will result in delays.

C. Types of Disclosures:

i. Annual Disclosure: Investigators are required to disclose their interests related to Research and Other Sponsored Projects annually during the NYU Langone Health Annual Conflict of Interest Reporting Cycle. Investigators are required to complete the annual disclosure within fifteen (15) days of receiving an annual disclosure request or as otherwise directed.

ii. Project-specific Disclosure Requirements*:* Investigators planning to participate in Research or Other Sponsored Projects are required to complete a conflict of interest disclosure no later than, depending upon sponsor requirements, (a) at the time that the Research or Other Sponsored Project is proposed to be undertaken ("at proposal") or (b) at the time of submission to the sponsor for its final review. The Office of Sponsored Program Administration ("SPA") is responsible for ensuring that research project-specific disclosure requests are sent to CIMU for review. In addition, while Research or a Sponsored Project is on-going, an Investigator must complete and submit a conflict of interest disclosure to CIMU and the Office of Science and Research ("OSR") for any new Financial Interest or Outside Activity held by themselves or a Related Individual prior to acquiring such interest or undertaking such activity if it is related to, or could be perceived as related to, the Research or Other Sponsored Project, its sponsor, or the intellectual property being tested or used. The Investigator must not acquire such a new Financial Interest or undertake the Outside Activity unless and until it has been disclosed, reviewed, evaluated, and managed as contemplated by this Policy.

iii. Ad hoc disclosures: Investigators are required to update their disclosures at least annually for the duration of the Research or Other Sponsored Project, and all personnel involved in research are required to report new or changed interests within thirty

(30) days of a change to a previously reported interest or activity, financial or otherwise, or acquiring any new outside interest or activity, financial or otherwise.

3. **Review of Interests and Conflicts in Research and Other Sponsored Projects:**

A. Generally: Upon receiving a Research Disclosure, CIMU will first make a determination as to whether an Outside Activity or Financial Interest is or may be related to the Research or Other Sponsored Project, and, if so, whether it constitutes a Research Conflict of Interest under the relevant sponsor guidelines and NYU Langone Health policies. In making any determination, CIMU will, as appropriate or required, consult with the discloser's department, the Chief Scientific Officer, the COI Committee, or other relevant institutional leaders.

B. Review of Financial Interests: With respect to the evaluation of Financial Interests, CIMU will evaluate such interests and escalate for review and approval as follows:

Interest Value	***Actions***
$25,000 or less	CIMU will evaluate and issue plans as appropriate.
$25,001 - $50,000; IP rights	CIMU will evaluate and issue plans as appropriate or escalate as needed to the CSO (or designee) and other members of the COI Committee as warranted.
$50,001 - $100,000; Equity of any value in privately held entity	CIMU will evaluate and consult with the CSO (or designee), for decision. The CSO (or designee) may escalate matters to the COI Committee as deemed necessary.
$100,000 and above (individually or in aggregate)	CIMU will evaluate and consult with the CSO (or designee) as appropriate and may escalate to the COI Committee for approval.

i. In making referrals and escalating matters for further review, CIMU will assess the role of the Investigator and weigh the potential (if any) to bias the results of the Research or Other Sponsored Project, the risks to human subjects (if any), the nature of the research being proposed, and the value of the Financial Interest in relation to the size and value of the entity. In addition, the following factors may also be considered, individually or in the aggregate:

a. *The Magnitude of the Financial Interest:* For instance, the amount of consulting, the percentage or value of equity, and the number and nature of relationships the Investigator has with an entity in the form of Outside Activities. Institutional Financial Interests may also increase the magnitude of the Financial Interest.

b. *Intent and Design of the Research or Other Sponsored Project:* For instance, the nature of the study (e.g., whether it is directed at understanding basic scientific processes or is to validate or invalidate a particular approach or methodology that could affect the value of the Financial Interest); whether the goal of the research is to evaluate an invention linked to the Financial Interest; whether the research involves human subjects; whether other scientific groups are independently pursuing similar questions; whether NYU Langone Health or its affiliates are best equipped (in terms of expertise, patient population, and resources) to conduct the research.

c. *Subjects Protections:* Where the research involves human subjects, whether there are double blind conditions or the involvement of a data and safety monitoring board; whether there is sufficient external review of the research conducted; and whether there is oversight over the reporting of research results to mitigate undue bias.

