Skidmore College Institutional Review Board
Policy and Procedures for Research Involving Human Participants

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1.0 Overview

1.1 Purpose

The purpose of the Institutional Review Board (IRB) of Skidmore College is to assure that all human subject research associated with the College conforms to related New York State and federal regulations. The IRB is charged with protecting the safety, welfare, rights, and privacy of all participants in human subjects research that proceeds under the guidance of faculty, staff, and students on our campus. These safeguards derive from the following ethical principles, which were first articulated in the Belmont Report issued by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in 1979.

1.2 Ethical Guidelines Governing Research

1.2.1 Respect for Persons: Recognition of the personal dignity and autonomy of individuals and special protection of those persons with diminished autonomy or particular vulnerabilities, including prisoners, children, those who are mentally or cognitively disabled, pregnant women, or economically or educationally disadvantaged persons. Human subjects should enter into research voluntarily and with adequate information.

1.2.2 Beneficence: The obligation to protect persons from harm by maximizing anticipated benefits and minimizing possible risks. Possible risks to human subjects should be weighed against possible benefits to the subjects, as well as against the possible improvement of knowledge.

1.2.3 Justice: Fairness in the distribution of research benefits and burdens. In selecting human subjects for research, investigators should ensure that no group of participants is either consistently selected to participate in research, or consistently deprived of the opportunity to do so.

1.3 Charge of the IRB

The procedures for review described below adhere to the regulations of the Department of Health and Human Services (45 CFR 46, as amended and published in the Federal Register on June 18, 1991), and to the Federal Wide Assurances filed with the HHS by the College. In addition, the IRB has adopted language from Federal Regulations that govern human subjects research.

The IRB is charged with reviewing human subject research proposals before the research begins. "Research" is defined as "systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalized knowledge" (45 CFR 46.102d). Research subject to review thus includes, but is not limited to: pilot studies; class projects that may lead to publication of results; MALS theses; student/faculty collaborative work; independent research; and senior theses, whether such research takes place on or off the Skidmore College campus.

2.0 Researcher Responsibilities

IRB policies are intended to protect the rights of human subject participants. However, researchers are also responsible for protecting those rights. In addition to the ethical principles enumerated earlier, researchers must abide by the Principles and Ethics summarized below, and they are encouraged to consult additional guidelines provided by their respective disciplinary groups.

2.1 Compliance

Faculty, staff, and students who participate in human subject research must act in compliance with federal, state and College regulations. In addition, professional disciplinary guidelines governing the conduct of human subject research should inform researchers as they plan and conduct their research. As required by IRB policies, researchers are required to obtain institutional approval prior to conducting research.

2.2 Informed Consent

Prior to conducting research with human participants (except when the research involves only anonymous surveys, naturalistic observations, or similar procedures), researchers enter into a social contract with participants, clarifying the nature of the research and what participants can expect to experience during the course of the study. Participants are informed of all features of the research that might influence their decision to participate. Researchers are to respect participant decisions to decline or discontinue participating in the research at any time for any reason and without penalty. Where possible, researchers make reference to participants' rights along these lines in their consent forms (see guidelines for the content of consent forms).

2.3 Minimizing Negative Effects of Participation (e.g., Intrusiveness, Harm)

Researchers protect participants from physical and psychological discomfort, harm and/or danger to the extent possible. Risks to participants are minimized and explained to the participant before he or she is asked to give consent. If the research inflicts undesirable side effects on participants, the researcher should find ways to remedy these effects. When human participants are younger than 18 years of age, the adult (e.g., parent or guardian) giving consent shall be fully informed of all risks on the child-participant's behalf. However, if it is reasonable to do so, the researcher shall explain the risks to the child-participant as well and provide them the opportunity to decline participation.

2.4 Deception in Research

Researchers conduct studies involving deception only when they have determined that the use of deceptive techniques is justified by the study's prospective scientific, educational or applied value and that equally effective alternative approaches that do not involve deception are not feasible. Researchers will never deceive participants about significant aspects of the procedure that might affect participants' willingness to participate (e.g., physical discomfort, physical risks, unpleasant emotional experiences).

Any other deception that is central to the design and implementation of the study must be explained to participants as early as is feasible, preferably at the conclusion of their participation, but no later than at the conclusion of the research.

