SKIDMORE COLLEGE

INSTITUTIONAL REVIEW BOARD

POLICIES AND PROCEDURES MANUAL

Updated September 2025

1. Introduction

The Skidmore College Institutional Review Board (IRB) is an appropriately constituted administrative body established to protect the rights and welfare of human subjects recruited to participate in research activities. In accordance with Skidmore College policy governing the use of human subjects in research and the Federalwide Assurance (FWA) for the Protection of Human Subjects (FWA00007297) maintained with the Department of Health and Human Services (DHHS), Office for Human Research Protections (OHRP), all research involving human subjects conducted by or under the auspices of Skidmore College will be performed in accordance with Title 45 Code of Federal Regulations, Part 46 (herein referred to as 45 CFR Part 46). In addition, the actions of the College's IRB will conform to all applicable federal, state and local laws and regulations.

In connection with research conducted or proposed to be conducted on human subjects the Skidmore IRB performs critical oversight functions to ensure applicable scientific, ethical, and regulatory standards are met. The IRB reviews and monitors biomedical and behavioral research conducted by Skidmore faculty, staff and students. It is charged with the responsibility and authority of reviewing research study proposals and granting approval, denying approval or granting approval subject to modifications or conditions for those proposals; requiring the cessation of unapproved or non-compliant research; periodically monitoring the progress of long-term records; and restricting research activities involving human subjects. The IRB is responsible for establishing and administering College policies and procedures related to the implementation of or compliance with federal, state and local regulations that govern the protection of individuals participating in research.

1.1 Applicability

All research involving the collection of information, data or biospecimens from or about human subjects or information, data, biospecimens gathered from humans at some prior time either by the researchers themselves or someone else, must be reviewed and approved by the IRB prior to such studies being undertaken. This policy applies to any research whether new, ongoing, or proposed, regardless of funding status and source, whether conducted at Skidmore College or elsewhere, even if approved by an IRB of another institution of higher education or other entity, by anyone affiliated with the College (i.e., faculty, staff, student). In addition, any investigator from outside Skidmore College that wishes to perform research on members of the Skidmore community or on the Skidmore campus must have a Skidmore faculty or staff member serve as sponsor or co-investigator.

The terms of the Skidmore College FWA (but not necessarily all of the policies and procedures in this manual) apply to all subcontractors and non-Skidmore collaborators of research conducted by Skidmore faculty, staff and students. The Skidmore College Principal Investigator (PI) is responsible for ensuring that appropriate human subjects protections are in place at any collaborating institution and notifying the IRB of any deficiencies or noncompliance.

2. Statement of Principles

Skidmore College is committed to the pursuit of excellence in teaching, research, and public service. Concomitantly, the College seeks to protect the welfare of every person who may be

involved in research and training projects. Members of the College community, while upholding the highest standards of freedom of inquiry and communication, accept the responsibility this freedom offers: for competence, for objectivity, for consideration of the best interests of the College and society, and for the welfare of every subject in a project. The College gives assurance that it will comply with the Common Rule in accordance with the guidance set forth by the OHRP of DHHS.

The following principles are affirmed and should be interpreted in the broad context provided by the code of medical and general ethics promulgated by the World Medical Association as the Declaration of Helsinki, by the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research known as the Belmont Report, and for funded research, any additional human subjects regulations and policies of the supporting department or agency.

1. The basic ethical principles set forth in the Belmont Report: “respect for persons, beneficence, and justice”, underlie the requirements for the ethical conduct of research involving human subjects at Skidmore College. “Respect for persons” involves recognition of the personal dignity and autonomy of individuals, and special protection of those persons with diminished autonomy. “Beneficence” entails an obligation to protect persons from harm by maximizing anticipated benefits and minimizing possible risks of harm. “Justice” requires that the benefits and burdens of research be distributed fairly.

2. Because the participation of humans in research and training projects may raise fundamental ethical and civil rights issues, no distinctions in the monitoring of projects will be drawn between funded and unfunded projects, sponsored and unsponsored projects, or between projects carried out by students, faculty, or other College employees, on-campus or off-campus.

3. All activities involving human subjects must provide for the safety, health, and welfare of every individual. Rights, including the right of privacy, must not be infringed.

4. The anticipated benefits to the subject or the importance of the knowledge gained must outweigh the risks to the individual inherent in the proposed research.

5. Participation in projects must be voluntary, and informed consent must be obtained from all participants, unless this requirement is specifically waived by the IRB. Methods that are in accordance with the requirements of 45 CFR §46.116 and 45 CFR §46.117 and appropriate to the risks of the project must be used to obtain the participants' informed consent.

6. When required, consent must be obtained from the participants themselves whenever possible. Further, if a subject is not legally or physically capable of giving fully informed consent, consent on that subject’s behalf must be obtained from a legally authorized representative of the subject. Careful consideration shall be given to the representative's depth of interest and concern with the subject's rights and welfare. Representatives, for example, may not expose their child to more than minimal risk except for the child's direct benefit.

7. An individual does not abdicate any rights by consenting to be a research subject. A subject has the right to withdraw from a research project at any time or to refuse to participate,

without loss of benefits to which the subject would otherwise be entitled. Further, a subject has the right to receive appropriate professional care, to enjoy privacy and confidentiality in the use of personal information, and to be free from undue physical risk, embarrassment, discomfort, anxiety, and harassment. These rights need to be clearly defined during the informed consent process for all potential participants.

8. The potential for a conflict of interest or coercion exists in an academic setting where participants in research studies are also students in a course taught at the College or by an investigator connected with the research study. The Principal Investigator ("PI") is responsible for avoiding such conflicts and coercion in recruiting participants.

9. Safeguarding information about an individual that has been obtained in the course of an investigation is a primary obligation of the PI. Investigators should detail to the IRB what security measures will be taken to ensure that privacy will be maintained. Records containing personal information shall be destroyed as soon as possible in keeping with the long-range goals of the project. Specific subject information shall not be communicated to others unless one of the following conditions is met:

    a. Explicit permission for the release of identifying data is given by the individual.

    b. Information about an individual is discussed only for professional purposes and only with persons directly involved in the research project. Written and oral reports should present only data germane to the purposes of the project, and every effort should be made to avoid a breach of confidentiality.

    c. The investigator is legally required to provide such information (e.g., child abuse, sexual abuse, or other illegal activities revealed by a subject).

10. An individual involved in the conduct or supervision of a specific project shall not participate in the IRB review of that project, except to provide information to the IRB.

3. Purpose of IRB Review of Proposed Research Studies

The purpose of the IRB review is to ensure, both in advance and by periodic monitoring, that appropriate steps are taken to protect the rights and welfare of human subjects according to federal guidelines. To accomplish this process, the IRB uses a deliberation process to review and approve research protocols and related material (e.g., informed consent documents, recruitment materials, survey instruments, questionnaires, etc.). The focus of the process is to ensure that:

1. The risks to human subjects are minimized by using procedures that are consistent with sound research design and that do not unnecessarily expose the research participants to risk.

2. The risks to human subjects are reasonable in relation to the anticipated benefits (if any) to the individual, and the importance of the knowledge that may be expected to result.

    a. For the purpose of IRB consideration, "risk" is defined as the probability of harm or discomfort (physical, psychological, social, economic or legal) occurring as a result of participation in a research study. In evaluating risk, the IRB is to consider the conditions

that make the situation dangerous, per se (i.e., as opposed to those chances that specific individuals are willing to undertake for some desired goals).

b. For the purpose of IRB consideration, "benefit" is defined as a valued or desired outcome enjoyed by the subject (therapeutic benefit), or accruing to a group under study, or to their family members, or to scientific knowledge (nontherapeutic benefit).

c. In evaluating risks and benefits, the IRB considers only those risks and benefits that may result from the research.

3. The selection of human subjects for research projects is equitable (i.e., selection criteria should be both fair and appropriate to the research question).

4. Human research subjects are adequately informed of the risks and benefits of research participation and the procedures that will be involved in the research; and that informed consent is obtained from each prospective human subject, or his/her legally authorized representative, in accordance with, and to the extent required by federal regulations and this IRB Policy and Procedures Manual.

