

Institutional Review Board
Standard Operating Procedures

TEACHERS COLLEGE

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- I. Institutional Review Board's Regulatory Mandate to Protect Human Subjects.** The Institutional Review Board (“IRB”) is an administrative committee of Teachers College (the “College”) whose purpose is to ensure that the rights and welfare of human subjects of research conducted at or sponsored by the College regardless of the source of funding are protected pursuant to federal regulations (45 CFR part 46 and 21 CFR part 56). In taking on this responsibility the IRB ensures that the human subject research is conducted ethically and in compliance with the *Belmont Report*, applicable federal, state, local and institutional requirements by performing prospective and continuing review of the protocol, the informed consent process, and the procedures utilized to enroll subjects.
- II. IRB Administration.** The conduct of research at the College is a shared responsibility. It requires cooperation and collaboration among the institution, investigators and their research staff, the subjects who enroll in research, and the IRB members and its staff. A clear delineation of the responsibilities of these parties in the IRB Standard Operating Procedures (“SOP”) helps ensure protection for the participants who volunteer for research.

As a committee of the College, the IRB reports directly to the Provost of the College. It is the responsibility of the College to assure federal agencies in writing that it will comply with regulations governing the protection of human subjects as part of its Federalwide Assurance (“Assurance”). The Provost of the College is the Assurance Signatory Official and is ultimately responsible for overseeing the protection of human subjects within the College. The Signatory Official must also ensure that open channels of communication are maintained between the IRB, research investigators and staff, and College administration, and that the IRB is provided with sufficient meeting space and staff to support its substantial review and confidential record keeping responsibilities.

The College IRB Office is staffed by a full-time IRB Administrator. The Administrator’s duties include: 1) assisting in the development and implementation of procedures to ensure the efficient flow of all IRB records; 2) maintaining documentation and records in accordance with federal regulatory requirements; 3) tracking records and the progress of all studies; and 4) ensuring meetings are conducted according to federal regulations, i.e., recording attendance and preparing and distributing materials for meetings. The Administrator reports to the Director, Office of Sponsored Programs and works closely with the Chair and other IRB members.

The responsibility of ensuring compliance with the College's Federal-wide Assurance is vested in the IRB. No research involving human subjects may be conducted at the College without IRB approval. Research approved by the IRB may be subject to further appropriate review and approval or disapproval by officials of the College. However, officials of the College shall not approve **any** research if it has not been approved by the IRB. There is no appeals process for any protocol disapproved by the IRB.

- III. IRB Membership.** The IRB will have sufficient expertise to review the broad variety of research in which the College becomes involved, will be knowledgeable about all relevant regulatory requirements and make every effort to be impartial and objective in its review (45 CFR 46.107(a) and 21 CFR 56.107(a)).

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- A. Appointment of IRB Chairperson, Length of Service and Duties. The Provost of the College shall appoint the IRB Chairperson. The Chairperson shall serve a term of three (3) years and may be reappointed. In addition to the responsibilities of IRB membership, the Chairperson has primary responsibility for conducting IRB meetings and secondary responsibility directing the IRB staff to ensure operation of the IRB within all applicable regulatory requirements. The IRB Chairperson works with IRB members, College officials, and investigators to ensure that the rights and welfare of research subjects are adequately protected. As a fair and impartial committee head, the Chairperson functions as a role model for how IRB business should be conducted. The Chairperson shall sign all official IRB correspondence, unless otherwise indicated, and shall report directly to the Provost of the College.
- B. Appointment of IRB Members, Length of Service, and Duties. The IRB Chairperson, with concurrence of the Provost, shall appoint members to the IRB. The members serve three (3) year staggered terms with reappointment permitted without limitation. Members are responsible for ensuring that the rights and welfare of research subjects are protected. Members vote to approve, require modifications in, disapprove, or defer research submitted to the IRB. Members are expected to attend IRB meetings on a regular basis and serve as general reviewers on all research discussed at convened meetings.
- C. Non-Voting Members. The IRB may choose to designate certain individuals to attend IRB meetings on a regular basis as ex-officio consultants. These consultants may not vote with the IRB.
- D. Consultants. On an as needed basis the IRB may at its discretion invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB. It is recommended that the IRB be given the curriculum vitae or qualifications of the consultant to evaluate the weight to be given to the consultant's recommendations during protocol review.
- E. IRB Membership Requirements. In compliance with federal regulations, the College's IRB must satisfy the following requirements:
- The IRB shall have at least 5 members.
 - The IRB shall be comprised of members possessing varying professional backgrounds to promote complete and adequate review of research activities commonly conducted at the College.
 - The IRB shall be comprised of members and be sufficiently diverse relative to race, gender, cultural background, and sensitivity to community attitudes to promote respect for the IRB's advice and counsel in safeguarding the rights and welfare of human subjects.