There may be instances in which deception is not involved but participants are not fully informed about the purpose of a study. For example, in the study of memory (e.g., for faces,

conversation, news releases), it may be important not to inform participants at the outset that the purpose of the study is to test the accuracy of memory. In these instances, the use of cover tasks (or instructions for processing materials) need not make mention of subsequent memory tests. Although these cover tasks do not necessarily involve deception (i.e., telling participants information that is not true), for adult participants, their role in the research should be mentioned in debriefing statements.

2.5 Confidentiality and Privacy

All personally identifiable information about participants' is kept confidential. When there is a possibility that others may have access to this information, participants should be informed of this possibility prior to giving their consent. All information is processed, stored and destroyed in a manner that preserves the confidentiality of the participant. Researchers include reference to the way(s) in confidentially is safeguarded in their consent forms. Issues related to confidentiality and length of time for data storage will be reviewed on a case-by-case basis depending on the nature of the data, e.g. verbal recordings and video. Typically, data are maintained for a period of five years, but this can vary according to academic discipline.

3.0 IRB Functions and Operations

3.1 Requirements

In order to fulfill the requirements of this policy the IRB shall:

3.1.1 Follow written procedures described in this policy, and as outlined in 45 CFR 46 (§46.103(b)(4) and to the extent required by §46.103(b)(5)).

3.1.2 Review all research involving human subjects prior to the commencement of data collection. The IRB will determine if the research is exempted from review, is eligible for expedited review, or requires full review.

3.1.3 Review proposed research requiring full review at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting.

3.2 IRB Membership

3.2.1 IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of human subject research activities conducted by College faculty, staff, and students. The IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas. The IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

3.2.2 The Sponsored Research Officer may also sit on the IRB as a non-voting (ex officio) member.

3.2.3 The IRB may, in its discretion, invite individuals with competence in special areas to aid the review of issues which require expertise beyond that available on the IRB. These individuals may not vote with the IRB.

3.2.4 No member of the IRB 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. When an IRB member's proposal is discussed during an IRB meeting in which that member is present, he/she must leave the room for the duration of the discussion and vote.

3.2.5 The Dean of Faculty will appoint the members of the IRB in accordance with state and federal regulations and in compliance with the IRB Policy and Procedures. Members will generally serve a three-year term. In selecting new members, the Dean of the Faculty will ensure that the IRB is sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.

3.2.6 Former IRB members and other qualified faculty and staff may be appointed to serve as ad hoc members of the IRB. Ad hoc members may 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.

3.2.7 Ex officio members also include the Departmental IRB Liaison (e.g., chairs of departmental review boards). These individuals may be invited by the IRB Chair to attend a particular meeting, but, in general, they are non-voting members and do not attend IRB meetings on a regular basis. At the beginning of each academic year, the IRB Chair will call a meeting of these ex officio members to discuss the criteria for classifying proposals as exempt. (See Section 5.2 for criteria for proposal classifications.)

3.3 Training

IRB members (voting and ex-officio) and others charged with responsibility for reviewing and approving research will receive detailed training in the regulations, guidelines, and policies applicable to human subjects research. Attending workshops and other educational opportunities focused on IRB functions is encouraged and supported to the extent possible. During their first year of service, IRB members will attend an IRB sponsored orientation session and complete one appropriate training activity. Appropriate training may include workshops, web-based modules, CD ROMs, books, articles, and relevant videos. Documentation of training should be submitted to the IRB Coordinator by the end of each member or reviewer's term.

3.4 IRB Records

The IRB Coordinator shall prepare and maintain adequate documentation of IRB activities, including the following:

3.4.1 Copies of all research proposals (including those classified as exempt and reviewed by individual departments), scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects.

3.4.2 Minutes of IRB meetings which shall be in sufficient detail to report attendance at the meetings; actions taken by the IRB; the vote on actions on proposals under review including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of disputed issues and their resolution.

3.4.3 Records of continuing review activities.

3.4.4 Copies of all correspondence between the IRB and the investigators. The one exception to this guideline is for proposals classified as exempt by the Departmental IRB Liaisons In these cases, all correspondence between the Departmental IRB Liaisons and the investigators are maintained in departmental files. One copy of the individual proposals along with other supporting materials (see Section 3.4.1) will also be maintained within the department files.

3.4.5 A list of IRB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications, licenses, etc., sufficient to describe each member's chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member and the institution (e.g., full-time employee, part-time employee, member of governing panel or board, stockholder, paid or unpaid consultant).