5. The research plan, when appropriate, makes adequate provision for monitoring the data collected to ensure the safety of the human subject.

6. There are adequate provisions to protect the privacy of human research subjects and to maintain the confidentiality of research data.

Appropriate additional safeguards may be included in the research study to protect the rights and welfare of human research subjects who are likely to be vulnerable to coercion or undue influence (e.g., children, prisoners, individuals with impaired decision-making ability, or economically or educationally disadvantaged persons).

4. Types of IRB Review of Proposed Research Studies

The review and approval by the IRB of all research activities involving human subjects that fall within its jurisdiction is a prerequisite to the implementation of such research activities. There are four categories of IRB review of proposed studies (additional information regarding categories can be found at https://www.skidmore.edu/irb/documents/RevisedExemptions45CFR46.pdf):

4.1 Exempt research
4.2 Limited review
4.3 Expedited review
4.4 Full-Board review

4.1 Exempt Research

Human subjects research that is classified as exempt means that the research qualifies as minimal risk to participants and is exempt from most of the requirements of the Federal Policy for the Protection of Human Subjects, but is still considered research requiring an IRB review for an exemption determination. The IRB Chair will determine whether research is exempt from review by the IRB, which will be confirmed in writing to the Principal Investigator. If a research study

falls into one of the exempt categories below, researchers still have ethical responsibilities to protect participants' rights.

Exempt Research Categories

Exempt Category 1 - Educational Practices
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.

This category does not apply to surveys, interviews, questionnaires, or focus groups which are covered under Exempt Category 2. The study cannot adversely impact the students' opportunity to learn required curriculum. Examples include:

- A study comparing two curricula being implemented at a school with observation and analysis of class evaluations.
- A study about professional development workshops.
- A study evaluating the effectiveness of a commonly accepted math curriculum.

Exempt Category 2 - Educational Tests, Interviews, Surveys, Observation of Public Behavior
Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior, if at least one of the following criteria is met:

i. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to them;

ii. Any disclosure of the human subject's responses outside the research would not reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, educational advancement or reputation; or

iii. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review for provisions for protecting privacy and maintaining confidentiality required by 46.111(a)(7).

This category does not apply to interviews or surveys with minors. This category only applies to observation of public behavior involving children if the study team does not participate in the activities being observed. Observations must be of public behavior in a public setting (i.e., park, intersection, parking lot, lobby, etc.). Examples include:

- An observational study of a pedestrian street crossing where the researcher takes notes of age, gender, clothing of pedestrians.
- A focus group involving college students and their STEM experiences.

- An online anonymous survey studying various types of social media use.

Exempt Category 3 - Benign Behavioral Interventions with Adults
Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written response or audiovisual recording if the subject prospectively agrees to intervention and information collection and at least one of the following criteria is met:

i. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to them;

ii. Any disclosure of the human subject's responses outside the research would not reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, educational advancement or reputation; or

iii. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the participants, and an IRB conducts a limited IRB review for provisions for protecting privacy and maintaining confidentiality required by 46.111(a)(7).

This category does not include minors. Benign behavioral interventions must be brief in duration, harmless, painless and not physically invasive and there is no reason to think the interventions will be offensive or embarrassing. Interventions should not have a last significant adverse impact on the participants. Research involving deception is allowed if the participant is prospectively informed, and agrees to, that they will be unaware of, or misled regarding the nature or purpose of the research. Examples include:

- A random assignment of participants to take a test under various noise conditions.
- A study involving randomly assigning participants to various experimental conditions where they decide how to allocate cash between themselves and others.

Exempt Category 4 - Secondary Uses of Identifiable Private Information or Identifiable Biospecimens
Secondary research for which consent is not required if at least one of the following criteria is met:

i. The identifiable private information or identifiable biospecimens are publicly available;

ii. Information is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the participants, and the investigator will not re-identify participants;

iii. The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR §164.501 or for "public health activities and purposes" as described under 45 CFR §164.512(b); or

iv. The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with applicable federal privacy standards found in the E-Government Act, Privacy Act and the Paperwork Reduction Act.

The data and/or biospecimens have been or will be collected for purposes unrelated to the proposed study (e.g. "secondary" analysis). Biospecimens can only be included in "i" above. However, a "no human subjects" determination can be made for studies involving biospecimens if criteria are met. Note that as of January 22, 2019, it is no longer a requirement that all data/biospecimens be retrospective (previously collected as of the date the protocol is submitted). Examples include:

- A study involving secondary research of audio archives in a public library.
- An analysis of biospecimens from an IRB-approved biorepository.
- A study involving review of national census data that contains zip codes.

Exempt Category 5 - Public Service Projects
Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads and that are designed to study, evaluate, improve, or otherwise examine:

i. public health 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.

This category is rarely applicable to research at Skidmore College.

Exempt Category 6 - Taste and Food Quality Evaluation and Consumer Acceptance Studies
Taste and food-quality evaluation and consumer acceptance studies, if:

i. wholesome foods without additives are consumed; or

ii. 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.

These exemptions do not apply to research involving prisoners. Further, the exemption in "ii" above does not apply to children, except in research involving educational tests or the observations of public behavior when the researcher(s) do not participate in the activities being observed.

4.2 Limited Review
For certain research exemptions listed in section 5.1 of this policy, the IRB Chair or other designated voting member of the IRB must conduct a limited review in order to determine that there are adequate provisions to protect privacy of subjects and to maintain confidentiality of data (see 46.111(a)(7)). Specifically:

- Limited Review is required for **Exemption 2iii** and **Exemption 3(C*)*** - when sensitive identifiable data are collected to ensure that adequate protections are in place to protect subject privacy and the confidentiality of data.

- This means that the IRB must review and approve procedures for data management and security where sensitive information is collected with **direct identifiers** (e.g., name, address, email, phone number, social security number, student ID, patient ID) OR **indirect identifiers**, such as a code that can link back to a subject, or data elements that could be combined to readily re-identify a subject (e.g., dates, employment history, etc.).

4.3 Expedited Review
For certain kinds of research involving no more than minimal risk as authorized by 45 CFR §46.110, for minor changes in approved research, and for research which limited IRB review is a condition of exemption, federal regulations permit the IRB Chair or a designated voting member or group of voting members to review and approve the proposed research through an expedited procedure if it meets the guidelines and falls into one of the categories outlined below. Such review and approval shall be reported at the next convened IRB meeting. If the IRB Chair 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.

Expedited 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 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 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 children 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 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 non-research 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 §46.104(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 §46.104 (b)(2) and (b)(3). This listing

refers only to research that is not exempt.)

4.4 Full Board Review
Human subjects research that is not exempt or eligible for expedited review must be reviewed at a convened meeting of the IRB. When full board review is necessary, the research proposal is presented and discussed and voted upon at a meeting at which a quorum of IRB members is present. For the research to be approved, it must receive the approval of a majority of those voting members present. (Note that, in effect, an abstention counts as a negative vote.)
A research proposal that includes a vulnerable subject, or population, of research subject(s) requires a full board review. However, while the use of minors in research usually requires a full board review, expedited review is allowed in research that would otherwise be considered exempt if not for the inclusion of minors as research participants.

5. 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)).

The IRB is directed by a Chair, and is comprised of members with multidisciplinary expertise and backgrounds as required by federal policy. The IRB determines the role and responsibilities of its members and researchers in human subject protection. If appropriate, the IRB reports all violations of guidelines and regulations to the Research Integrity Officer. The IRB provides the Dean of the Faculty with an annual report of its activities and recommendations for IRB membership the following year. A current list of the IRB members is posted on the IRB website (https://www.skidmore.edu/irb/members.php).

The IRB has an IRB administrator, whose 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, preparing and distributing materials for meetings, and taking minutes). The IRB administrator reports to the Director of Sponsored Research and works closely with the IRB Chair and members.

1. Appointment of IRB Chair, Length of Service and Duties. The Dean of the Faculty shall appoint the IRB Chair. The Chair shall serve a term of two (2) years and may be reappointed for additional one-year terms. In addition to the responsibilities of IRB membership, the Chair 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 Chair works with IRB members, College officials, and investigators to ensure that the rights and welfare of research participants are adequately protected. As a fair and impartial committee head, the Chair functions as a role model for how IRB business should be conducted. The Chair shall sign all official IRB correspondence, unless otherwise indicated, and shall report directly to the Dean of the Faculty.