d. *Benefits to the Investigator:* Whether the Investigator's Financial Interest could result in the Investigator having influence over sponsor or entity decisions; whether the goal of the project is an evaluation of a technology in which an Investigator has a Financial Interest; whether the project involves a subaward to an entity in which the Investigator has a Financial Interest.

e. *Potential Commercial Value to the Investigator, an Entity they control, and/or Sponsor:* Whether conducting the research makes commercialization more likely; the amount of payments (royalties, licensing fees, etc.) received by the Investigator from related technology, both currently and in the future from the study sponsor; when the Financial Interest is in a privately held company, whether the research could have a significant impact on the company's business plan or financial outlook.

C. Ongoing Review*:* During the period of a Research or Other Sponsored Project, CIMU will conduct additional reviews of Outside Activities and Financial Interests and make determinations about whether they constitute Research Conflicts of Interest when (i) an Investigator who is new to participating in the Research or Other Sponsored Project discloses Outside Activities and/or Financial Interests; (ii) an existing Investigator discloses any new Outside Activity or Financial Interest; (iii) an Outside Activity or Financial Interest was not disclosed timely by an Investigator; and/or (iv) for whatever reason, an Outside Activity or Financial Interest was not previously reviewed by CIMU, including but not limited to those instances where: (a) a Subrecipient institution does not timely receive and report to CIMU a Subrecipient Investigator's Research Conflict of Interest or (b) CIMU does not timely receive and evaluate a Subrecipient Investigator's Outside Activities or Financial Interests when this Policy applies.

D. Timing**:** Determinations as required under this Policy will be made and issued prior to expenditure of funding for the project, prior to the participation of new or additional research personnel on the project, and prior to IRB and/or SPA activation of the study.

4. **Conflict Management:**

A. Research Conflict of Interest Plans*:* When a determination is made that an Investigator's Outside Activities or Financial Interests are permitted notwithstanding an identified potential Research Conflict of Interest, the Investigator's participation in the Research or Other Sponsored Project must be subject to a written Research COI Plan issued by CIMU. The Research COI Plan must be agreed to by both the Principal Investigator and the Investigator with the disclosed interest, if a different individual. The Research COI Plan will aim to foster transparency, maintain the objectivity of research design, conduct, and reporting, serve the rights and welfare of subjects enrolled in research, and set forth the conditions or restrictions pursuant to which the Investigator will be permitted to engage in the Research of Other Sponsored Project. CIMU is responsible for monitoring compliance with the Research Conflict of Interest Plan until the Research or Other Sponsored Project is completed.

B. Research Conflict of Interest Plans – Conditions and Restrictions: Conditions or restrictions that may be included in a Research Conflict of Plan include, but are

not limited to:

i. The appointment by the Chief Scientific Officer or their designee of an objective party to serve as a Data Monitor to oversee and advise the Investigator with the Research Conflict of Interest. The Data Monitor will be responsible for certifying the Investigator's compliance with the Research Conflict of Interest Plan to CIMU on an ongoing basis until the completion of the Research or Other Sponsored Project;

ii. Modification of the research plan;

iii. Change of personnel or personnel responsibilities, or disqualifications of conflicted personnel from participation in all or a portion of the research;

iv. Reduction or elimination of the Outside Activity or Financial Interest;

v. Disclosure of the Research Conflict of Interest: in publications, articles, and presentations; to students, postdocs, staff, and collaborators working on the project; to human subject research participants as appropriate through the informed consent process; or to all sponsors as required;

vi. Ensuring a distinct separation of roles, duties, and scope of work (including research records); and

vii. Implementation of safeguards for intellectual property rights and proper data management, including data confidentiality and data security.

5. **Presentations and Publications***:* All Investigators must disclose their financial interests in publications and presentations whenever the Investigator has financial relationships with entities that could be perceived to influence, or that give the appearance of potentially influencing, what was included in the publication or presentation. Investigators with financial interests must adhere to any disclosure requirements in their Research Conflict Management Plan and must comply with any disclosure requirements of the applicable journal or conference. If a disclosure requirement is not clear, Investigators should broadly disclose all applicable financial interests. Failure to make required disclosures or to comply with a Research Conflict Management Plan is a violation of this Policy.