3.4.6 Changes in IRB membership shall be reported to the Department or Agency head, unless in accord with §46.103(a), the existence of a DHHS-approved assurance is accepted. In this case, change in IRB membership shall be reported to the Office of Human Research Protection, National Institutes of Health, DHHS.

3.4.7 Written procedures for the IRB.

3.4.8 Statements of significant new findings provided to subjects. A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject.

3.5 IRB Maintenance of Records

Records pertaining to human subjects that come under IRB purview will be kept on a secure computer server (electronic records) or in a locked space in an administrative office under supervision of the IRB Coordinator for three years after the completion of an approved project or declination of a proposal. Records may include: certification of completion in human subjects protection training, applications for approval to the IRB, descriptions of research protocols, sample consent forms, sample questionnaires, copies of grant proposals, minutes of

IRB meetings, and related memoranda and correspondence. For departments with their own review boards, the IRB Departmental Liaison is expected to keep records that pertain to the exempt protocols reviewed at the departmental level for three years after the completion of an approved project.

4.0 Submitting a Proposal to the IRB

4.1 Qualified Investigators

Only qualified faculty and staff investigators with appropriate credentials related to human subjects research may submit a proposal to the IRB. Students and other members of the Skidmore community who do not have the appropriate credentials are required to have a research sponsor (most often a member of the faculty) who will submit the research to the IRB and assume responsibility for the research activities outlined in the proposal.

4.2 Use of Skidmore College IRB Forms

Investigators are to utilize the Skidmore College IRB standardized templates for proposal submission and development of informed consent forms. These templates are found on the IRB's website.

4.3 Components of the Proposal

- A purpose statement
- A description of the participants, including recruitment procedures and sample
- A full description of all procedures and instruments (e.g., including copies of questionnaires and surveys)
- Informed Consent Forms (see Section 4.4)
- Debriefing statement (if relevant, see Section 4.6)

4.4 Guidelines for Informed Consent Forms

Except under special conditions specified in the IRB Policy and Procedures, researchers are required to obtain written informed consent from all adult participants. Investigators are required to provide prospective adult participants with sufficient information and opportunity to consider that information. Every consent form should obtain a statement of the participants' rights. Basic elements of consent forms are summarized below:

4.4.1 A statement that the study involves research, an explanation of the purpose(s) of the research, the expected duration of the participant's involvement, a description of the procedures from the participant's point of view, and the identification of any procedures that are experimental in nature

4.4.2 A description of any reasonably foreseeable risks or discomforts

4.4.3 A description of possible benefits (including educational) to the participants or to others which may reasonably be expected

4.4.4 A statement describing the extent, if any, to which confidentiality of records of the participant will be maintained

4.4.5 For research involving minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs, and, if so, what they consist of, or where further information may be obtained

4.4.6 An explanation of whom to contact for answers to relevant questions about the research and/or participants' rights, and whom to contact in the event of an injury related to the research

4.4.7 A statement that participation is voluntary, and that refusal to participate (or the decision to discontinue participation) will not lead to any penalty or loss to which participants are otherwise entitled. This section should specify that the participant may discontinue participation at any time without penalty

4.4.8 Additional elements of the informed consent form might include the following:

- A statement that the procedure(s) may involve risks that are not currently anticipated.
- References to circumstances under which the researcher may discontinue the participant's involvement without consulting the participant himself or herself;
- Reference to any additional cost to the participant that may result;
- A statement that significant new findings developed during the course of the study may relate to the participant's willingness to continue involvement;

4.4.9 An IRB may approve a consent procedure that does not include, or which alters, some of the guidelines listed above under certain circumstances:

- The research project is conducted by and is subject to the approval of state or local government officials and is designed to evaluate the study
- The research could not be carried out without the waiver of consent

4.4.10 Waiver of consent: The IRB may approve a consent procedure that does not involve the guidelines specified above when:

- The research involves no more than minimal risk
- The waiver does not adversely affect the rights and welfare of the participants
- The research could not be carried out in any other way practically
- Whenever possible, participants will provide additional information and/or consent after participating (e.g., releasing use of video)

4.5 Consent of Child Participants

4.5.1 Parental Consent

When the participants are under 18 years of age, parental (or guardian) consent must be obtained. This consent could be specific to an individual project or inclusive of all projects receiving IRB approval for a given year. Parents and guardians may sign a consent form giving permission for their child(ren) to participate in a series of projects conducted over a period of an academic year. It is understood that although parental consent is obtained, child participants are free to decline invitations to participate without any penalty. Parent consent letters should provide information about the purpose of the research as well as information about the procedure itself from the child's point of view. As with research involving adult participants, this letter should indicate how confidentiality would be maintained.