2. Appointment of IRB Members, Length of Service, and Duties. The Dean of the Faculty, with input from the IRB Chair and members, 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 participants are protected. Members vote to approve, approve pending revisions, require modifications in, or deny approval. Members are expected to attend IRB meetings on a regular basis and serve as general reviewers on all research discussed at convened meetings.

3. Associate Members. The IRB may include Associate Members who are former IRB members appointed to review exempt and expedited protocols as assigned by the IRB Chair. Associate Members do not serve as voting members, do not count toward the quorum requirement, and do not attend regular IRB meetings. The Dean of the Faculty, with input from the IRB Chair, shall appoint Associate Members who serve two-year renewable terms.

4. Non-Voting Members. The IRB may choose to designate certain individuals to attend IRB meetings on a regular basis as ex-officio members. The Director of Sponsored Research may also sit on the IRB as a non-voting ex officio member.

5. 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.

6. IRB Membership Requirements. In compliance with federal regulations, the College's IRB must satisfy the following requirements:

   a) The IRB shall have at least 5 members.

   b) 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.

   c) 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.

   d) The IRB shall consist of qualified persons of both genders.

   e) The IRB will not consist entirely of members of one profession.

   f) The IRB shall have at least one (1) member whose primary concerns are in non-scientific areas.

   g) 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.

7. Changes in IRB Membership. Changes in IRB membership shall be reported to the Chair

within 90 days.

8. 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 Chair, 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 advisor).

   Former IRB members and other qualified faculty and staff may be appointed to serve as ad hoc members of the IRB in order to review and vote on protocols submitted by current IRB members if there are not at least 5 regular eligible IRB members to review the submission.

9. Initial Training and Continuing Education of IRB Members. The terms of the College's Assurance specify that the College is required to ensure that IRB members are provided education about human subject protections. All members must take the CITI Training. 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 this manual to review research from an ethical and regulatory perspective, copies of all templates used to submit studies, the Belmont Report, and copies of 45 CFR §46.

6. IRB Operations

6.1 Protocol Submission

All human subject research proposals affiliated with the College, even if previously approved at another institution, must be submitted to Skidmore's IRB prior to the start of the research project (including, without limitation, the collection of any subject data). All research studies involving human subjects should be submitted to the IRB through the College's IRB electronic protocol management system. Instructions on how to submit documents are available on the Skidmore IRB website along with templates of forms required. The IRB will determine the category of review. Researchers cannot exempt from review their own research study for which they are responsible. Similarly, individuals involved in the conduct and/or supervision of a research project cannot participate in its review, except to provide information to the IRB.

All documents submitted to the IRB for review must be in final format, using standard templates, where applicable. Researchers may not begin recruitment or research activities until they receive a final IRB approval letter on Skidmore College letterhead. Consent forms must also contain an official IRB authorization stamp only after final approval. Copies of the official IRB authorized stamped consent form and supporting documents must be used for research work. All forms of advertising or dissemination of information for recruitment of participants into a research protocol must be approved by the IRB prior to distribution or publication of the material. Research proposals that include research and/or recruitment conducted at a site other than Skidmore must

include a signed letter or email from the person authorized to give permission on behalf of the institution, with enough information to demonstrate that the institution understands the proposed research, granting permission for research and recruitment to be conducted at the institution.)

6.2 Review Schedule
Convened Meetings of the IRB are held approximately every two weeks during the fall and spring semesters.

The expected review duration is based on the review type required for the submitted research proposal by the IRB:

a) Exempt proposals – a minimum of one week; exempt protocols are reviewed on a rolling basis (i.e., first come, first served)

b) Expedited and limited review proposals – a minimum of two weeks; expedited protocols are reviewed on a rolling basis (i.e., first come, first served)

c) Full-Board proposals – must be electronically submitted to the IRB a minimum of 10 days prior to the next occurring scheduled IRB meeting. Duration of the review process will vary according to the specifics of the research proposal.

Regardless of the type of review, the investigator will be notified in writing of the IRB's determination.

Meetings are not held during the summer term. From June 1 until the beginning of fall semester, the IRB operates under limited capacity and will not review any new protocols. During this period, the IRB will only review and approve amendment requests related to personnel changes. The IRB will announce relevant submission deadlines in advance of the summer period each year and researchers are encouraged to plan the timing of their submissions accordingly.

6.3 Review Process
A quorum of the members of the IRB, including at least one member whose primary concerns are in non-scientific areas, must be present at a meeting in order to conduct business. Members may be present in person, by audio (telephone), or by interactive teleconference (Zoom). Members present via audio or teleconference shall be noted as such in the meeting minutes.

The PI may attend the IRB meeting held to consider the PI’s proposal. Even if the consensus of the IRB is favorable, the IRB may elect to impose additional restrictions or recommendations under which the study shall be conducted.

Any member requesting revisions to a protocol may authorize the Chair of the IRB to request such changes, with or without requiring that they personally approve the revisions prior to the issuance of the approval letter. That member may also call for a meeting of the full IRB to review the changes.

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 revisions. 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 made and verified by the IRB Chair.

3. Revise and Resubmit. The research is approvable but requires 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. Denied. The IRB has determined that the research cannot be conducted by the investigator(s) at the College. If the IRB denies a research activity, it shall include in its written notification a statement of the reasons for its decision

IRB actions will be provided to investigators within ten (10) days after the convened meeting at which the specific research application was discussed.

Final approval by the IRB shall require a two-thirds vote by members present. If the IRB agrees that the proposed research protects human subjects in accordance with established standards, its conclusion shall constitute certification of approval. A letter of approval will be sent to the Principal Investigator (PI). A copy of the letter of approval will be maintained by the IRB.

The IRB does not provide retroactive approval for research studies.

Protocols that remain in “Approved pending revisions” or “Revise and Resubmit” status because the investigator has not resubmitted the protocol for more than 90 days will be administratively withdrawn by the IRB. Principal investigators will receive a notification at the 60-day mark, providing them with 30 additional days to submit their revised protocol before administrative withdrawal occurs. If a protocol is administratively withdrawn, investigators wishing to pursue that research must submit a completely new protocol application through the standard submission process.

6.4 Study Closure

All principal investigators are required to notify the IRB when their research activities have concluded. As stated in all approval letters, the online Study Closure and Update Form (available as a link from the IRB website) must be submitted within 30 days of the termination of all research involving human subjects conducted under the approved protocol.

All principal investigators with approved protocols are required to provide annual updates on the status of their studies. Each August, principal investigators will receive an email from the IRB reminding them to complete the online Study Closure and Update Form to report on the current status of their research. This requirement applies to all active protocols, regardless of exemption status. Failure to submit the required annual update within 90 days will result in administrative closure of the protocol.

6.5 Continuing Review

The IRB will make a determination at the time of initial review if substantive continuing review of a non-exempt protocol is required and document that determination in the meeting minutes. The

IRB may require continuing review more frequently than annually at the IRB's discretion - for example, due to the nature of the study, degree of uncertainty regarding the risks involved, the vulnerability of the subject population, the inexperience of the investigator, prior noncompliance with the investigator or sponsor, or use of novel therapies. This decision shall be included in writing to the principal investigator. The IRB Chair may, at his/her discretion, audit and/or review research records of individual protocols.

Principal Investigators will receive a notice at least two weeks 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 or terminate the study.

6.6 Protocol 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. All new documents which are part of the request must be submitted as well. Minor changes can be reviewed and approved by the IRB chair 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.

Once accepted, amendments do not change the original expiration date of a research proposal (the original expiration date designated when the research proposal was first approved will remain effective).