6. **Reports to SPA and the IRB**: Following review and determination of interests, CIMU will advise SPA and the IRB of its determinations (including transparency requirements) and ensure that identified Research Conflicts of Interest are reported to the research sponsor, as necessary. CIMU determinations will indicate that: (A) no reportable interests were disclosed; (B) Outside Activities and Financial Interests were disclosed but were found to be unrelated to the Research or Other Sponsored Project; (C) Outside Activities and Financial Interests were disclosed and determined to be related to Research or Other Sponsored Projects but were not considered to be a Research Conflict of Interest; or (D) Outside Activities and Financial Interests were disclosed, determined to be related to Research or Other Sponsored Projects, and constitute a Research Conflict of Interest, whether the Research or Other Sponsored Project can proceed as proposed and, if so, under what circumstances.

7. **Retrospective Reviews**

A. CIMU will complete a retrospective review whenever it determines that an Outside Activity or Financial Interest related or that could be perceived as being related to the Research or Other Sponsored Project has not been timely disclosed, identified, or managed. CIMU will complete the retrospective review within 120 days of this determination.

B. The retrospective review will include a review of the Investigator's activities on the Research or Other Sponsored Project to determine whether any funded Research or Other Sponsored Project, or portion thereof, conducted during the time period that the Investigator did not disclose was biased in the design, conduct, or reporting of such research, in consultation with the IRB, Internal Audit, Compliance, and Enterprise Risk Management, OSR, and other institutional stakeholders as needed. CIMU will document the retrospective review and share the results with the Chief Scientific Officer.

C. Based on the results of the retrospective review, and after consultation with the Chief Scientific Officer, if bias is found in the design, conduct, or reporting of the Research or Other Sponsored Project, (i) CIMU will notify the Investigator's Department Chair; (ii) the Chief Scientific Officer and Department Chair will coordinate notice to the sponsor and any other affected party as deemed appropriate; (iii) NYU Langone Health may require other notifications (e.g., to journals and sponsors of public presentations) as appropriate, and (iv) NYU Langone Health may take any other appropriate corrective action to maintain the appropriate objectivity in the sponsored research. (For PHS-funded Research and Other Sponsored Projects, see Section _ for additional requirements).

8. **Appeals**: Unless otherwise provided under this Policy, an Investigator may appeal a decision made under this Policy by CIMU to the Chief Scientific Officer or the COI Review Committee, as applicable, and a decision made by any of them may be appealed to the COI Committee for final determination. All appeals must be made in writing to the Director of CIMU within seven (7) days of notification of the decision being appealed. The CIMU Director will facilitate the consideration of all appeals to the CSO and COI Committee. All decisions of the COI Committee shall be final.

9. **Training**: Investigators must complete annual conflict of interest compliance training, including research conflicts of interest, as required in accordance with applicable NYU Langone Health policies. Investigators will also be required to complete research training immediately if (A) NYU Langone Health revises this Policy and/or research conflict disclosure requirements materially; (B) an Investigator is new to NYU Langone Health; or (C) an Investigator is not in compliance with this Policy or their existing Research Conflict Management Plan.

10. **Subrecipient Requirements***:* In those cases in which a Subrecipient has been engaged for Research or an Other Sponsored Project, NYU Langone Health is responsible for ensuring that Subrecipient complies with all sponsor research conflict of interest requirements by either (A) confirming that they are subject to a conflict of interest policy that complies with sponsor requirements or (B) requiring that the Subrecipient comply with this Policy by making conflict disclosures using NYU Langone Health's COI disclosure process. Where a Subrecipient seeks to operate under its own policy, NYU Langone Health will also require the Subrecipient to provide such compliance attestations as may be required by the applicable sponsor. NYU Langone Health's Chief Scientific Officer shall have discretion to determine how this Policy should be implemented and/or adjusted for the specific Research or Other Sponsored Projects.

11. **Maintenance of Records***:* CIMU will maintain records of all disclosures it receives, all determinations made, all Research COI Plans, all final decisions, and all other actions under this Policy for the longer of (A) three (3) years from the date of submission of the final expenditure reports for the Research and Other Sponsored Project, (ii) any other period required by the research agreement with the research sponsor, or (iii) until the resolution of any action involving those records.