4.5.2 Child Assent

Child participants should be given an age-appropriate explanation about the procedures used and what to expect by way of participation. Children should be asked if they want to participate. Mere failure to object on the child participant's part should not, in the absence of an affirmative response, be interpreted as assent. In the proposal, the researcher should indicate how assent would be obtained and documented. The researcher should also indicate how parental consent would be obtained including an example of the letter of consent (if relevant).

4.6 Debriefing Statement

Debriefing statements are required for some research projects. The purpose of debriefing is to inform the participants of the goal(s) of the study and to remove (or minimize) any negative effects of the study. When course credit is offered for participation (e.g., by way of extra credit), the debriefing should also be educational in that it informs the participants of some of the issues (e.g., psychological) of concern in the study. Debriefing is of particular importance if deception is involved and/or if the study involved sensitive or potentially embarrassing issues. It is the researcher's responsibility to remove any negative feelings that a participant might experience as a result of his or her participation. Note: Materials submitted to the IRB Committee should include a script of the debriefing statement.

When there are potential risks (e.g., inducing negative emotional reactions) even if minimal in nature, participants should be provided with appropriate contact information (e.g., counseling center, disabilities specialists) in the debriefing form. In studies where deception used, the researcher has the obligation to allow participants to learn about the nature of the deception (and its purpose) upon completing the session or study.

5.0 IRB Review of Proposals

5.1 Introduction

Qualified investigators (see section 4.1) who are planning research projects involving human subjects are responsible for initiating the review process by submitting their research proposals electronically to the IRB. Only electronic submissions are accepted. Typically, the Chair of the IRB will determine the category of review for all proposals. However, for those departments with their own review boards in place, the Departmental IRB Liaison (e.g., the Chair of the Participant Review Board in the Psychology Department), serving as an ex officio member of the IRB will review proposals initially. In consultation with the Chair of IRB, and following the criteria listed below for designating a proposal as exempt, the Departmental IRB

Liaison may designate a proposal as exempt. In this case, the Departmental IRB Liaison informs the IRB Chair about the approval, and sends a copy of the proposal to the IRB Coordinator to have on file. If the proposal requires further consideration, the Departmental IRB Liaison will send all relevant materials to the IRB Chair for further processing.

5.2 Categories of Review

Depending on the level of risk associated with the research, a protocol may be classified as **exempt** from review, eligible for **expedited** review, or require a **full** review. A proposal can be deemed exempt from IRB review at the departmental level (through the Department IRB Liaison) or through the IRB Chair. The Chair and/or another IRB member complete expedited reviews. A full review requires a meeting of the full IRB.

5.2.1 Criteria for Exempt Proposals

Part A (all items must apply):

1. The research does not involve as subjects prisoners, fetuses, pregnant women, the seriously ill, or mentally or cognitively compromised adults, including economically or educationally disadvantaged persons.

2. The research does not involve the collection or recording of behavior which, if known outside of the research, could reasonably place subjects at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, or reputation.

3. The research does not involve the collection of information regarding sensitive aspects of subjects' behavior (e.g., drug or alcohol, use illegal conduct, sexual behavior).

4. The research does not involve subjects under the age of 18 (except as they are participating in projects that fall under categories 1, 3, 4, and/or 5 in Part B). Category B2 (see below) studies that include minors can be eligible for expedited review.

5. The research does not involve deception.

6. The procedures of this research are generally free of foreseeable risk to the subject.

Part B (at least one item should apply):

1. Research conducted in established or commonly accepted educational settings, such as: Research on regular and special education, instructional strategies, or cognitive processes, or research on the effectiveness of, or the comparison among, instructional techniques, curricula, or classroom management methods.

2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects, or any disclosure of the human subjects' responses outside the research could

reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability or reputation.

3. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

4. Research and demonstration projects which are conducted by, or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: Public benefit or service programs; procedures for obtaining benefits or services under those programs; possible changes in, or alternatives to, those programs or procedures; possible changes in methods or levels of payment for payment for benefits or services under those programs.