6.7 Suspension or Termination of Approved Protocol

The IRB may decide to suspend or terminate approval for a study that is not being conducted in accordance with IRB requirements or that has been associated with unexpected serious harm to the research subjects, including, but not limited to:

1. Inappropriate involvement of human subjects in research
2. Inhibition of the rights or welfare of participants
3. Serious or continuing noncompliance
4. New information regarding increased risk to human participants

When potential cause for further investigation is demonstrated, an inquiry into the specific circumstances giving rise to concern with a specific protocol will be conducted. If a protocol is determined to be in non-compliance or a detrimental change in the risk/benefit ratio occurs, further action will be taken by the IRB. In most instances, the IRB will review the circumstances of the case and make a determination of suspension or need for termination. The Research Integrity Officer (RIO) may be consulted as needed in the decision-making process leading up to bringing the issue to the full board at a convened meeting. In emergency situations, the IRB Chair, in consultation with the RIO (whenever appropriate), will make a determination of the need to suspend or terminate a study immediately.

The IRB Chair will write a report of the event and action that includes the following:

1. A description of the event

2. The determination of the IRB (i.e. suspension, termination)

3. Justification for the determination

4. Requirements for the investigator to follow (e.g. cease all data collection)

The report will be sent to the investigator or faculty advisor (if applicable), department head, RIO, Sponsored Research and any sponsors (if applicable), and applicable federal agencies (e.g. OHRP). A copy of the form will be retained by the IRB.

When a protocol is suspended or terminated, the investigator must stop all activity on the protocol, including subject recruitment and enrollment, procedures, and analysis and/or publication of existing data. When a suspension or termination of a research protocol involving the withdrawal of current participants from the research, the investigator will be required to:

1. Inform the enrolled participants that the study has been suspended or terminated; and

2. Develop procedures for withdrawal that protect the rights, safety, and welfare of participants, and describe those procedures to participants.

To reinstate a project that has been suspended, the investigator must resolve satisfactorily any pending issues as required by the IRB. The investigator must contact the IRB in writing within 60 days of the suspension and address the following requirements in a letter, to be reviewed by the IRB at a convened meeting:

1. Reason for requesting the study to be reinstated.

2. Short summary of the purpose of the study and intended objects/outcomes. This may be incorporated into the protocol, noting any changes, revisions, or clarifications to the protocol.

3. Description of how the study has changed, if applicable, since initial approval.

4. Summary of the status of the study, including:

    a) How many subjects were enrolled and anticipated enrollment;
    b) At what point in the procedures were the subjects at the time of the suspension;
    c) Any adverse events since the last continuing review and how these adverse events will be mitigated in the future;
    d) Any additional relevant information.

5. Documented plan to ensure that the reason for suspension will not occur again and that the study will be in compliance with all applicable laws and regulations.

6. In the case that IRB-approval of a protocol is reinstated, the IRB may require that subjects who were previously enrolled be re-consented.

Terminated studies may be reinstated or reactivated with appropriate modifications to address the reason(s) for why the study was terminated. Investigators must submit a completely new application if they wish to resume a terminated study. Previously terminated studies must be reviewed by the IRB at a convened meeting to ensure risks of harm to the subjects are minimized. When a decision has been made to suspend or terminate approval, the IRB may suspend or terminate approval of the entire research study or just certain research activities and allow the research to go forward without those activities.

6.8 Re-opening a Closed Study

Closed studies may be re-opened up to 12 months after the study has been closed. A memo must be submitted to the IRB Chair explaining why the request is being made, and a continuing review form must be submitted as well. Additionally, if the study has a sponsor, evidence must be provided showing the sponsor agrees that the study may be re-opened. Study activities may not resume until the IRB has approved the re-opening of the study.

6.9 IRB Record Retention

The IRB shall prepare and maintain adequate documentation of IRB activities. 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 IRB Chair, the administration staff of the IRB, IRB members, officials of federal and state agencies, sponsors, and individuals designated by the College to audit research records. IRB records will include the following:

a. Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved consent/assent forms, continuing reviews/annual check-ins submitted by investigators, protocol deviations, and adverse event reports.

b. Minutes of IRB meetings, which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or denying approval for research; and a written summary of the discussion of controverted issues and their resolution.

c. Records of continuing review activities, including the rationale for conducting continuing review of research that otherwise would not require continuing review as described in Section 6.5. above.

d. Copies of all correspondence between the IRB and the investigators.

e. A list of IRB members.

f. Written procedures for the IRB.

g. Record of certification of education of investigators, IRB members, and other individuals involved in the protection of human subjects.

h. Statements of significant new findings provided to participants.

i. The rationale for an expedited reviewer's determination under §46.110(b)(1)(i) that research appearing on the expedited review list described in §46.110(a) is more than minimal risk.

j. Documentation of Exemptions. Documentation for exempt review and approval will consist of the IRB Chair's written notification that the research has been verified as exempt according to 45 CFR §46.104(d). Letters of exemption determination will be maintained in the IRB records. All projects that are determined to be exempt will be included in the agenda and minutes of the next convened meeting.

k. Documentation of Expedited Review. Documentation for expedited review and approval will consist of the IRB Chair's written approval letter that the research described in the application satisfies the conditions set forth in 45 CFR §46.110. 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.

l. 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:

    1. Attendance by name, absent members, alternate members and the name of the person for whom they are the alternate, consultants, invited investigators and guests.

    2. Quorum requirements.

    3. Actions taken by the IRB on new and continuation applications; review of protocol and informed consent modifications or amendments; unanticipated problems involving risks to participants or others; adverse event reports; reports from sponsors; waiver or alteration of elements of informed consent; waiver of documentation of informed consent; suspensions or terminations of research; and other actions.

    4. Votes on these actions categorized as "for, against, abstain, and absent."

    5. The basis for requiring changes in or denying approval for research.

    6. Required findings and determinations.

    7. 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.

    8. Members who absented themselves by name and name of protocol.

7. Criteria for IRB Approval of Research

7.1 General Requirements (45 CFR §46.111)

In order to approve a research proposal, the IRB must determine that protocols are specified in the proposal to meet all of the following requirements:

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

2. Risks to participants are reasonable in relation to anticipated benefits, if any, to participants, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those that may result from the research, as distinguished from risks and benefits of therapies those participants would receive even if not participating.

3. Selection of participants is equitable. The IRB should consider the purposes of the research and the setting in which the research will be conducted and be particularly mindful of the special problems of research involving vulnerable populations. Participants should share equally in foreseeable benefits and risks.

4. Informed consent is sought and obtained from each prospective subject or the subject's legally authorized representative in advance of the subject's involvement in the research in accordance with, and to the extent required by 45 CFR §46.116.
5. Informed consent is appropriately documented or appropriately waived in accordance with, and to the extent required by 45 CFR §46.117.

6. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of participants. 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.

7. When appropriate, there are adequate provisions to protect the privacy of participants 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.

8. When some or all of the participants are likely to be vulnerable to coercion or undue influence (e.g., children, prisoners, pregnant women, fetuses, and neonates, cognitively impaired participants, non-English speaking persons, economically disadvantaged, or educationally disadvantaged persons) additional safeguards are included in the research study to protect the rights and welfare of these participants. (See Section 12 for more details.)

    - Prisoners: All research involving prisoners or other legally restricted persons must comply with the additional protections outlined in 45 CFR §46, Subpart C.

- 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 Participants: 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 participants is automatically referred to the full IRB for review.

7.2 Assessment of Risks and Benefits

When approving research, the IRB must assess whether the anticipated benefit of the research—either new knowledge or improved health for the research participants—justifies inviting anyone to undertake the risks. The IRB should not approve research in which the risks are judged unreasonable in relation to the anticipated benefits. Risks to individuals are classified as physical, psychological, social, legal, and economic. In the process of determining what constitutes a risk, only those risks that may result from the research, as distinguished from those associated with therapies participants would undergo even if not engaged in research, should be considered.

Once risks have been identified, the IRB must assess whether the research poses minimal or greater than minimal risk. Minimal risk is defined such that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests (45 CFR §46.102).

The concept of minimal risk has three purposes. First, the concept guides the IRB to determine if the proposed research should be reviewed by the full board or if it may qualify for expedited review. Second, it is used to determine what research can proceed without consent. Third, the concept is used to decide when documentation of subject consent may be waived.

The IRB must ensure that risks to participants are minimized. Researchers should include strategies for reducing risks in the protocol. For example: precautions, safeguards, and alternatives should be incorporated into the protocol to reduce the probability of harm or to limit its severity or duration. The IRB should determine whether the researchers are competent in the proposed scientific area and whether they serve dual roles (e.g., as clinician and researcher) that may result in conflicts of interest and lead to a "therapeutic misconception" being held by the research subject. The IRB should also assess whether the research design will yield useful data, so that research participants are not exposed to risks without sufficient justification.