IV. RESEARCH AND OTHER SPONSORED PROJECTS COVERED BY THE PHS REGULATIONS

1. **Generally**: This Section applies to all Research and Other Sponsored Projects subject to the PHS Regulations and are in addition to the requirements of Section III; to the extent there is a conflict between the requirements of this Section and Section III, the requirements contained in this Section will control. The purpose of this Section is to provide procedures specific to the implementation of the PHS Regulations. CIMU will collaborate with SPA and the principal investigator/project director of the applicable research or Other Sponsored Project to comply with any public access, reporting and/or other requirements required by the PHS Regulations arising from a finding of a PHS Conflict of Interest.

2. **Review of Interests and Conflicts in Research and Other Sponsored Projects**: PHS-funded Research and Other Sponsored Projects will be reviewed, and determinations made, as set forth in Section III of this Policy; provided, however, that reviews and determinations will be based on applying the PHS thresholds set forth below, with identified PHS FCOIs managed in accordance with the PHS Regulations and this Policy.

3. **PHS -Specific Reporting Requirements**:

A. Reporting Requirements to the National Institutes of Health (NIH): NYU Langone Health will send to NIH initial, annual (for the duration of the award), and revised PHS FCOI reports for NYU Langone Health's Investigators and Subrecipients, if applicable, including all required information as defined at 42 CFR 50.604(h) and 42 CFR 50.605(b), via the eRA Commons FCOI Module, as required by regulation and as stated below:

i. Prior to the expenditure of funding;

ii. Within sixty (60) days of identification of a PHS FCOI for an Investigator who is newly participating in the project;

iii. Within sixty (60) days for new, or newly identified, PHS FCOIs for existing Investigators;

iv. At least annually (at the same date as the annual progress report, multi-year progress report, if applicable, or at the time of extension). The annual report will provide the status of the PHS FCOI and any changes to the Research COI Plan, if applicable, until the completion of the project; and

v. After a retrospective review to update a previously submitted report, if information is discovered following completion of the review.

4. **Retrospective Reviews and Mitigation Reports**:

A. Additional Requirements for Retrospective Reviews: In addition to the requirements for retrospective reviews in Section III, in the case of a retrospective review for PHS Research or Other Sponsored Projects, NYU Langone Health is required to document such review, which shall include, but not necessarily be limited to, all of the following key elements: project number; project title; PD/PI or contact PD/PI if a multiple PD/PI model is used; (iv) name of the Investigator with the PHS FCOI; name of the entity with which the Investigator has the PHS FCOI; reason(s) for the retrospective review; detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed); findings of the review; and conclusions of the review.

i. Following a retrospective review, or as otherwise determined by NYU Langone Health, NYU Langone Health will take corrective action and notify the applicable PHS institute or agency promptly if an Investigator (or Subrecipient) fails to comply with this

Policy or noncompliance with a Research Conflict of Interest Plan appears to have biased the design, conduct, or reporting of the PHS/NIH-funded research.

ii. NYU Langone Health will retrospectively report a PHS FCOI as required for a PHS/NIH-funded clinical research project whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment, as required by the regulation.

B. Mitigation Reports: In those instances in which a retrospective review has been completed pursuant to this Policy and bias found with the design, conduct, or reporting of PHS-funded research, CIMU will prepare a Mitigation Report and submit it promptly to the relevant federal sponsor. The Mitigation Report will include the key elements of the retrospective review, plus additional information to explain what action(s) have been or will be taken to mitigate the effects of any bias found, such as a description of the impact of the bias on the research project and NYU Langone Health's plan of action or actions taken to eliminate or mitigate the effect of the bias.

5. **PHS FCOI - Public Accessibility Requirements**:

A. The PHS Regulations impose public access and reporting requirements with respect to a PHS FCOI. NYU Langone Health shall make its conflict of interest policies publicly available electronically. In addition, prior to its expenditure of any funds under PHS-funded Research or Sponsored Projects, NYU Langone Health will ensure public accessibility, via a publicly accessible Web site or written response to any requestor within five (5) business days of a request for information concerning any PHS SFI that meets the following three criteria: (i) the PHS SFI was disclosed and is still held by the Senior/Key Personnel defined by this Policy; (ii) the PHS SFI is related to PHS-funded research; and (iii) the PHS SFI is an FCOI.

B. The information that will be provided in a written response will include: (i) the Investigator's name; (ii) the Investigator's title and role with respect to the research project; (iii) the name of the entity in which the PHS SFI is held; (iv) the nature of the PHS SFI; and (v) the approximate dollar value of the PHS 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.

