Institutional Review Board Standard Operating Procedure (SOP) Manual

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Date: 9.12.2022 3.2.2023	**Prepared by:** Bruce Park	**Approved by:** Board- 11.15.2022 Board- 3.22.2023
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The Institutional Review Board (IRB) is a critical component of the ethical conduct of research that involves human subjects. The IRB serves to protect the rights and welfare of human subjects and ensure that research conducted by the institution meets ethical standards. This Standard Operating Procedure (SOP) manual outlines the procedures for the IRB of the New York College of Health Professions (hereafter NY College).

The Institutional Review Board (IRB) of NY College is responsible for ensuring the ethical conduct of research involving human subjects. The purpose of this manual is to provide guidance and direction for the IRB in the performance of its duties.

SECTION 1: PURPOSE & SCOPE

1.1 The Institutional Review Board (IRB) at NY College has created a manual to ensure that all research involving human subjects is conducted ethically and in compliance with federal regulations, state law, and institutional policy. The purpose of the manual is to protect the rights and welfare of human subjects involved in research at NY College. All research involving human subjects conducted at NY College must follow the manual, and the IRB oversees all human subjects research to ensure that ethical principles and guidelines are followed, including the Belmont Report.

1.2 The IRB is responsible for reviewing research proposals to ensure that they meet ethical standards, evaluating risks and benefits, ensuring informed consent, and monitoring ongoing research. The IRB has the authority to approve, disapprove, or request changes to all proposed research. The IRB is composed of NY College administrative and clinical staff and representatives from outside/community-based organizations. They meet once every three months and derive legal authority from the Federal Policy for the Protection of Human Subjects.

1.3 NY College staff or faculty members must serve as primary or co-principal investigators on research submitted for IRB review. For studies involving clinical interventions, NY College's research director and appropriate senior clinic officer must approve the research.

SECTION 2: APPLICATION PROCESS

2.1 All NY College faculty, staff, interns, and students seeking IRB approval for research must follow specific steps. NY College principal investigators (PIs) must seek and receive approval

from NY College's research director before submitting an application to the IRB.

2.2 Application Submission Process: Potential researchers must complete the Application for Approval to Use Human Subjects in Research and may need to provide additional forms and documentation.

2.2.1 The application must be signed and submitted to the IRB administrator or designee after completing all necessary forms.

2.2.2 The administrator will conduct a pre-review to ensure that the application contains all necessary materials.

2.2.3 The IRB administrator may require researchers to make modifications or provide additional information before processing the application for review.

2.2.4 Applications must be submitted at least two weeks before the scheduled IRB meeting date to ensure that they are reviewed at the next meeting.

2.3 Principal/Primary Investigator (PI) Requirements: All PIs and study personnel must maintain up-to-date human subjects protection certification, which is valid for three years. Certifications from the CITI training program or the Association of Clinical Research Professionals will be recognized by NY College.

2.4 Informed Consent Process: The informed consent process is critical in human subjects research. Its purpose is to ensure that potential research subjects understand the nature of the research, risks and benefits, and the voluntary nature of their participation. The informed consent process also helps protect the rights and welfare of human subjects by ensuring that they are not coerced or misled into participating in research.

2.4.1 All research projects involving human subjects must have a plan for obtaining informed consent from study participants or their legally authorized representatives. The IRB will evaluate the adequacy of the informed consent process and documentation during the review process.

2.4.2 Informed consent must be obtained from all participants or their legally authorized representatives before participation in research activities. Exceptions to informed consent may be granted by the IRB in certain circumstances where informed consent is not possible or practical, such as emergency situations or when the research involves minimal risk to subjects.

2.4.3 The informed consent document must include information about the research purpose, procedures, risks and benefits, compensation, and contact information for the principal investigator or research team. The document must also state that participation is voluntary, and subjects have the right to withdraw from the study at any time without penalty or loss of benefits. If the research involves vulnerable populations, such as children or individuals with limited capacity to consent, additional safeguards must be put in place to ensure that informed consent is obtained from a legally authorized representative and that the subject's assent is also obtained where possible.