The IRB must be notified of any unanticipated problem involving risks to participants or others, including physical or psychological injury to participants, improper disclosure of private information, economic loss, or other potentially harmful occurrences. The PI shall have primary responsibility to provide that notice, but all investigators on a research project shall share the obligation to ensure that the IRB is notified.

8. Additional Considerations

8.1 Research Approved by IRBs at Other Institutions

Every institution that conducts non-exempt human subjects research files a Federalwide Assurance (FWA) with DHHS. The FWA documents the institution's commitment to comply with HHS regulations for the protection of human subjects. An institution's responsibilities under the FWA apply whenever the institution, its agents, or its employees are engaged in human subjects research, regardless of the geographic location of the research.

There are situations that arise when Skidmore College researchers are involved in multi-site research or collaborative projects with investigators at other institutions. Such research requires IRB review by each site engaged in the research unless an IRB Authorization Agreement (IAA) is in place. An IAA is a joint review arrangement where one IRB relies upon the review of another qualified IRB to avoid duplication of effort. The IRB that performs the review is called the IRB of Record, the Reviewing IRB, the Lead IRB, and/or the Primary IRB.

An IAA helps to reduce the burdens of multi-site research, which typically includes multiple IRB applications for the same project, multiple changes (sometimes conflicting) to secure approval, and multiple continuing review and amendment submissions. The following examples are the most common situations where an IAA is used:

- Skidmore acts solely as the funding recipient of an award and no human subjects research activities will be taking place at Skidmore.

- The involvement of Skidmore investigators is limited to analysis of data collected through the other institution or other minimal risk, non-exempt activities.

- The other institution's reviewing IRB is more properly constituted to review a certain scope or topic of work, or may have knowledge of the local context (For example, an international research project where the interaction with subjects is performed at an external site and that site has an FWA).

- The Skidmore investigator is involved in non-exempt research to be performed at another institution that either has or will have IRB approval.

When Skidmore College, its agents, or its employees are not engaged in human subjects research, IRB review (and therefore an IAA) is not required. In addition, an IAA is not appropriate for research seeking or granted an exempt determination.

Usually, the institution of primary employment of the lead PI or the institution where most of the research is taking place will be the IRB of Record. The protocol should describe the specific procedures to be conducted at each research site, and the research personnel at each institution who will conduct those procedures. Each IRB may decide the appropriateness of ceding or accepting responsibility for the review of any research involving human subjects.

The IAA must be approved and signed by the designated Human Subjects or IRB Signatory

Official at each institution. Protection of participants in research projects remains the responsibility of all institutions involved in the research. Designating a reviewing IRB does not absolve another institution in the research of such responsibility.

8.2. Certificates of Confidentiality

The IRB may determine that special protections are needed to protect participants from the risks of investigative or judicial processes in research projects that include the collection of highly sensitive information about individually identifiable participants 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 participants 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.

8.3 Reporting Adverse Events

Adverse events can occur in any type of research (biomedical or social/behavioral/educational research). Some events are expected (e.g., lightheadedness during blood collection), while others are unexpected (e.g., theft of devices containing data). Events also vary in seriousness and the extent to which they are related to the research. Reporting serious adverse events facilitates protection of research participants by allowing investigators and the IRB to determine whether the event/problem indicates changes are necessary to minimize risk, ensure the risk/benefit ratio remains favorable, and ensure participants are fully informed.

An **adverse event** is any untoward or unfavorable occurrence in a research participant that is temporally associated with the participant's involvement in the research. An adverse event encompasses physical, psychological, social, economic, legal, or informational harms. It may or may not be directly related to the individual's participation in the research. A **serious adverse**

event is an adverse event temporally associated with the individual's participation in research that meets any of the following criteria:

- Results in death;
- Is life threatening (places the subject at immediate risk of death from the event as it occurs);
- Requires inpatient hospitalization or prolongation of existing hospitalization;
- Results in a persistent or significant disability/incapacity;
- Results in a congenital anomaly/birth defect;
- Based upon appropriate medical judgment, may jeopardize the individual's health and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition;
- Results in a breach of confidentiality that is damaging to the participant's rights, employment, financial standing or reputation; or
- Causes significant psychological, social, economic, or legal harm to the participant or others.

Investigators must report to the IRB within 7 days of an occurrence or within 7 days of the principal investigator becoming aware of any **serious adverse event** that is related or possibly related to the research.

If the problem poses an immediate risk of serious harm to a participant or others, it must be reported immediately to the IRB.

8.4 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.

8.5 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 violation.

8.6 Financial Conflict of Interest/Significant Financial Interest
Each investigator who is participating in research under an award or a subaward where the prime award originates from the Public Health Service (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 should be responsible for making sure that Financial Conflict of Interest (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 must be created and become 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) within thirty (30) days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new SFI. Skidmore College requires all faculty and staff to adhere to its FCOI Policy. 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.

9. Informed Consent

Informed consent in research means more than simply obtaining the signature of the potential research subject. It is a process that involves conveying accurate and relevant information about the research study and its purpose; disclosing known risks, benefits, alternatives, and procedures; answering questions; and enabling the potential subject to make an informed decision about whether to participate.

General requirements for informed consent are described in 45 CFR §46.116.

9.1 Elements of Consent

In order for consent to be valid, it should be based on the following critical elements:

1. The subject must be competent to begin the informed consent process. If the subject is not competent because of age, illness, incapacity, or any other reason, special provisions apply, or the subject may not be included in the research.
2. The research team must disclose all relevant information to the potential subject. The information must be sufficient to allow the potential subject to discuss and consider whether to participate. The potential subject must be given the key information that is most likely to assist a prospective subject in understanding the reasons why one might or might not want to participate in the research. This includes the following information:

    a. The purpose of the research and the expected duration of the participants participation;

    b. The nature of the procedures to be followed and identification of any procedures which are experimental;

    c. A description of reasonable alternatives to the proposed intervention;

    d. A description of the risks, potential discomforts, benefits, and uncertainties expected of the research;

    e. A description of the extent to which confidentiality of records identifying the subject will be maintained;

    f. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs;

g. An explanation of whom to contact for answers to pertinent questions about the research and research participants' rights;

h. 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;

i. One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:

    i. A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative; or

    ii. A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

One or more of the following elements of information, when appropriate, shall also be provided to each subject or the legally authorized representative:

j. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) that are currently unforeseeable; (2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or the legally authorized representative's consent;

k. Any additional costs to the subject that may result from participation in the research;

l. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

m. A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject; and (6) The approximate number of participants involved in the study;

n. A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;

o. A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to participants, and if so, under what conditions;

p. For research involving biospecimens, whether the research will (if known) or might

include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

3. The subject must comprehend the information. Information must be presented in sufficient detail related to the research and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or legally authorized representative's understanding of the reasons why one might or might not want to participate. The research teams must evaluate the potential subject's ability to understand the proposed intervention in the research study.

4. The subject must agree to the proposed intervention in the research study.

5. The subject's agreement must be voluntary and free from undue influence and coercion.

9.2 Preparation of Consent Document

The first step in the process of informed consent is preparing the written consent document for presentation to the IRB. Sample consent forms can be found on the IRB webpage.

Informed consent documents should be written in nontechnical language that can be understood by the proposed subject population—consistent with their educational level, familiarity with research, and cultural views. The consent document must make clear that participation in research is voluntary, and it shall not include any exculpatory language through which the subject or representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence. In some cases, the researcher may request that the IRB approve a modification or waiver of the elements of informed consent permitted under 45 CFR §46.116(b) and (c).

Advertisements, fliers, or brochures prepared to recruit and inform potential participants about a research study are considered part of the informed consent process and, as such, also require review and approval by the IRB.

9.3 Waiver or Alteration of Informed Consent

Under 46.116(f)(3), the IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

IRB may approve a consent procedure that alters some or all of the elements of informed consent provided the IRB finds and documents that:

1. <u>The research involves no more than minimal risk to participants</u>: Investigators and the IRB must ensure incomplete disclosure/deception are only used in minimal risk research and do not increase risks beyond what participants would agree to had they been fully informed about the research.