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- The IRB shall consist of qualified persons of both genders.
- The IRB will not consist entirely of members of one profession.
- The IRB shall have at least one (1) member whose primary concerns are in non-scientific areas.
- The IRB shall include at least one (1) member who is not otherwise affiliated with the College and who is not part of the immediate family of a person who is affiliated with the College.

F. Conflict of Interest/Significant Financial Interest. No IRB member may participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB. For example, an IRB member may also be a Principal Investigator for a study being reviewed by the IRB. The member cannot vote on or otherwise participate on IRB's review assignment of his/her study. Another example would be a financial interest in a study being reviewed. IRB members, including the Chairperson, who have conflicting interests, are required to disclose such interests and to absent themselves from deliberations, quorum counts, and votes on the relevant protocol. Such absences are recorded in the meeting's minutes as absences, or as "excused," not as abstentions. The reason for the conflict is also documented in the minutes. IRB members must absent themselves from discussions and votes for protocols submitted for review by their advisees (i.e., faculty sponsor).

For research sponsored by any unit of the (PHS) Public Health Service including the National Institutes of Health (NIH), The Federal Public Health Service has adopted regulations (42 CFR Part 50 Subpart F and 45 CFR Part 94) on Promoting Objectivity in Research. Each Investigator who is participating in research under an award or a subaward where the prime award originates from PHS must submit an updated disclosure of Significant Financial Interest (SFI) at least annually, during the period of the award. Such disclosure must include any information that was not disclosed initially to College, pursuant to this policy, or in a subsequent disclosure of SFI (e.g., any financial conflict of interest identified on a PHS-funded project directly as a PHS Grantee and/or indirectly through a subaward) that was transferred from another Institution), and must include updated information regarding any previously disclosed SFI (e.g., the updated value of a previously disclosed equity interest).

The IRB chair or administrator should be responsible for making sure that FCOI disclosures made by study personnel do not impact the protocol. If there is impact, then a management plan for that protocol and that individual needs to be created and is part of the IRB review. Each investigator who is participating in research under an award or a subaward where the prime award originates from PHS must submit an updated disclosure of SFI (including reimbursed travel)

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within thirty (30) days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new SFI. Teachers College requires all Faculty and staff of the College to adhere to its Policy on Conflict of Interest and Conflict of Commitment (2013). All investigators, including student investigators are required to disclose new SFIs pertaining to the specific protocol at time of review in the allotted space on the New Study Application form, regardless of the source of funding. This must include a detailed explanation of the nature of the investigator's position or role, if any, at any participating data collection or recruitment site. Conflict of interest may also include instances when the primary researcher or research staff is recruiting a population (or sample) of convenience. In these cases, the researcher will be asked to disclose their role at the study site or role with potential participants and if they are family, students, employees, or managers.

- G. Initial Training and Continuing Education of IRB Members, Principal Investigators, Doctoral Students, and Faculty Advisors. The terms of the College's Assurance specify that the College is required to ensure that IRB members and investigators are provided education about human subject protections. All members, investigators and students must take the CITI Training for researchers in the Social/Behavioral Sciences plus the required number of modules tailored to their role or area of research. CITI Training must be updated every three (3) years. IRB members are provided with information concerning the IRB website which contains educational and operational materials. They shall also receive a copy of these standard operating procedures to review research from an ethical and regulatory perspective, copies of all templates used to submit studies, HIPAA information, the Belmont Report, and copies of 45 CFR 46, and 21 CFR 50 and 56. IRB Members are provided with continuing education opportunities by the College.