SECTION 3: REVIEW OF PROTOCOLS

3.1 IRB Review: IRB applications will be assigned a primary reviewer, who may be assisted by a secondary reviewer, if needed. The reviewer will have the primary responsibility of determining whether the protocol can be approved for exempt or expedited studies. If the reviewer is unable to approve the protocol, it will be referred to the full committee for review. If a protocol is assigned for presentation at an upcoming meeting, the reviewer will lead the discussion of their designated applications. The full IRB committee may approve, disapprove, or conditionally approve applications.

3.2 Specific Review Criteria: The IRB will evaluate each application based on the following criteria:

3.2.1 Risks to subjects are minimized: (i) By using procedures that are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

3.2.2 Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. The IRB will evaluate risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research).

3.2.3 Selection of subjects is equitable. In making this assessment, the IRB will consider the purposes of the research and the setting in which the research will be conducted. It will be particularly cognizant of the special problems of research involving children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons. The IRB will consider whether a participant may be particularly vulnerable to coercion and undue influence (46.111(a)(3) and 46.111(b)).

3.2.4 Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by §46.116.

3.2.5 Vulnerable populations. The IRB should be particularly cognizant of the special problems of research that involve subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons. Additional protections or conditions may be required.

3.3 Review Notification: The status of the IRB review, including the final IRB approval, will be indicated within the IRB's protocol management system. The applicant will receive an email from the IRB staff, reminding them that they must complete a continuing review form or annual administrative review form within the specified timeframe, and that adverse events must be reported to the IRB within 10 days of the event.

3.4 Continuing Review: Within one year of approval or the timeframe established by the IRB,

PIs must complete and submit a continuing review request within the management system. Continuing review of research will follow the same procedure as the initial review.

3.4.1 Formal Continuing Reviews (CRs) are no longer required for protocols originally approved via the exempt or expedited review processes, unless a reviewer explicitly justifies why the review would enhance the protection of research subjects (46.109(f)(1)(i)). This determination will be made on a case-by-case basis. However, a modified administrative review will still be required to address internal controls.

3.4.2 The IRB reserves the right to randomly audit projects to ensure that no protocols have been implemented without its prior review and approval.

3.5 Reporting Requirements: PIs are responsible for promptly reporting any significant protocol deviations or unanticipated problems (UPs) to the IRB. A protocol deviation is any change or departure from the study design or procedures of a research protocol that is under the investigator's control and has not been approved by the IRB, but does not impact subject safety, compromise study data integrity, or affect subject willingness to participate in the study. UPs are events that pose a significant risk to participants' safety or welfare, including AEs that were not anticipated or that are more severe than anticipated. UPs also include breaches of confidentiality, HIPAA violations, and any other events that may compromise participant safety or privacy. The IRB must be notified of all UPs within 10 days of the PI becoming aware of the event.

3.6 Changes in PI: If a PI leaves NY College or is unable to continue serving as the PI for a study, the study must be put on hold until a new PI is identified and approved by the IRB. All study personnel changes, including the addition or removal of PIs or co-PIs, must be reported to the IRB via an amendment request.

3.7 Noncompliance: Any noncompliance with IRB policies and procedures must be reported to the IRB as soon as possible. The IRB may take various actions in response to noncompliance, including but not limited to requiring additional monitoring, suspending or terminating approval of the study, or imposing sanctions on the PI or other study personnel.

3.8 IRB Records: All IRB records will be maintained in the IRB's protocol management system. These records will include all study documents, including applications, consent forms, amendments, continuing reviews, and adverse event reports. All records will be retained for at least 3 years after the completion of the study or the submission of the final report, whichever is later.

SECTION 4: REPORTING REQUIREMENTS

4.1 Reporting Adverse Events: The PI must immediately report any unanticipated problems involving risks to subjects or others to the IRB. This includes any adverse events, serious adverse events, or non-compliance issues. The IRB will review the report and take appropriate action to ensure the safety and welfare of the subjects.