2. <u>The research could not practicably be carried out without the waiver or alteration</u>: Investigators must provide sufficient information for the IRB to determine that the research questions could not be answered without the use of incomplete disclosure/deception.

3. If the research involves using identifiable private information or identifiable biospecimens the research could not practicably be carried out without using such information or biospecimens in an identifiable format: Investigators must provide sufficient information for the IRB to determine that the research questions could not be answered without using identifiable private information or identifiable biospecimens.

4. The waiver or alteration will not adversely affect the rights and welfare of participants: Investigators and the IRB must ensure incomplete disclosure/deception do not compromise participants' privacy, interests, or well-being.

5. Whenever appropriate, participants are to be provided with additional pertinent information after participation: When investigators use incomplete disclosure or deception, they must include a process for informing participants about the incomplete disclosure/deception unless debriefing is not possible or would cause unacceptable risk to the participants.

9.4 Waiver of Documentation of Informed Consent

Under 46.117(c), the IRB may waive the requirement for the investigator to obtain a signed consent form for some or all participants if it finds either:

1. That the only record linking the subject and the research would be the informed consent form, and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject (or legally authorized representative) will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern.

2. That the research presents no more than minimal risk of harm to participants, and involves no procedures, for which written consent is normally required outside of the research context.

3. If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

When the requirement for written documentation of consent is waived, the IRB must review a written description of the consent form that will be provided to participants. This information must include the basic elements of informed consent unless an alteration of consent has also been approved by the IRB.

9.5 Special Issues in Informed Consent

Third Party Consent or Consent by Proxy (Legally Authorized Representative)

Proxy consent, or consent to participate in research by one competent adult on behalf of another individual, may be appropriate under certain circumstances. All uses of proxy consent must be approved by the IRB.

If the prospective subject is identified as incompetent to provide informed consent, and if the condition of being incompetent is temporary, (if for example, potential participants have

received sedating or pain-relieving medications and consent must be obtained before the effects wear off), the duration of the incompetence is unknown (for example, when a potential subject is in a coma resulting from traumatic injury), or the potential subject is cognitively impaired, the subject's legally authorized representative is responsible for deciding whether the subject should participate in the research. This person may, if participation is so decided, sign the consent form on behalf of the subject and will indicate his or her relationship to the subject.

Consent from the subject's legally authorized representative should be obtained by the researcher in person and documented on the approved consent form.

Consent provided by a proxy should never be accepted if the potential subject has indicated refusal to take part in the research.

Research with Children and Assent to Research

Legally, children have not attained an age at which they can consent to their own participation in human subject research. Therefore, special provisions for agreement to participate in research are established in 45 CFR §46.408. This section establishes the requirements for obtaining permission from parents or guardians and assent from children. The parent or guardian may provide "permission" for the child to participate in a research study. Permission means the agreement of parent(s) or guardians(s) to the participation of their children or wards in research. Valid permission can be given only following an explanation incorporating the information currently required for informed consent.

In most cases, the child must also indicate willingness to participate by assenting to the research study. Assent means a child's affirmative agreement to participate in research. By law, failure to object may not be construed as assent. The IRB shall make the final determination if sufficient protections exist for children and how assent should be documented.

Language Barriers

Information relevant to participation in research must be communicated to participants "in language understandable to the subject," and in most situations, such informed consent must be documented in writing (See 45 CFR §46.116, 117).

Written consent documents must include all elements necessary for legally effective informed consent in a language comprehensible to the intended participants. Thus, participants who are not native or fluent English speakers should be provided with a consent document in their native language, written at a level that makes the information comprehensible.

Deception in Research

The principle of respect for persons demands that participants enter the research voluntarily and with adequate information. When deceptive methodologies are used, participants are given incomplete or misleading information about what to expect during the study activities which compromises their ability to give fully informed consent.

Ordinarily, research proposals failing to adhere to the principle of respect for persons by compromising the consent process would not be approved. However, in unique circumstances where the study design requires omission of details that might alter the participant's responses that

are being investigated, vital information about the study or study activities can be withheld from participants until after their participation.

Deception and incomplete disclosure can be valuable research methods, and studies involving the use of deception have resulted in significant contributions to science. However, the use of deceptive methodologies places a special burden of responsibility on researchers to provide scientific justification for the deception. Researchers must also provide the appropriate additional safeguards, beyond those safeguards normally in place, to protect the rights and welfare of participants. Investigators are urged to explore the literature within and outside of their field in order to fully understand the history and critical issues related to deceptive methods.

The IRB recognizes that incomplete disclosure/deception is sometimes necessary for human research.

- *Incomplete disclosure* applies when information about the real purpose or nature of the research is withheld from participants.
- *Deception* in the context of human research refers to providing false information to prospective participants.

Incomplete disclosure or deception may NOT be used in greater than minimal risk research. Only study procedures that involve minimal risks (as determined by the IRB) can include deception or incomplete disclosure. Please note that studies involving deception will not be considered for Exempt Category 1 (research conducted in established or commonly accepted educational settings) because deception is not a "normal educational practice." In addition, Exemption Category 3 is not applicable unless the participant authorizes the deception through a prospective agreement to participate in research in circumstances in which the participant is informed that he/she/they will be unaware of or misled regarding the nature or purposes of the research.

Use of deception or incomplete disclosure must be justified by its impact on the potential scientific value to the research. Investigators should clearly state that the study involves deception and/or incomplete disclosure Investigators using incomplete disclosure/deception must provide sufficient information in the IRB application to make it clear that the incomplete disclosure/deception:

- is necessary for the conduct of the research; and

- does not increase risks beyond what participants would agree to had they been fully informed about all aspects of the research.

In general, deception is not acceptable if, in the judgment of the IRB, the participant may have declined to participate had they been informed of the true purpose of the research. Investigators may be vague as to the purposes of the study or omit information in consent materials in order to maintain the incomplete disclosure or deception necessary for the research.

Rarely, it is necessary to continue the deception by providing false or misleading information in consent materials. Investigators must justify the inclusion of false/misleading information in consent materials. The IRB will evaluate the effects of the continued deception on participant risk, and will determine if continuing the deception in the consent materials is warranted.

The use of incomplete disclosure/deception means one or more of the basic elements for informed consent are being withheld or distorted. Consequently, the use of incomplete disclosure/deception requires the IRB to approve an *alteration* of informed consent (See Section 9.3).

Debriefing is an essential part of the informed consent process and is mandatory when the research study involves deception or incomplete disclosure. Debriefing must include the rationale for the study design, the study purpose, and a description of the information that was false or incomplete. Considering that participants may feel a range of emotions at different intervals about being deceived, a process for continuous or staged debriefing may be needed. The debriefing process should:

- inform participants that incomplete disclosure/deception was used, specify what information was withheld or falsified, align with the details and risks of the study;
- explain why it was necessary to use incomplete disclosure/deception;
- provide participants the opportunity to ask questions about the new information.

After the debriefing, investigators may ask participants to refrain from talking to others about the incomplete disclosure/deception to minimize the possibility that results may be skewed if subsequent participants knew in advance that incomplete disclosure/deception was being used in the study.

Although not a requirement, investigators may wish to allow individual participants to withdraw their data after learning of the incomplete disclosure/deception, and the true purpose/goals of the research. This may be a reasonable option when participant data contain personal identifiers or codes that are linked to a master key, or the debriefing and option to withdraw are provided before a participant submits her/his/their data. This option is not feasible when data are collected without participant identifiers or links to identifiers. Investigators wishing to exercise this option should provide clear instructions for participants to withdraw their data.

10. Guidance on Payments to Research Participants

Skidmore College supports faculty conducting research in a variety of academic fields. For certain studies, community (faculty, staff, student, or outside party) involvement is required to help carry out this important research. Modest financial payments are sometimes made to participants. The below guidance is intended to ensure that Skidmore College makes all reasonable efforts to comply with IRS guidelines in order to avoid costly penalties, audit findings, unnecessary risk, or issues with federal funding or our tax-exempt status.