IRB MEETINGS

1. Meeting Schedule. Meetings of the IRB are held once per month, every month except August, on the third or fourth Wednesday of the month, depending on the academic calendar.
2. Quorum Requirements and Voting at IRB Meetings. IRB quorum requirements are based on the following standards:
 - A majority of the IRB members, including at least one member whose primary concerns are in non-scientific areas. A non-scientific member must be present to conduct a convened meeting. For research to be approved, it must receive the approval of a majority of the IRB members present at the meeting.
 - Members may be present in person or audio (telephone) or interactive teleconference. Members present via teleconference shall be noted as such in the meeting minutes.
 - For research to be approved, it must receive the approval of a majority of

those members present at the meeting.

IV. Substance of IRB Review

- A. Principal Investigators' Submission to IRB. All research studies involving human subjects should be submitted to the IRB through <https://www.axiommentor.com> (MENTOR), the College's IRB electronic protocol management system (or through MyTC/Research Tab/Mentor IRB). Instructions on how to submit documents are available on MENTOR's home page along with training videos for investigators and department chairs and templates of forms required. Instructions are also available in the Mentor/Documentation tab. For full board protocols, all documentation must be submitted nine (9) days prior to the meeting of the IRB at which the research study is to be presented. Expedited and exempt protocols are reviewed on a rolling basis (first-come-first served).

IRB Review and Approval of Research. Unless categorized as exempt from IRB review as discussed in Appendix C, all human research conducted at the College must be prospectively reviewed and approved by the IRB. Regardless of the type of review (exempt, limited IRB review, expedited or full review at a convened meeting), the investigator will be notified in writing of the IRB's determination. Federal regulations require the IRB to conduct initial and continuing reviews of all non-exempt research at a convened IRB meeting (45 CFR 46.108(b) or 21 CFR 56.108).

1. Initial Review: For initial review, upon a determination by the IRB Administrator that the Principal Investigator has fulfilled all requirements for submission, the proposed research study will be placed on the IRB agenda. All documents submitted to the IRB for review must be in final format, using standard templates, where applicable.

Researchers may receive a request for revisions from the IRB department. Researchers may not begin recruitment or research activities until their response to revisions has been reviewed and they receive a final IRB approval letter on Teachers College letterhead. Consent forms must also contain an official IRB authorization stamp only after final approval. Only IRB administrators or authorized IRB staff can issue an IRB authorization stamp. Copies of the official IRB authorized stamped consent form and supporting documents must be used for research work.

The completed submission will be available for review by the IRB seven (9) days prior to the IRB meeting at which the study is presented. All forms of advertising or dissemination of information for recruitment of subjects into a research protocol must be approved by the IRB prior to distribution or publication of the material. In addition, recruitment letters to fellow researchers, both within and without, the College must be approved by the IRB. See Appendix A for a detailed list of required forms.

2. Continuing Review: The IRB will make a determination at the time of initial

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review if substantive continuing review of a protocol is required and document that determination in the meeting minutes. The IRB may require continuing review more frequently than annually for research conducted in settings subject to high degrees of volatility, for example, refugee camps, active duty military settings, nations experiencing major political/social upheaval, etc. Research projects reporting multiple adverse events and/or protocol deviations or multiple inquiries from potential and enrolled subjects may require verification that no substantial changes have been made to the research by the IRB chair, member, staff, appropriate third party at recruitment data collection sites or some combination of the above.

Continuing review of research approved under the pre-2019 Common Rule that under the new Common Rule would not be subject to a continuing review requirement will undergo a primary review by the Chair and voted upon at a convened IRB meeting.

For research approved under the New Common Rule, effective January 19, 2019, where continuing review is no longer a requirement for all non-exempt research, the IRB will still require an annual “check in” to confirm the research is still ongoing, to disclose any yet unreported protocol changes or adverse events, and to ensure the approved consent form is in use.

Expedited review and approval of modifications in the protocol or consent form that are reviewed during an approved project period will not modify the original 365-day approval period granted to the project. If, at the time of the initial review, it is determined by the IRB that a study needs to be reviewed more than once a year, it shall be included in writing to the primary investigator. The IRB Chairperson (or his/her designee) may, at his/her discretion, audit and/or review research records of individual protocols.

Principal Investigators will receive a notice at least thirty (30) days before the approval expiration date that a continuing review report is due. If the form is not approved prior to the expiration date, the IRB may suspend enrollment of new subjects until approval is received. See Appendix A for a detailed list of required forms.