C. Any responses to written requests will include updated information regarding the PHS SFI. The information will remain available for three (3) years from the date the information was most recently updated.

6. **Subrecipient Requirements**: In addition to the Subrecipient requirements set forth in Section III of this Policy, Subrecipients of a PHS-funded Research or Other Sponsored Research Project must attest in writing that either (A) they are subject to a conflicts of interest in research policy that complies with the PHS Regulations or (B) that they agree to be subject to, and comply with, this Policy.

7. **Training:** In addition to the training requirements set forth in Section III, Investigators whose Research or Other Sponsored Project is funded by PHS are required to have PHS-COI training at least every four (4) years as provided by NYU Langone Health. Such training shall provide an overview of the PHS regulations; Investigator disclosure requirements; PHS monitoring, reporting, and public access requirements; and relevant NYU Langone Health policies addressing the PHS regulations.

8. **Maintenance of Records***:* Notwithstanding any other provision of this Policy, NYU Langone Health will maintain all Research Disclosures and related records relating to

PHS-funded Research and Sponsored Projects (whether or not a disclosure resulted in a determination of a PHS FCOI) and all actions for at least three (3) years from the date of submission of the final expenditures report (or such longer period as required by the federal sponsoring agency) or, where applicable, from other dates specified in 45 CFR 75.361.

V. INSTITUTIONAL CONFLICTS OF INTEREST IN RESEARCH

1. **Generally**: NYU Langone Health must identify when an Institutional Financial Interest may affect or appear to affect the design, conduct, reporting, review, or oversight of Research or Other Sponsored Projects. In cases where an Institutional Financial Interest exists, NYU Langone Health must determine whether the interest creates an Institutional Conflict of Interest and whether the conflict can be managed or must be eliminated in order for NYU Langone Health to engage in the Research or Other Sponsored Project. NYU Langone Health will not engage in Research or Other Sponsored Project (including Human Subjects Research) where there is an Institutional Financial Interest unless it is disclosed to CIMU, evaluated by the COI Committee as necessary, and any Institutional COI is managed, mitigated or eliminated in accordance with this Policy. Where the Institutional Financial Interest poses no risk or minimal risk to Human Subjects in the conduct of the Research or Other Sponsored Project, the Research or Other Sponsored Project will generally be permitted to proceed subject to CIMU review and the issuance of a Conflict Management Plan as deemed necessary and appropriate. The review and evaluation of an Institutional COI as contemplated by this Policy shall be completed prior to the expenditure of any awarded funds for the research project, and a COI Plan must be in place prior to any commencement of the project (including enrollment of any research subjects).

2. **Reporting of Institutional Financial Interests**:

A. Technology Opportunity Ventures ("TOV") will maintain a list of Institutional Financial Interests, including (i) all drugs, devices and other possible investigational products covered by any patent (whether issued or pending), copyrights, licenses or other intellectual property rights held by NYU Langone Health which may be the subject of research at NYU Langone Health, and the entities that have licensed the intellectual property rights covering such drugs, devices and other investigational products, and (ii) the entities in which NYU Langone Health has acquired any equity interests (or entitlements to the same) of any amount through NYU Langone Health's technology licensing activities.

B. TOV will periodically provide such lists to CIMU, SPA, and the IRB. TOV, SPA, and the IRB will review all proposed Research and Other Sponsored Projects against such lists to identify potential Institutional Conflicts of Interest and report identified matters to CIMU for further evaluation in accordance with this Policy. CIMU will identify potential Institutional Conflicts of Interest in the course of its conflict reviews and escalate matters as necessary to the Chief Scientific Officer and/or COI Committee, appropriate, for further review.