Per IRS tax regulations, if the participant is an independent contractor, the reporting threshold is $600 (i.e., payment made to an independent contractor totaling $600 or more in a calendar year is reportable to the IRS, and the recipient would be issued a Form 1099-MISC). If the participant is an employee (not a contractor), payments received as part of a human subjects research study (whether it's cash, check or gift card) are subject to income tax and other withholdings as applicable on their W-2.

All human subjects research studies that involve cumulative participant incentives totaling $50 or

above in a calendar year, the following language should be included in the informed consent form:

> "By participating in this research study, I acknowledge that any payments received will be considered taxable to me (unless such payments are for the reimbursement of actual expenses incurred) and my name may be shared with Skidmore's Office of Financial Services for IRS tax reporting purposes only."

Additionally, investigators are required to:

1. maintain a log of all incentives valued at $50 or more and a log of multiple incentives given to a single person totaling $600 or more within a calendar year; and
2. provide Accounts Payable with the names of all participants (both employees and non-employees) who receive such incentives.

Accounts Payable will keep the names of all participants confidential, and the title/description of the study does not need to be referenced.

11. Guidance for Involvement of College Students

The Belmont report, which is the foundation for which human subjects research regulations are based on, stresses that a subject's participation must be voluntary, based upon full and accurate information. Research with one's own students inherently challenges the subject's "voluntariness" due to the power difference between students and instructor. Students may feel as though they have to participate or risk having their non-participation impact their grade or relationship with the professor. The IRB understands that real coercion is rare in research, but the perception of coercion potential can be a problem in obtaining voluntary informed consent. For this reason, the IRB has taken the position that instructors should not use their own students as subjects in their research if it can be avoided.

The Skidmore IRB recognizes, that in some situations, it may be acceptable to use one's own students to conduct research. This may apply to research of teaching methods, curricula and areas related to scholarship of teaching and learning. The following model of research design can be approved by the IRB.

11.1 Collection of Data by Third Party

An independent third party, who does not have power or authority over the students, must be part of the recruitment, consent process and data collection, if applicable. This third party can recruit in-person or via email, conduct the consent process and explain and provide assurances to the student that no penalties will result by not agreeing to participate in the research. Please note: The specific role of the third party may nor may not require them to be listed as a project team member on the IRB submission. Individuals who are tasked with obtaining consent (describing the study procedures, answering questions about the study, ensuring comprehension, etc.) are engaged in human research activities and are considered investigators by the IRB.

Investigators must wait until the end of the professor-student relationship before accessing the consent forms collected by the third party (i.e., after all marks have been submitted to the Registrar's Office). This will mitigate any real, or perceived influence toward the student's grades. Identifiable data can only be analyzed after grades have been submitted. If the third

party is only tasked with temporarily holding of consent, then they would not be considered part of the project team.

11.2 Informed Consent

Student academic records are regulated by federal law, specifically, the Family Educational Rights and Privacy Act (FERPA) that protects the privacy of personally identifiable information within a student's educational record. The Skidmore IRB requires instructors to obtain a signed FERPA Release Form to access educational records as part of any research study.

The informed consent document must clearly explain the following:

- Risks – address how the risk of coercion will be minimized;
- That participation will not affect grades or standing in class;
- What information from their student records may be disclosed, the purpose of the disclosure and who this information may be disclosed to;
- That a student may withdraw from the research at any time without penalty and withdrawing prior to the end of the research will not affect their grade or standing in class.

Investigators should consider the following:

- Students should not be used as a population of convenience for faculty/staff research. In any proposed research project involving recruitment through classrooms, student listservs, or other student groups, a clear explanation or justification should be provided as to why those students are the most appropriate participants for the project;
- Permission must be obtained from the instructor of a class/course where research activities may take place, including student recruitment. For research through student programs or services, permission from an appropriate administrator should be requested. Documentation of support or permission may be required by the IRB;
- Researchers must ensure that the recruitment and informed consent processes minimize the possibility of coercion or undue influence;
- Many research activities can be similar to or overlap with normal course work or class projects. The researcher is responsible for ensuring that students can truly understand what participation involves and can distinguish voluntary research activities from required course activities.
- Research activities that occur within a classroom, including recruitment, consent, or data collection, have the potential to identify to other classmates and the professor/instructor who is participating and who is not. To protect identities of research subjects, research activities should be done in a way that does not identify them to each other or their professors/instructors. For example, sign-up sheets should be collected individually from student (no public sign up list), and alternative classroom activities can be given to students

who decide not to participate so an observer could not distinguish between research and non-research activities (e.g., both are working on a computer).

12. Research on Vulnerable Populations

Vulnerable participants are persons who are susceptible to undue influence or coercion or relatively or absolutely incapable of protecting their own interests. The researcher and research team should be cognizant of the special problems of research involving vulnerable populations, justify the proposed involvement of these populations in the research, and include additional safeguards for their safety and welfare.

12.1 Research with Children (45 CFR §46 Subpart D)
Research involving children demands a particularly high level of care and consideration by investigators. In recent years, ethical and legal standards have changed, and investigators who conduct research in this area should consult with the IRB.

The issue of children as research participants is complex since they are not considered able to make informed choices independently. Further, exposure of children, particularly healthy children, to more than minimal risks must be weighed carefully.

12.2 When including children in research, the role of the family should be considered in devising the protocol as well as in obtaining informed consent from the parents or guardians. If the research is based in schools, appropriate involvement and permission must be obtained from the school. Adequate measures must be developed to protect children's privacy and to ensure that their participation does not stigmatize them in the present or future. **Research with Prisoners**

Because prisoners are a vulnerable research population, the Office of Human Research Protection (OHRP) requires and enforces additional protections (45 CFR 46 Subpart C). OHRP Guidance on the Involvement of Prisoners in Research will be useful to PIs who conduct prisoner research.

In addition to all the basic human subject protection requirements (45 CFR 46, Subpart A), the IRB must review prisoner research and find that the research complies with seven additional requirements [45 CFR 46.305(a)].

Research involving prisoners must be reviewed by an IRB that fulfills the following membership requirements [45 CFR 46.304]:

- At least one member of the IRB must be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity.
- A majority of the IRB (exclusive of prisoner members) shall have no association with the prison(s) involved, apart from their membership on the IRB

Note: If a research project is reviewed by more than one IRB, only one IRB must satisfy the requirement that at least one member is a prisoner or a prisoner representative.

The institution responsible for conducting prisoner research must provide a Prisoner Certification Letter to the OHRP citing that the IRB has completed its review of permissible research and that the seven additional requirements are met.

Note: The research cannot proceed until OHRP issues written approval to the institution.

12.3 Cognitively Impaired Participants

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 participants is automatically referred to the full IRB for review.

12.4 Equitable Recruitment and Selection

With these caveats and an understanding of the Federal regulations in mind, researchers must also be careful not to overprotect vulnerable populations to the extent that they are excluded from participating in research in which they wish to participate, particularly where the research involves therapies for conditions with no available treatments. So, too, patients with serious or poorly understood disorders may want to participate repeatedly in research designed to provide a better understanding of their conditions. The fact that participants may be either patients of the principal researcher or patients in the clinic or hospital in which the researcher conducts the research study should not preclude them from the opportunity to choose to participate as often as they wish.

Appendix 1 - Definitions of Common Research Terms

Adverse event: An unwanted and unintended occurrence affecting a human subject during research. Types of adverse events include internal, external, expected, unexpected, and serious.

Adverse event report: A report by the researcher of all serious adverse events, injuries, and/or deaths given to the sponsor, the IRB, any applicable grantor, and federal, state, or local agencies.

Assent: Affirmative agreement, provided verbally or in writing, by an individual not competent to give legally valid informed consent (e.g., a child or cognitively impaired person) to participate in research.

Assurance: A written, binding commitment filed with a Federal agency by an institution that wishes to conduct human research. The institution promises to comply with applicable regulations governing human subject research and stipulates the procedures through which compliance will be achieved.

Autonomy: Personal capacity to consider alternatives, make choices, and act without undue influence or interference of others.