4.2 Continuing Review: All studies approved by the IRB must undergo continuing review at least once per year. The PI must submit a progress report to the IRB that includes information on any changes made to the study, recruitment status, adverse events, and any other relevant information. The IRB will determine if the study can continue as approved or if modifications are necessary to ensure subject safety.

4.3 Study Completion: When the study is complete, the PI must submit a final report to the IRB that includes a summary of study results, any unexpected findings, and a statement that the study was conducted in accordance with the approved protocol and informed consent document.

SECTION 5: MEMBERSHIP AND OPERATIONS

5.1 Membership: The IRB committee is composed of individuals with varying backgrounds, expertise, and experience, including at least one member whose primary concerns are in scientific areas, at least one member whose primary concerns are in non-scientific areas, and at least one member who is not affiliated with NY College or part of the immediate family of a person who is affiliated with NY College. The President of NY College appoints the IRB committee members for a three-year term, and they can serve up to two consecutive terms. All members are required to complete training in human subjects research ethics and regulations.

5.2 Operations: The IRB committee meets at least once every three months to review research proposals. The committee may also review and approve certain types of research using an expedited review procedure, conduct continuing review of approved research, and review adverse events or unanticipated problems that occur during the course of the research. The IRB committee maintains minutes of each meeting, including attendance, a summary of the discussion, decisions made, and any recommendations for changes to research proposals.

5.3 Review of Research Proposals: The IRB committee reviews all proposed research involving human subjects to ensure that it complies with federal regulations, state law, and institutional policy. The committee considers the risks and benefits of the research, as well as the protection of the rights and welfare of the research participants. The committee may require modifications to the research protocol to address concerns or may deny approval of the research proposal if it does not meet ethical standards. Researchers must submit their research proposals to the IRB committee for review and approval before beginning the research. Researchers must also submit any modifications to the research protocol and any adverse events or unanticipated problems that occur during the course of the research.

5.4 Authority and Responsibilities: The IRB committee has the authority to suspend or terminate approval of a research project if it determines that the research is not being conducted in accordance with federal regulations, state law, institutional policy, or the approved research protocol. The committee may also require additional monitoring or reporting to ensure that the research is being conducted in an ethical manner.

5.5 Composition, Appointment, and Term of Service: The IRB shall be composed of no fewer

than five members, including at least one member who is not affiliated with NY College. Members shall be selected based on their expertise in the areas of research and ethics, and the IRB shall strive for diversity in its membership to represent different areas of expertise, race, gender, and ethnicity. IRB members shall be appointed by the President of NY College for a term of three years, with the option for reappointment for additional terms. The President of NY College shall consider recommendations from the IRB Chairperson in the appointment process. The IRB Chairperson shall be appointed by the President of NY College and shall be responsible for overseeing the IRB's activities, presiding over IRB meetings, and representing the IRB to the College and the public.

5.6 All researchers at NY College must follow specific steps and requirements for IRB approval, including the informed consent process and continuing review of approved studies. The IRB committee is composed of individuals with varying backgrounds, expertise, and experience, and they conduct thorough reviews of research proposals to ensure that they meet ethical standards. The IRB committee also has the authority to monitor ongoing research, require modifications to the research protocol, and take action if necessary to protect research participants.

5.7 Membership of the IRB committee is diverse and selected based on their expertise in the areas of research and ethics, with a focus on the representation of different areas of expertise, race, gender, and ethnicity. All members are required to complete training in human subjects research ethics and regulations. The IRB Chairperson oversees the IRB's activities and ensures that the committee operates in compliance with all applicable regulations and policies.

SECTION 6: PROCEDURES

6.1 Meeting Schedule: The IRB committee will convene at least once every three months, or more frequently if necessary, to review research proposals and conduct other IRB business.

6.2 Submission of Research Proposals: Before initiating any research activities involving human subjects, researchers must submit their research proposals to the IRB committee for review and approval.

6.3 Review of Research Proposals: The IRB committee will assess all research proposals to determine whether they meet ethical standards and present reasonable risks to human subjects. The review process will take into account the following:

6.3.1 Risks and Benefits: The IRB committee will evaluate the potential risks and benefits associated with the research activities. If the risks outweigh the benefits, the proposal may be denied.