3. **Procedure:**

A. CIMU is responsible for reviewing each disclosure of an Institutional Financial Interest related to Research and Other Sponsored Projects. The review and evaluation of an Institutional Financial Interest must be completed prior to the commencement of the contemplated research.

i. Human Subjects Research of Greater than Minimal Risk: In general, where CIMU determines that an Institutional Financial Interest may potentially affect the design, conduct, or reporting of Human Subjects Research that the IRB has determined

poses greater than minimal risk to subjects, NYU Langone Health may participate in such research only where the Chief Scientific Officer and the COI Committee determine, in writing, that Compelling Circumstances exist to permit the research to proceed pursuant to an appropriate Conflict Management Plan. Examples of such research include testing a product, device, technology, or drug involving or incorporating intellectual property owned by NYU Langone Health or the investigator. The Chief Scientific Officer will conduct an initial review and refer matters for further review and determination by the Committee as deemed necessary. The following factors will be considered by the CSO and COI Committee when assessing whether Compelling Circumstances exist to allow research to proceed:

a. Whether the research addresses an unmet medical need or is of significant public health importance;

b. Whether there is a feasible alternative institution where the research can be conducted, free from the Institutional Financial Interest;

c. Whether the Institutional Financial Interest can be structured or managed to avoid influencing study design, conduct, or reporting of the research;

d. Whether appropriate safeguards exist for participant safety, transparency, and independent oversight;

e. Whether the magnitude of the Institutional Financial Interest is proportionate to the research benefit;

f. Whether results will be published or disclosed irrespective of outcome; and can be monitored; and

g. Whether a robust management plan has been implemented

h. Any additional factors as determined relevant by the Chief Scientific Officer or COI Committee.

ii. <u>All Other Research and Sponsored Projects</u>: For all other Research and Sponsored Protects, including Human Subjects Research where the IRB has determined there are minimal or no risks to human subjects, and Basic or Non-Human Subjects Research, CIMU will review and evaluate the Institutional Conflict of Interest in accordance with Section III of this Policy.

B. **Research Conflict of Interest Management Plan**: CIMU is responsible for issuing and monitoring all Research Conflict of Interest Management Plans in connection with Institutional Conflicts of Interest. The Research Management Plan must be agreed upon in writing by the Principal Investigator and is to be considered as part of the IRB's review.

C. **Appeals**: Unless otherwise provided under this Policy, an Investigator may appeal a decision made under this Policy by CIMU to the Chief Scientific Officer or the COI Review Committee, as applicable, and a decision made by any of them may be appealed to the COI Committee for final determination. All appeals must be made in writing to the Director of CIMU within seven (7) days of notification of the decision being appealed. The CIMU Director will facilitate the consideration of all appeals to the CSO and COI Committee. All decisions of the COI Committee shall be final.

VI. ENFORCEMENT

Violations of this Policy are subject to disciplinary action, up to and including termination of employment or association with NYU Langone Health in accordance with the disciplinary policies and procedures applicable to the respective Investigator.

VII. DEFINITIONS

Basic Research (also called fundamental research or pure research) means a systematic investigation conducted to expand knowledge and understanding of fundamental principles, mechanisms, or phenomena without a specific immediate practical application or commercial objective in mind.

Chief Scientific Officer means the NYU Langone Health Executive Vice President and Vice Dean for Science, Chief Scientific Officer.

Compelling Circumstances means specific, well-documented justifications that will allow research to proceed despite a Institutional Conflict of Interest (as defined herein), taking into account: the unique qualifications/expertise of the Investigator; safety and risk to subjects; scientific impact and importance; time-sensitive nature of the research; feasibility of alternative sites; benefits to patients; and manageability of the conflict.

Conflict of Interest Committee ("COI Committee") is the Committee established by the Dean and CEO to review, evaluate, and determine matters referred to it in accordance with this Policy. The Dean and CEO shall serve as the Chair of the COI Committee, whose members shall include (a) the Chief Academic Officer; (b) the Chief Scientific Officer; (c) the Chief Clinical Officer; (d) the Executive Vice President and Vice Dean, Chief Financial Officer; (e) the Executive Vice President and Vice Dean, General Counsel; (f) the Executive Vice President and Vice Dean for Human Resources; and (g) and such other person(s) as may be designated by the Dean and CEO from time to time. The Director of CIMU shall be the liaison to the COI Committee. Personnel within the Office of General Counsel and Technologies, Opportunities, and Ventures, and other subject matter experts, shall serve as advisors to the COI Committee.

Conflict of Interest Review Committee ("COI Review Committee") is a subcommittee of the COI Committee with members appointed from time to time by the Dean and CEO. The COI Review Committee shall have the authority to review, evaluate, and determine matters between meetings of the COI Committee, with all such determinations reported to the COI Committee at its next meeting. Except as otherwise expressly provided, references in this Policy to the COI Committee will include the COI Review Committee.