3. Expedited Approval: Federal regulations permit the IRB Chair to review and approve proposed research through an expedited procedure if it meets the criteria outlined in Appendix B. Such review and approval shall be reported at the next convened IRB meeting and IRB members will be given an opportunity to review or comment on any project approved by expedited review. If the Chairperson decides that a project should not be approved by expedited review, the project will be reviewed at the next convened meeting using the standard practices for new and continuation applications.
4. All research that is potentially exempt from IRB review shall be submitted to

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the electronic IRB system via the New Protocol Application or A Request for Exemption Form to be created later. The IRB Chair or their designate may deem a protocol exempt after obtaining enough information from the investigator to determine whether the claimed exemption applies.

Research activities which may qualify for exemption for IRB review are outlined in Appendix C.

- B. Criteria for IRB Approval of Research. To approve any proposed research to be conducted at Teachers College, the IRB shall determine that all the following requirements are satisfied:
- a. Risks to subjects are minimized: (i) by using procedures which 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
 - b. 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. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research. The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.
 - c. Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research, and the setting in which the research will be conducted. The IRB should be particularly cognizant of the special problems of research involving populations such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons. For research involving children and prisoners, the IRB ensures all special provisions detailed in 45 CFR 46.107
 - d. Informed consent shall be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by 45 CFR 46.116.

The following information will be provided to each subject:

- A statement that the study involves research, an explanation of the purposes of the research the expected duration of the subject's participation, a description of the procedures to be followed and identification of any procedures which are experimental;
- A description of any reasonably foreseeable risks or discomforts to the subject;

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- A description of any benefits to the subject or to others which may reasonably be expected from the research;
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
- A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
- For research involving more than minimal risk, an explanation as to whether any compensation and/or medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
- Any financial contributions made to the research team or College.
- An explanation of who to contact for answers to pertinent questions about the research and research subjects' rights and whom to contact in the event of a research-related injury to the subject; and
- A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits, to which the subject is otherwise entitled.

When appropriate, one or more of the following elements of information shall also be provided to each subject:

- A statement that the treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;
- Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
- Any additional costs to the subject that may result from participation in the research;
- The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
- A statement that significant new findings developed during the research which may relate to the subject's willingness to continue participation will be provided to the subject; and
- The approximate number of subjects involved in the study.
- IRB may approve a consent procedure that does not include or alters some

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or all of the elements of informed consent set forth in this section. The IRB may waive the requirements to obtain informed consent, provided the IRB finds and documents that:

- e. Informed consent will be appropriately documented in accordance with and to the extent required by 45 CFR 46.117. The consent form will include the elements of informed consent stated above. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator should give either the subject or the representative adequate opportunity to read the document before it is signed.

An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects, if it finds either:

1. That the only record linking the subject and the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality or
2. That the research presents no more than minimal risk of harm to subjects, and involves no procedures, for which written consent is normally required outside of the research context.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research. The rationale for approving a partial or full waiver of informed consent. The IRB will issue the primary researcher a “waiver granted” approval notification to document the waiver of consent.

- f. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects. A general description of the data and safety-monitoring plan shall be submitted to the IRB as part of the research proposal. The plan must include procedures for reporting adverse events.
- g. When appropriate, the research study provides adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data. Information contained in medical records (patient charts) is privileged and cannot be accessed for research purposes except with IRB approval. Research protocols that include the medical record must also specify what procedures will be used to ensure confidentiality of the information abstracted from the record.
- h. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, (i.e. children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons), additional safeguards have been included in the study to protect the rights and welfare of these subjects.

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- i. Prisoners: All research involving prisoners or other legally restricted persons must comply with the additional protections outlined in 45 CFR 46, Subpart C.
- ii. Children: All research involving children are provided additional protections as outlined under Subpart D of 45 CFR 46 or 21 CFR 50. Children are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.

Cognitively Impaired Subjects: When the subject's ability to give consent to participate in research presents ethical challenges, investigators should make provisions for subject assent when the subject is able to express assent. The IRB shall follow the recommendations in 45 CFR 46.111(b) to provide safeguards appropriately to the study. Research involving cognitively impaired subjects is automatically referred to the full IRB for review.