6.3.2 Informed Consent: The IRB committee will scrutinize the informed consent process to ensure that it is comprehensive and that the subject is fully aware of the potential risks and benefits associated with the research activities.

6.3.3 Recruitment of Subjects: The IRB committee will scrutinize the recruitment process to ensure that it is ethical and that subjects are not coerced or deceived into participating.

6.3.4 Selection of Subjects: The IRB committee will scrutinize the selection criteria for subjects to ensure that they are equitable and unbiased.

6.3.5 Privacy and Confidentiality: The IRB committee will assess how the privacy and confidentiality of the subjects will be safeguarded during the research activities.

6.3.6 Data Safety Monitoring: The IRB committee will scrutinize how the data will be monitored during the research activities to ensure that the subjects are not exposed to unreasonable risks.

6.4 Approval or Disapproval of Research Proposals: The IRB committee will approve research proposals that meet ethical standards and present reasonable risks to human subjects. If a proposal is disapproved, the IRB committee will provide a written explanation of why it was disapproved and provide guidance on how the proposal can be revised to meet ethical standards.

6.5 Record Keeping: The IRB committee will maintain detailed records of all research proposals, IRB meetings, and any other relevant documentation. These records will be kept confidential and stored in a secure location.

In summary, the IRB committee has established clear procedures for the submission, review, and approval of research proposals involving human subjects. The committee is responsible for ensuring that research activities comply with ethical standards and pose reasonable risks to human subjects. The committee maintains detailed records of all research proposals, IRB meetings, and relevant documentation, which are kept confidential and stored in a secure location.

SECTION 7: RESPONSIBILITIES

7.1 Ethical Standards: The IRB committee will review all research proposals to ensure they comply with ethical standards, including respect for persons, beneficence, and justice.

7.2 General Responsibilities: The IRB committee is responsible for reviewing all research proposals involving human subjects to ensure they meet ethical standards. The IRB committee is also responsible for the oversight, administration, implementation, and management of all IRB business, including policies and procedures related to the protection of the rights and welfare of human subjects.

7.3 Auditing: The IRB administrator may perform routine and for-cause audits using systematic methods to evaluate compliance with federal regulations, state and local laws, and institutional policies. The objective of a routine IRB audit is to ensure proper documentation, record keeping, data analysis, and adherence to Federal regulations and IRB policy to monitor,

measure, and improve the effectiveness of the human research protection program.

7.4 Protocol Audit Process: The IRB administrator or designee selects an Investigator or study for a routine audit based on criteria that include, but are not limited to, studies involving procedures that present greater than minimal risk to subjects, vulnerable populations, Investigator-initiated drug/device studies, and Investigators conducting a large number of studies.

7.5 Adverse Events/Noncompliance/Research Misconduct/Conflict of Interest: If a PI identifies an adverse event, the instance of noncompliance, or conflict of interest, or if during a routine audit, an issue of noncompliance or conflict of interest is discovered, it will be assigned to NY College's Management Committee for review and evaluation. If the Committee determines that research misconduct has occurred, the Committee will recommend appropriate penalties to the College administration.

7.6 Determinations: If the Management Compliance Committee determines that the research should be suspended, the PI and relevant parties will be notified in writing of the decision and the reasons for it. The suspension will remain in effect until the Committee determines that the issue has been resolved and lifts the suspension.

7.7 Reporting: The IRB administrator is responsible for reporting any unanticipated problems involving risks to subjects or others, unexpected adverse events, serious or continuing noncompliance with federal regulations or IRB policies, and any suspension or termination of IRB approval, any supporting Agency or Department Heads, and OHRP, if federally funded.

7.8 Conflict of Interest: The IRB will review each protocol for potential conflicts of interest and will request additional information from the PI, as needed. If a conflict of interest is identified, the IRB will manage, reduce, or eliminate the conflict, as appropriate. If a conflict of interest cannot be managed, reduced, or eliminated, the IRB may determine that the research cannot be approved.