Data Monitor: An independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the Conflict of Interest, as designated by either the Chief Scientific Officer or their designee.

Financial Interest means a financial, ownership, equity interest, anything of monetary value, whether or not the value is readily ascertainable, that is received, held, or expected to be received, either directly or indirectly, by an Investigator or their Related Individuals from an external entity during the relevant 12-month period. Financial Interests include, but are not limited to: stock and stock options, warrants, convertible debt, partnership interests, or other ownership interests in a publicly-traded or non-publicly-traded entity; compensation or remuneration, including salary, wages, consulting or expert witness fees, and honoraria; licensing and royalty income (; patent (whether issued or pending), copyright, license or other

intellectual property right; gifts; loans; and sponsored travel or reimbursed travel. Financial Interests do not include interests in any amount in publicly-traded, diversified investment vehicles, such as broad-based publicly-traded, diversified mutual funds and exchange traded funds, as long as the Individual or their Related Individuals, collectively, do not have a 15% or greater direct or indirect interest in the vehicle and do not have a management, board, or employment Position in the vehicle. The value of a Financial Interest is generally determined through reference to public prices or other reasonable measures of fair market value where public prices are not available.

*Human Subjects Research means r*esearch involving human participants conducted at or under the auspices of NYU Langone Health, as defined by the IRB under NYU Langone Health policies.

Immediate Family Members: As defined by the PHS regulations, an Investigator's spouse or domestic partner and dependent children.

Institutional Conflict of Interest arises in research when an Institutional Financial Interest may affect or appear to affect the design, conduct, reporting, review, or oversight of research. Institutional Conflicts of Interest are of significant concern when an Institutional Financial Interest creates the potential for inappropriate influence over a research project, particularly to the integrity of the research and the safety and care of patients enrolled in the research.

Institutional Financial Interest is considered to be held when either (i) NYU Langone Health receives or might reasonably be expected to receive royalty income from the sale of a product covered by any patent (whether issued or pending), copyright, license or other intellectual property right, held by NYU Langone Health and proposed to be used in a research project; and/or (ii) NYU Langone Health holds or proposes to hold, directly or indirectly, equity interests of any amount (or entitlement to the same), in the research sponsor for the research project, whether such research sponsor is public or non-public, through NYU Langone Health's technology licensing activities or investments related to such activities.

Institutional Responsibilities means an Investigator's professional responsibilities on behalf of NYU Langone Health, including research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as institutional review boards or data and safety monitoring boards.

Investigator means any person, regardless of title or position, who is any of the following in connection with Research or a Sponsored Project at or under the auspices of NYU Langone Health: (A) responsible for the design, conduct or reporting of the Research or Sponsored Project; (B) proposing to be the principal investigator/program director, or key personnel in a grant application for the Research or Sponsored Project submitted by NYU Langone Health; (C) serving as the principal investigator/program director, co-investigator, sub-investigator, or key personnel on the Research or Sponsored Project; (D) listed as an investigator or coordinator on an IRB application for the Research or Sponsored Project; or (E) any person identified by NYU Langone Health for such purposes.

IRB means the NYU Langone Health Institutional Review Board or any other authorized institutional review board for Human Subjects Research conducted at or under the auspices of NYU Langone Health.

Non-human subjects research refers to research that involves organisms or entities that are not human beings as defined by the IRB and federal regulations. This type of research can involve animals, plants, microorganisms, or inanimate objects.

NYU Langone Health means NYU Langone Health System, NYU Langone Hospitals, NYU Grossman School of Medicine, and NYU Grossman Long Island School of Medicine, and all entities controlled by any of them except where specifically excluded. This Policy has been adopted by the Family Health Centers at NYU Langone Health.

Outside Activity means any activity or interest outside of a NYU Langone Health Community Member's duties and responsibilities at NYU Langone Health, including but not limited to consulting or other business activities; professional or academic endeavors; public service; board or officer positions in public or private; employment outside of NYU Langone Health; service on a professional board or committee; and faculty appointments.)