5. Taste and food quality evaluation and consumer acceptance studies: if wholesome foods without chemical additives are consumed, or if a food is consumed that contains a food ingredient at or below the level of safety and for a use found to be safe, or agricultural chemical or environmental contaminant at or below a 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.

5.2.2 Criteria for Expedited Review

Part A (all items must apply)

1. The research does not involve as subjects prisoners, fetuses, pregnant women, the seriously ill, or mentally or cognitively compromised adults, including economically or educationally disadvantaged persons.

2. The research does not involve the collection or recording of behavior which, if known outside of the research, could reasonably place subjects at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, or reputation.

3. The research does not involve the collection of information regarding sensitive aspects of subjects' behavior (e.g., drug or alcohol, use illegal conduct, sexual behavior).

4. The procedures of this research present no more than minimal risk to the subject. (Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.)

Part B (at least one item should apply)

1. Research that collects data from voice, video, digital, or image recordings;

2. Research on individual or group characteristics or behavior, including but not limited to survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodology as follows:

    a. Involving adults, where (i) the research does not involve stress to subjects, and (ii) identification of the subjects and/or their responses would not reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation;
    b. Involving children where (i) the research involves neither stress to subjects nor sensitive information about themselves or their family; (ii) no alteration or waiver of regulatory requirements for parental permission has been proposed; and (iii) identification of the subjects and/or their responses would not reasonably place them or their family members at risk of criminal or civil liability or be damaging to the financial standing, employability, or reputation of themselves or their family members.

3. Continuations of projects previously approved by the IRB if (a) no new human subjects are enrolled in the study, all research-related interventions on human subjects have been completed, and the research remains active only for long-term follow-up of subjects; OR (b) no additional risks to subjects have been identified or the remaining research activities are limited to data analysis;

4. Certain classes of clinical studies of drugs or medical devices (i.e., clinical studies of drugs for which a new investigational drug application is not required; or research on medical devices for which an investigational device application is not required or the device is approved for marketing and is being used according to approved labeling);

5. Research involving existing identifiable data, documents, records, or biological specimens (including pathological or diagnostic specimens), where these materials, in their entirety, have been collected prior to the research for a purpose other than the proposed research. These sources are not publicly available and, although confidentiality will be strictly maintained, information will not be recorded anonymously (e.g., use will be made of audio or video tapes, names will be recorded, even if they are not directly associated with the data);

6. Collection of data through use of the following procedures: (a) non-invasive procedures routinely employed in clinical practice and not involving exposure to electromagnetic exposure or electromagnetic radiation outside the visible range (i.e., not involving x-rays, microwaves, etc.); (b) 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; (c) weighing, testing sensory acuity, electrocardiography,

electroretinography, echography, sonography, ultrasound, magnetic resonance imaging (MRI), diagnostic infrared imaging, doppler blood flow, and echocardiography; (d) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing involving subjects; (e) collection of blood samples by finger stick or venipuncture.

7. Continuations of projects that do not fall into the above categories, and have been previously subject to the Full Review process by the IRB, which has determined that the research involved poses not more than minimal risk, and no additional risks have been identified.

5.2.3 Criteria for Full Review

If ANY of these apply:

1. The research involves as subjects prisoners, fetuses, pregnant women, the seriously ill, or mentally or cognitively compromised adults, including economically or educationally disadvantaged persons.

2. The research involves the collection or recording of behavior, which, if known outside the research, could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

3. The research involves the collection of information regarding sensitive aspects of the subjects' behavior (e.g., drug or alcohol use, illegal conduct, sexual behavior).

4. The procedures of the research involve more than minimal risk to the subject (where "more than minimal risk" means that the probability and magnitude of harm or discomfort anticipated in the proposed research is greater than that ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests).

5. Any research that does not fall into any of the categories explicitly identified as qualifying for exempt or expedited status.

5.3 Review Process

5.3.1 All proposals must be prepared using the Skidmore College's IRB Research Proposal format (see 4.2).

5.3.2 All proposals (except as specified in 5.3.3) should first be submitted to the IRB Coordinator who will enter them into the proposal tracking system and assign a case number. Proposals will then be routed to the appropriate party.