7.8 Training and Education: The IRB committee is responsible for ensuring that all individuals involved in human subject research are trained in the ethical principles and regulations governing research involving human subjects.

7.9 Communication: The IRB committee will communicate with investigators and other relevant parties to ensure that they understand the IRB policies and procedures and are aware of any changes or updates to these policies and procedures. The IRB committee will also communicate with sponsors and regulatory agencies as necessary to ensure compliance with regulations and policies governing research involving human subjects.

7.10 Collaboration: The IRB committee will collaborate with other institutional committees and departments involved in human subject research, such as the Institutional Animal Care and Use Committee (IACUC), the Biosafety Committee, and the Radiation Safety Committee, to ensure that all research involving human subjects is conducted in an ethical and safe manner.

7.11 Authority: The IRB committee has the authority to suspend or terminate research activities that do not comply with ethical standards or pose risks to human subjects. The committee also has the authority to approve or disapprove research proposals involving human subjects and to monitor ongoing research activities to ensure that they comply with ethical standards and pose reasonable risks to human subjects.

In summary, the IRB committee has a range of responsibilities, including ensuring compliance with ethical standards, reviewing and approving research proposals involving human subjects, monitoring ongoing research activities, conducting audits to ensure compliance with regulations and policies, and providing training and education to investigators and research staff. The committee communicates with relevant parties and collaborates with other institutional committees and departments to ensure that all research involving human subjects is conducted in an ethical and safe manner. The committee has the authority to suspend or terminate research activities that do not comply with ethical standards or pose risks to human subjects.

8. HIPAA

8.1 Protection of Privacy: The IRB at NY College serves as the Privacy Board for the Health Insurance Portability and Accountability Act (HIPAA) and reviews requests for waivers of authorization to use protected health information (PHI) for research purposes. The IRB ensures that all use or disclosure of PHI for research purposes complies with the Privacy Rule, either with individual written permission or under certain conditions.

8.2 Informed Consent: The IRB ensures that informed consent is obtained from all research participants, with the process scrutinized to ensure it is comprehensive and that participants understand the potential risks and benefits.

8.3 Monitoring of Ongoing Research: The IRB monitors ongoing research to ensure that ethical standards are upheld and that any new risks are identified and addressed to protect research participants.

8.4 Suspension or Termination of Research: The IRB has the authority to suspend or terminate research activities that do not comply with ethical standards or pose risks to participants, ensuring that research activities are conducted in an ethical and safe manner.

8.5 HIPAA Compliance: The IRB ensures that all research involving PHI complies with HIPAA regulations, including obtaining necessary authorizations and maintaining appropriate safeguards to protect the privacy and confidentiality of research participants' PHI. The IRB will also review any requests for waivers of HIPAA authorizations and determine whether they are appropriate based on the specific circumstances of the research.

9. SHARING RESEARCH DATA

9.1 Sharing Data with External Research Partners: NY College researchers who plan to share research data with external partners must follow one of the approved pathways outlined below. They must request permission via one of these options in the IRB application. Any sharing of data without the appropriate documentation or secure method in place will be considered a protocol noncompliance.

9.2 Approved Pathways for Sharing Research Data with External Partners: NY College offers several pathways for sharing research data with external partners, each with its own approval criteria. These pathways are:

9.2.1 CollegeLink: External co-PIs can review patient charts in NY College's Electronic Health Record (EHR) through a web-based portal. This option is only approved in limited circumstances, as it grants access to the patient record and requires significant oversight.

9.2.2 Direct but Limited Access: External PIs can log into NY College's EHR directly. This option is only approved in limited circumstances, as it grants access to the patient record and requires significant oversight.

9.3 The IRB will evaluate each request for external data sharing on a case-by-case basis to ensure that it complies with ethical standards and protects participants' privacy and confidentiality. It is the responsibility of the NY College researcher to ensure that any external partners are aware of and comply with these requirements. Any external partners who fail to comply with these requirements may be excluded from future research collaborations with NY College.