PHS means the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including Administration for Children and Families (ACF); Administration for Community Living (ACL); Agency for Healthcare Research and Quality (AHRQ); Agency for Toxic Substances and Disease Registry (ATSDR); Centers for Disease Control and Prevention (CDC); Food and Drug Administration (FDA); Health Resources and Services Administration (HRSA); Indian Health Service (IHS); National Institutes of Health (NIH); Office of Global Affairs (OGA); Office of the Assistant Secretary for Health (OASH); Office of the Assistant Secretary for Preparedness and Response (ASPR); and Substance Abuse and Mental Health Services Administration (SAMHSA).

PHS Financial Conflict of Interest (PHS FCOI) exists when an NYU Langone Health Designated Official reasonably determines that a PHS SFI could directly and significantly affect the design, conduct, or reporting of Research or Other Sponsored Project subject to the PHS Regulations.

PHS Regulations means 42 CFR Part 50, Subpart F —*Promoting Objectivity in Research*.

PHS Significant Financial Interest (PHS SFI) means:

1. A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's Immediate Family Members, as defined above) that reasonably appears to be related to the Investigator's Institutional Responsibilities:
    A. With regard to any publicly traded entity, a PHS Significant Financial Interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds $5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;

    B. With regard to any non-publicly traded entity, a PHS Significant Financial Interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds $5,000, or when the Investigator (or the Investigator's Immediate Family Members) holds any equity interest (e.g., stock, stock option, or other ownership interest); or

C. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests; or

2. The occurrence in the twelve (12) months preceding the disclosure of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their Institutional Responsibilities; provided, however, that this does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency, an institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

The following are not PHS Significant Financial Interests under this Policy:

1. Salary, royalties, or other remuneration paid by NYU Langone Health to the Investigator if the Investigator is currently employed or otherwise appointed by NYU Langone Health, including intellectual property rights assigned to NYU Langone Health and agreements to share in royalties related to such rights;

2. Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles;

3. Income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, an institution of higher education as defined at 20
U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education; and

4. Income from service on advisory committees or review panels for a Federal, state, or local government agency, an institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

Principal Investigator means the individual(s), including a Project Director, designated by an organization to have the authority and responsibility for leading and directing Research or Other Sponsored Projects, including scientific, technical, administrative, and fiscal compliance. They are responsible for the overall design, conduct, and reporting of the research.

Related Individual means, with respect to an individual covered under this Policy, (i) an individual's spouse, domestic partner, significant other, or roommate; children, grandchildren, and great-grandchildren; siblings; and living ancestors (e.g., parents, grandparents, great-grandparents) and the spouses of all such individuals and (ii) individual who is not legally related to but who resides with a NYU Langone Health employee. This definition applies to current relationships and former relationships in the categories above.

Research and Other Sponsored Project means any research project conducted at or under the auspices of NYU Langone Health, whether or not externally funded, and any externally funded training or professional service project conducted at or under the auspices of NYU Langone Health. Research and Other Sponsored Projects include any systematic investigation, study,

or experiment designed to develop or contribute to generalizable knowledge, including basic and applied research; human and non-human subjects research; product development of a diagnostic test, drug, or device; and non-research projects such as training, clinical services, educational conferences, and exhibitions processed by and through the SPA and the IRB. Research and Other Sponsored Projects includes any activity for which funding is available from external sources through a grant, contract, or agreement, including but not limited to research grants, fellowship awards, training grants, programs, projects, and research resource awards. It does not include industry-funded CME activities.

Senior/Key Personnel means the Project Director or Principal Investigator and any other person identified as senior/key personnel by NYU Langone Health in the grant application, progress report, or any other report submitted to PHS (or other research sponsor) by NYU Langone Health.

Subrecipient means outside persons (e.g., sub-grantees, contractors, collaborators or consultants of NYU Langone Health) who are determined by NYU Langone Health, in consultation with the principal investigator/program director of the Research or Sponsored Project, to be responsible for the design, conduct, or reporting of the Research or Sponsored Project conducted at or under the auspices of NYU Langone Health.

History/Other Policies

This Policy replaces (1) NYU Langone Health's *Policy on Conflicts of Interest in Research and Other Sponsored Projects* issued on April 1, 2009 and updated on April 1, 2011, July 1, 2014, June 29, 2016, March 1, 2018, December 31, 2019, and November 13, 2020; and (2) NYU Langone Health's *Policy on Institutional Conflicts of Interest in Human Subjects Research* issued on April 1, 2009 and updated August 1, 2014, November 1, 2016, December 1, 2017, and December 31, 2019.