5.3.3 For departments with their own review boards, proposals are submitted to the Departmental IRB Liaison who determines if the proposal is exempt. If the proposal is not exempt, the IRB Liaison instructs the Principal Investigator to electronically submit the proposal to the IRB. The IRB Chair then determines if the review will be expedited

or full. Even in departments with their own review boards, the principal investigator may submit the proposal to the IRB based on the level of risk associated with the research and/or external funding requirements.

5.3.4 Departments with their own review boards are expected to keep records of the exempt proposals. Departmental IRB Liaisons are responsible for directly corresponding with their own investigators regarding exempt protocols reviewed by their own boards.

5.3.5 Under the expedited review process, the Chair and/or other members of the IRB selected by the Chair will review the proposal. Under full review, all members of the IRB will receive a copy of the proposal to review and discuss at the next scheduled IRB meeting.

5.3.6 For all proposal classifications, official written (e-mail) IRB approval is necessary before data collection can begin.

5.4 Proposal Review Timeline and Deadlines

As a committee, the IRB meets on a regular basis during the academic year. The IRB attempts to review proposals in a timely manner. The full IRB meets every two weeks and investigators must submit proposals 5 working days before the meeting in which they would prefer their proposal be considered. Investigators can expect feedback on their submitted proposals within five days after the meeting in which the proposal was discussed. Specific IRB meeting dates change each semester and are listed on the IRB website. Investigators whose proposals are exempt from review will be notified about exempt status within two weeks after the IRB Coordinator receives the proposal. For reviews deemed exempt at the departmental level, the Departmental IRB Liaison will notify the principal investigator.

5.5 Review Outcomes

Researchers will be notified in writing as to the outcome of the review. The possible outcomes are as follows:

5.5.1 Approved: No further action is required from the investigator prior to initiating the study.

5.5.2 Approval Pending: If minor changes are requested by the IRB, the principal investigator will write a memo to the Chair indicating that such changes were made. The memo will be kept on file with the research protocol.

5.5.3 Revise and Resubmit: In order to fully protect subjects, changes have been identified by the IRB and must be addressed in writing before the study activities may begin. The Chair of the IRB will summarize the changes and communicate those in writing to the investigator. Every effort will be made to have the resubmission reviewed by the members who originally read the proposal and provided initial feedback. Once the proposal has been re-reviewed, the Chair will communicate with the investigator as to the outcome of the review (approved, approval pending, revise and resubmit, or denied).

5.5.4 Denied: The proposed research, due to the benefit to risk ratio and/or ethical concerns, cannot be initiated.

5.6 Review of Continuing Research

5.6.1 IRB-approved research that is continuing or has been changed must be re-reviewed by the IRB at least annually depending on level of risk. Research that is more than minimal risk will be reviewed more often than annually. Approximately one month prior to the year anniversary of the IRB approval date, the investigator will be sent a letter regarding the need for Continuing Review. The investigator is expected to complete the Review of Continuing Research form and submit it to the IRB Coordinator by the date indicated in the notice letter. The continuing review will be designated as exempt, expedited, or full and will be subjected to the review process delineated above. Continuing review is required for all proposals.

5.6.2 If the scope of the research changes or deviates from the description originally provided to the IRB, investigators must submit a memo to the IRB Chair or Departmental IRB Liaison describing such changes. The changes will be reviewed under the exempt, expedited, or full review process.

5.6.3 Failure to comply with the Continuing Review process can result in suspension or termination of IRB approval for the project.

5.6.4 After a proposal is underway, investigators must promptly report to the IRB Chair any unanticipated problems or adverse events that pose risks to subjects or others.

5.6.5 Complaints/Questions/Concerns: Questions, complaints, or concerns regarding compliance with Skidmore College's IRB Policy and Procedures should be directed to the Chair.

5.7 Research Approved by IRBs at Other Institutions

Skidmore faculty and/or student research that has been approved by an IRB at another institution where the data collection will occur under the auspices of that institution does not require additional review by Skidmore College's IRB. Principal investigators of such research are required to submit the protocol and official IRB approval to the IRB Coordinator. Research approved at another institution that utilizes Skidmore College community members as subjects does require IRB review according to the procedures described herein.

6.0 IRB Appeals Process

The decision of the IRB may be appealed. The principal investigator(s) initiates the appeal in writing to the Chair of the IRB. The investigator may submit information pertinent to the proposal and may request a meeting with the IRB. The IRB may request additional information relevant to the proposal from either the investigator or others. The appeal will be considered by the full IRB and the decision will be determined by the majority vote of all voting members of the IRB.