10. CONCLUSION

The protection of human subjects is of utmost importance in research activities, and NY College's IRB is dedicated to ensuring that all research proposals meet ethical standards and pose reasonable risks to human subjects. The IRB has established clear procedures for the submission, review, and approval of research proposals involving human subjects, as well as procedures for monitoring and ensuring compliance with ethical standards. In addition, the IRB serves as the Privacy Board for HIPAA and reviews requests for waivers of authorization to use protected health information for research purposes.

NY College recognizes the importance of sharing research data with external partners to advance scientific knowledge and encourages data sharing through several approved pathways. The IRB plays a critical role in evaluating requests for external data sharing to ensure compliance with ethical standards and participant privacy and confidentiality.

In summary, NY College's IRB is committed to upholding ethical standards and protecting the welfare of human subjects in research activities.

DEFINITIONS

Adverse Event (AE): Any negative occurrence associated with participation in research, including physical or psychological harm, that may require changes to the protocol. AEs are reviewed to determine if they are also Unanticipated Problems (UPs), which are events that pose significant risks to participants' safety or welfare. Most AEs are not UPs and do not need to be reported to OHRP.

Benefit: The potential advantage or improvement to a subject or society resulting from participating in research activities.

Children: Individuals who have not yet reached the legal age for consenting to treatments or procedures involved in the research, as determined by the jurisdiction where the research is conducted.

Clinical trial: A research study that assigns one or more human subjects to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

Documentation: The process of obtaining a subject's signature (or authorized representative) on consent forms to document their agreement to participate in the research.

Exempt: Research that meets the definition of human subjects research but is exempt from federal regulations on the protection of human subjects because it meets one of six exempt study designs.

Generalizable Knowledge: Results or outcomes of research that can be applied universally or widely, beyond the site of data collection or the population studied.

Human subject: A living individual from whom an investigator collects data through interaction or intervention, or identifiable private information. If a survey collects information about an individual's opinions or characteristics, the research involves human subjects.

Informed consent: The process of obtaining consent from a subject after providing all necessary information about the research.

Intervention: Procedures or manipulations performed for research purposes, including physical procedures and manipulations of the subject's environment.

Interaction: Communication or interpersonal contact between investigator and subject, such as online surveys, telephone interviews, and focus groups.

Limited Data Set: PHI that has had identifying information removed to meet criteria for sharing purposes.

Minimal risk: Harm or discomfort anticipated in research that is not greater than that ordinarily encountered in daily life or during routine physical or psychological examinations or tests.

Noncompliance (NC): Failure to comply with the research plan, regulations, or institutional policies and procedures, including any deviation from the IRB-approved protocol.

Protected health information (PHI): Individually identifiable health information that includes demographic data related to an individual's past, present, or future physical or mental health or condition, the provision of health care, or payment for health care.

Principal Investigator (PI): The lead scientist responsible for the design and conduct of the research and the protection of human subjects involved in the research.

Protocol deviation (PD): Any change or departure from the study design or procedures of a research protocol that is under the investigator's control and has not been approved by the IRB, but does not impact subject safety, compromise study data integrity, or affect subject willingness to participate in the study.

Risk: The probability of harm or injury to a subject resulting from participation in research activities.

Systematic Investigation: Research activity that seeks to answer a pre-set research question using consistent and organized methods to collect and analyze data, and draw conclusions from the results.

REFERENCES

This manual conforms to the regulations outlined in 45 CFR Part 46, Protection of Human Subjects, as well as any subsequent revisions and updates. The U.S. Department of Health and Human Services has codified these regulations, including the Common Rule (subpart A) and subparts B-E, in 45 CFR 46. Readers can access the regulatory text through the provided links, and OHRP provides additional information about the revisions to the Common Rule, including an annotated version highlighting changes between the pre-2018 and 2018 versions.

The manual references the following sites: Office for Human Research Protections (OHRP), which offers guidance documents, FAQs, letters addressing regulatory issues, and other media; 45 CFR 46, which provides a robust set of protections for research subjects and additional protections for certain populations; and The Belmont Report, which identifies basic ethical principles and guidelines for research with human subjects.