V. IRB Record Keeping and Required Documentation.

A. IRB Records. Federal regulations require that the IRB retain records for at least three (3) years after the completion of the research. All IRB records shall be kept in a password protected database and/or in a secure locked place. Access to IRB records shall be limited to the Chairperson of the IRB, the administrative staff of the IRB, the IRB members, officials of federal and state agencies, sponsors and individuals designated by the College to audit research records.

1. IRB records will include the following:
 - a. IRB Standard Operating Procedures.
 - b. IRB membership roster.
 - c. Record of certification of education of investigators, IRB members and other individuals involved in the protection of human subjects.
 - d. Correspondence (not protocol related) between the IRB and the investigators.
 - e. IRB research application files including the protocol, investigator brochure, requests for waiver of informed consent or signed consent, annual enrollment form, Unanticipated Problems Adverse Event Reports, advertisements, conflict of interest forms and protocol-related correspondence.
 - f. Minutes of the convened IRB meetings including documentation of full Committee new and continuation applications, expedited projects, final reports, terminated projects and summary discussions.

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- B. Membership Roster. The IRB Administrator shall ensure that a current IRB membership roster is maintained. Membership rosters shall include the following:
- a. Names of IRB members.
 - b. Names of alternative members and the corresponding regular member for whom the alternate may serve.
 - c. Earned degrees of each member and alternate.
 - d. Indication of experience and qualifications of each member, scientific or non-scientific.
 - e. Relationship of each member with the College (i.e., full-time, part-time, non-affiliated).
 - f. Representative capacity of each member and alternate.
- C. Education and Training Record. The IRB Administrator will maintain records of all IRB staff, IRB members, investigators, administrators and other individuals who have fulfilled the human subject protection training requirements.
- D. Documentation of Exemptions. Research protocols that may be eligible for exemption must be submitted along with a Request for Exemption from IRB Review Form and must indicate the criteria for exemption. The basis for exemption must satisfy the federal regulations set forth the types of research that may be exempt from IRB review (45 CFR 46.101(b)(1-6) listed in Appendix C. Documentation of such exemption must be maintained in the IRB records.
- E. Documentation of Expedited Review. Documentation for expedited review and approval will consist of the IRB Chairperson's written concurrence in the IRB research application file that the research described in the application satisfies the conditions set forth in 45 CFR 46.110 or 21 CFR 56.110 and listed in Appendix B. All projects that are granted approval, including partial or full waivers of documentation of informed consent, by expedited review will be included in the agenda and minutes of the next convened meeting.
- F. Documentation of Convened IRB Meetings. The minutes of IRB meetings shall be compiled by the IRB Administrator and approved by the IRB Chairperson. The following specific information shall be included in the minutes:
- a. Attendance by name, absent members, alternate members and the name of the person for whom they are the alternate, consultants, invited investigators and guests.

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- b. Quorum requirements.
 - c. Actions taken by the IRB on new and continuation applications; review of protocol and informed consent modifications or amendments; unanticipated problems involving risks to subjects or others; adverse event reports; reports from sponsors; waiver or alteration of elements of informed consent; suspensions or terminations of research; and other actions.
 - d. Votes on these actions categorized as “for, against, abstain, and absent.”
 - e. The basis for requiring changes in or disapproving research.
 - f. Required findings and determinations.
 - g. A list of research approved since the last meeting utilizing expedited review procedures and specific citation for the category of expedited review of the individual protocol.
 - h. Members who absented themselves by name and name of protocol.
- G. Actions Taken by Convened Meeting. IRB minutes will include all actions taken by the convened IRB and the votes that underlie those actions (45 CFR 46.115(a)(2) or 21 CFR 56.115). These actions will be provided to investigators within ten (10) days after the convened meeting at which the specific research application was discussed. IRB actions for initial or continuing review of research will include the following:
- 1. Approved with no changes or no additional changes. The research may proceed.
 - 2. Approved pending administrative review Minor changes that are clearly delineated by the IRB so the investigator may simply concur with the IRB's revisions. The research may proceed **after** the required changes are verified by the IRB Administrator.
 - 3. Tabled. Tabled research applications are approvable but require substantive changes or additional substantive information that must be reviewed at a subsequent convened meeting of the IRB. The research may proceed only **after** the convened IRB meeting has reviewed and approved the required changes to the research or the information provided.
 - 4. Disapproved. The IRB has determined that the research cannot be conducted by the investigator(s) at the College. If the IRB disapproves a research activity, it shall include in its written notification a statement of the reasons for its decision and afford the investigator an opportunity to respond in person or in writing.