Belmont Report: The report entitled Ethical Principles and Guidelines for the Protection of Human Participants of Research generated by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in 1979. The ethical principles identified in this document: respect for persons, beneficence, and justice, became the cornerstone of Federal regulation of protection for research subjects.

Beneficence: An ethical principle discussed in the Belmont Report that entails an obligation to protect persons from harm. The principle of beneficence can be expressed in two general rules: (1) do no harm; and (2) protect from harm by maximizing anticipated benefits and minimizing possible risks of harm.

Benefit: A benefit in research is a valued or desired outcome enjoyed by the subject (therapeutic benefit), or accruing to a group under study, or to their family members, or to scientific knowledge (nontherapeutic benefit).

Child or children: Persons who have not attained the legal age for consent to treatments or procedures involved in research under the applicable law of the jurisdiction in which the research will be conducted. Special rules and protections govern the participation of children in research. In New York, a child (sometimes referred to in this policy as a "minor") is any person under the age of 18.

Common Rule: The "Common Rule" refers to Federal statutes governing the protection of human subjects in research, enacted in 1991 and adopted by 17 Federal agencies. The Common Rule is set forth in the Code of Federal Regulations, 45 CFR §46, and covers all federally funded research supported by the Departments of Agriculture, Energy, Commerce, HUD, Justice, Defense, Education, Veterans Affairs, Transportation, and DHHS, as well as NSF, NASA, EPA, AID, Social Security Administration, CIA, and the Consumer Product Safety Commission. The provisions are identical to the DHHS Regulations (45 CFR §46, Subpart A).

Data: Multiple facts (usually, but not necessarily, empirical) used as a basis for inference, testing, analysis, etc. or used as the basis for decision-making.

Data and Safety Monitoring Plan: A plan with a general description of data and safety monitoring of a clinical research study. The plan is developed by the researcher, included in the protocol, and submitted to the IRB for review and approval before the study begins. An appropriate plan reflects the risks of the study, including its size and complexity.

Declaration of Helsinki: Statement of ethical principles for human participation in biomedical research. The Declaration was first adopted in 1964 by the World Medical Association. It has been revised five times, most recently in 2000. Like the Nuremberg Code that preceded it, the Declaration of Helsinki makes consent a central requirement of ethical research. The Declaration initially established a distinction between the standards for therapeutic and non- therapeutic research; however, this has been eliminated in recent revisions.

Expedited Review: Review of proposed research by the IRB Chair or a designated voting member or group of voting members rather than the entire IRB.

Exclusion Criteria: The list of participant characteristics that would prevent an individual from participating in a research study.

Guardian: An individual entitled or authorized to make decisions affecting the health or medical care of another, including the ability to consent.

Human participant, research participant, human research participant, participant, human subject, research subject, human research subject, subject: These interchangeable terms refer to a living human individual about whom an investigator conducting research: (1) Obtains or seeks to obtain information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; (2) Obtains or seeks to obtain, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

Inclusion criteria: The list of participant characteristics required in order to participate in a research study.

Informed consent: A person's voluntary agreement, based upon adequate knowledge and understanding of relevant information, to participate in research. Informed consent also refers to the process of information exchange between researcher and subject prior to participation in research. The information to be conveyed to the subject is factual information, including an assessment of the risks of participation, eight specific elements required by federal regulations, a description of the procedures that will be performed, and the persons responsible. The information conveyed by the subject to the researcher is an indication of his or her comprehension of the process, the voluntary nature of participation, and understanding of his or her rights, including the right to withdraw.

Institutional Review Board (IRB): A specially constituted review body established to protect the welfare of human subjects in research. Federal law states that all institutions supported by a federal department or agency to which the Common Rule applies must establish an Institutional Review Board to review and approve research involving human subjects.

IRB approval: The determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements.

Interaction: Includes communication or interpersonal contact between investigator and subject.

Intervention: An action that produces an effect or that is intended to alter the course of a pathologic process. Includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment performed for research purposes.

Institution: Any public or private entity, or department or agency (including Federal, state, and other agencies).

Investigator: In research studies, an individual who actually conducts an investigation. Any interventions (e.g., drugs) involved in the research study are administered to participants under the immediate direction of the Investigator.

Justice: An ethical principle discussed in the Belmont Report requiring fairness in the distribution of burdens and benefits; often expressed in terms of treating persons of similar circumstances or characteristics similarly.

Legally authorized representative: An individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to his or her participation in the procedure(s) involved in the research. If there is no applicable law addressing this issue, legally authorized representative means an individual recognized by institutional policy as acceptable for providing consent in the non-research context on behalf of the prospective subject to the subject's participations in the procedure(s) involved in the research.

Minor: A person who has not attained the age of majority in a particular jurisdiction. In New York, a person under age 18 is considered a minor.

Minimal risk: The probability and magnitude of harm or discomfort normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons. This also includes the normal exercise and training routine of athletes and athletic teams.

Noncompliance: Failure to comply with the regulations, institutional policies, laws, or the requirements or determinations of the IRB.

Nuremberg Code: A code of research ethics developed during the trials of Nazi war criminals following World War II. This code became the first international standard for the conduct of research and began the modern era of protection for human research subjects.

Office for Human Research Protection (OHRP): The office within the Department of Health and Human Services responsible for implementing DHHS regulations (45 CFR §46) governing research involving human subjects. The OHRP has direct oversight and educational responsibilities wherever DHHS funds are used to conduct or support research involving human subjects.

Additionally, it serves as a research, guidance and educational resource for all institutions involved in conducting research that involves human partnership, regardless of the funding status of the research.

Parent: A person's biological or adoptive parent. In the conduct of research, the permission of the parent is generally necessary if the potential subject is a minor.

Permission: The agreement of parent(s) or guardian(s) to the participation of their child or ward in research.

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.

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.

Quorum: A simple majority of the IRB members qualified to vote.

Randomization: Assignment of participants to different treatments, interventions, or conditions according to chance rather than systematically (e.g., as dictated by the standard or usual response to their condition, history, or prognosis, or according to demographic characteristics). Random assignment of participants to conditions is an essential element of experimental research because it makes more likely the probability that differences observed between subject groups are the result of the experimental intervention.

Recruitment: The act of selecting and enrolling research participants for a research study using proper inclusion criteria.

Research: A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Research does not include: (1) scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected; (2) public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority; (3) collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes; (4) authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions; and (5) studies for internal management purposes such as program evaluation, quality assurance, quality improvement, fiscal or program audits, marketing studies or contracted-for services.

Research Integrity Officer: The official responsible for assessing allegations of scientific misconduct and determining when such allegations warrant inquiries and for overseeing inquiries and investigations. At Skidmore, the research integrity officer is the designated associate dean of

the faculty.

Researcher: The individual who conducts and directs the research study and carries the primary responsibility for the research. The Researcher is referred to as the "Principal Investigator" when acting as the leader of a research team.

Respect for Persons: An ethical principle discussed in the Belmont Report requiring that individual autonomy be respected and that persons with diminished autonomy be protected.

Risks: The probability of harm or injury (physical, psychological, social, economic or legal) occurring as a result of participation in a research study. Both the probability and magnitude of possible harm may vary from minimal to significant.

Serious adverse event: An adverse event resulting in death, hospitalization, disability or incapacity, congenital anomaly or birth defect, or is life-threatening.

Sponsor: An individual, company, institution, or organization that initiates and finances a research study. A sponsor is not necessarily the entity that conducts the research.

Suspension: IRB-approved research or some of the activities in the research are temporarily stopped in order to protect human subjects pending completion of an investigation. Once the investigation is complete, a determination is made as to: 1) lift the suspension and allow protocol activities to resume or 2) terminate the study or some activities of the protocol.

Termination: IRB-approved research is permanently stopped. No further work may be done on this research.

Voluntary: Free of coercion, duress, or undue inducement. Used in the research context to refer to a subject's decision to participate (or to continue to participate) in a research activity.

Vulnerable participants/population: Individuals or groups of participants who, by reason of disability, illness, age, or other status exhibit diminished personal autonomy. Neither the federal regulations nor ethical codes, including the Belmont Report, proscribe inclusion of vulnerable persons as research participants. However, DHHS regulations mandate special justification for research involving children [45 CFR Part 46, Subpart D].