VI. Additional Considerations.

- A. Certificates of Confidentiality. The IRB may determine that special protections are needed to protect subjects from the risks of investigative or judicial processes in research projects that include the collection of highly sensitive information about individually identifiable subjects necessary to achieve the research objectives. Research will be considered sensitive if it involves the collection of information in any of the following categories:
- Information relating to sexual attitudes, preferences or practices;
 - Information relating to the use of alcohol, drugs or other addictive products;
 - Information relating to illegal conduct;
 - Information that if released could reasonably be damaging to an individual's financial standing, employability or reputation within the community;
 - Information that would normally be recorded in a patient's medical record and the disclosure of which could reasonably lead to social stigmatization or discrimination;
 - Information pertaining to an individual's psychological well-being or mental health.

For such sensitive information the IRB may require that the investigator obtain a Certificate of Confidentiality from the Department of Health and Human Services. Federal funding is not a prerequisite to such a determination that a Certificate of Confidentiality is necessary. The purpose of the Certificate of Confidentiality is to protect against any involuntary release of sensitive information about individual subjects for use in federal, state or local civil, criminal, administrative or other legal proceedings. The Certificate does not prohibit the disclosure of information by an investigator including, but not limited to, child abuse or a communicable disease. The investigator must detail in the informed consent document what information will and will not be protected by the Certificate of Confidentiality.

- B. Amendments. A research protocol must be carried out as approved by the IRB. Any changes in the protocol, including but not limited to, changes in subject population, recruitment activities, advertisement material, study procedures, or research personnel must be approved by the IRB *prior to* implementation. If the request involves a change to the protocol and/or Consent Form, the revised documents or pages must be submitted with the changes highlighted (or using Tracked Changes). All new documents which are part of the request must be submitted as well. Minor changes can be reviewed and approved by the IRB administrator and discussed at the full IRB meeting. Major changes to research approved at a convened IRB meeting require full IRB discussion and action at a meeting.
- C. Reporting Suspected Unexpected Serious Adverse Reactions. Federal regulations 21 CFR 46.108(b)(1) and 45 CFR 46.103(b)(5) requires that the IRB follow written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and the department or agency head of (1) any unanticipated problems involving risks to subjects or others; (2) any serious or continuing noncompliance

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with the regulations or the requirements or determinations of the IRB; and (3) any suspension or termination of IRB approval.

Any adverse event involving subjects enrolled at the College must be reported to the IRB as soon as possible, but no later than five (5) days after the event's occurrence. Adverse events occurring at other study sites must be reported to the College IRB within 30 days if, in the opinion of the principal investigator, the event is (1) unexpected; (2) related or possibly related to participation in the research; and (3) suggests that the research places subjects or others at a greater risk of physical or psychological harm than was previously known or recognized. The Mentor IRB system has a module for reporting adverse events and reports made via telephone or email are referred to the module for formal documentation purposes.

All unanticipated problems reported to the IRB should indicate why the event is unanticipated and why it places subjects or others at a greater risk of physical or psychological harm than was previously known or recognized. The Director of the Office of Sponsored Programs (OSP) will, upon recommendation by the IRB, report serious adverse events to the Office of Risk Management and the Provost. Investigators will report such adverse event to the relevant sponsor program officer with a copy of the report to both OSP and the IRB office.

The IRB Administrator, Chair, and the OSP Director will conduct inquiries into serious or continuing noncompliance with the regulations and/or IRB determinations. If the initial inquiry determines further investigation is warranted, the research will be suspended and the matter will be referred to the Provost for a formal investigation under the terms of the College's Research Misconduct policy. The OSP Director will inform sponsors and or OHRP (for PHS-funded research) of the suspension and the formal investigation, as well as findings, terminations and/or corrective measures taken at the investigation's close.

- E. Protocol Deviation: A protocol deviation is a minor or administrative departure from the study design or procedures of a research protocol that has not been approved by the IRB and which DOES NOT have a major impact on the subject's rights, safety or well-being, or the completeness, accuracy and reliability of the study data. The deviation should be reported to the IRB in a timely fashion. The investigator will also include what will be done to prevent reoccurrence, a type of corrective action plan.
- F. Protocol Violation: A protocol violation is defined as non-compliance with the study protocol and/or procedures that may impact study participant safety, the integrity of study data and/or study participant willingness to participate in the study. Protocol violations require prompt reporting, but no later than 5 days after the deviation. The investigator will also include what will be done to prevent reoccurrence, a type of corrective action plan.

APPENDIX A

PROTOCOL SUBMISSION REQUIREMENTS

1. **INITIAL REVIEW**

The following templates must be completed and uploaded to Mentor for all initial submission:

1. Documentation of training in the protection of human research subjects, completed within the last three (3) years.
2. New Study Application for Research Involving Human Subjects (i.e., IRB Protocol Application).
3. If applicable, an Informed Consent Form (for adults competent to consent), Parental Permission form, and/or Assent form (for minors).
4. Copies of all data collection tools, questionnaires, interview/survey forms, assessment materials, and descriptions of materials that subjects will encounter.
5. If applicable, advertisement(s), scripts, and postings for subject recruitment.
6. If applicable, a site permission form granting the researcher access to the site.
7. If applicable, a non-disclosure agreement, for a hired transcriptionist.
8. If applicable, a protocol giving a complete description of the proposed research in technical language
9. If applicable, a data sharing agreement describing the relationship between institutions and researchers.

B. **CONTINUING REVIEW**

Requests for continuing reviews must be completed and submitted for IRB approval prior to the expiration date. Please remember to allow sufficient time for approval at a convened IRB meeting (or expedited approval process if applicable) prior to the expiration date. The following information must be included:

1. A completed Continuing Review/Termination of Research Involving Human Subjects Form
2. Copy of two most recently signed Informed Consent Form (or Parental Permission form or Assent form). If the study was online, the researcher should indicate this case in his/her continuing review.
3. For research approved under the January 2019 New Common rule where continuing review IS NOT required, there will be an annual check in that lists the number of subjects enrolled, indicates what stage the research is at (recruitment, data collection, analysis, etc.) and also provides two recently signed consent/assent forms.

C. **TERMINATION**

The following information must be submitted for a termination/closure request

1. A completed Continuing Review of Research Involving Human Subjects Form
2. A protocol progress report/summary, if applicable

APPENDIX B

GUIDELINES FOR EXPEDITED REVIEW

Federal regulations permit the IRB Chairperson to review and approve proposed research through an expedited review process if (a.) the research constitutes a minor change in a previously approved research project during an approved period; or (b) the research is not greater than minimal risk and falls into one of the categories listed below. 45 CFR 46.110 or 21 CFR 56.110.

The expedited review procedure may not be used if the risks related to invasion of privacy and breach of confidentiality are not greater than minimal.

Research Categories

- (1) Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
 - (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
 - (b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
- (2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
 - (a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
 - (b) from other adults and children² considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.
- (3) Prospective collection of biological specimens for research purposes by noninvasive means.

Examples: (a) Hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or

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stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

- (4) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

Examples: (a) Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

- (5) Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)
- (6) Collection of data from voice, video, digital, or image recordings made for research purposes.
- (7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects 45 CFR 46.101 (b)(2) and (b)(3). This listing refers only to research that is not exempt.)

- (8) Continuing review of research previously approved by the convened IRB as follows:

(a) Where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or

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- (b) Where no subjects have been enrolled and no additional risks have been identified; or
 - (c) Where the remaining research activities are limited to data analysis.
- (9) Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

Such review and approval shall be reported at the next convened IRB meeting. The IRB members will be given an opportunity to review or comment on any project approved by expedited review. If the Chairperson decides that a project should not be approved by expedited review, the project will be reviewed at the next convened meeting using the standard practices for new and continuation applications.

APPENDIX C

CRITERIA FOR EXEMPTION FROM IRB REVIEW

Certain research activities may be exempt from review, if approved by the IRB Chair and confirmed in writing to the Principal Investigator. Research may be exempt from review when the only involvement of human subjects in the research falls into one of the following categories:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. 45 CFR 46.101(b)(1)
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation. 45 CFR 46.101(b)(2)
3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not otherwise exempt if: (i) The human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter. 45 CFR 46.101(b)(3)
4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. 45 CFR 46.101(b)(4)
5. Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs. 45 CFR 46.101(b)(5)
6. Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture. 45 CFR 46.101(b)(6)