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Russell Sage COLLEGE Institutional Review Board Policy and Procedures Manual



RUSSELL SAGE COLLEGE POLICY AND PROCEDURES MANUAL FOR

RESEARCH ACTIVITIES INVOLVING HUMAN PARTICIPANTS

2021-2022

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# Russell Sage College IRB Policies and Processes

# ONE- Statement of Principles

It is the policy of Russell Sage College to ensure that the rights and welfare of human research participants are adequately protected in research activities conducted under its auspices. See Appendix A.

In addition, federal and state laws and regulations require these protections. In order for Russell Sage College to fulfill its responsibility and to comply with the law and regulations, all human participants research conducted under the auspices of Russell Sage College must receive appropriate review and approval. Russell Sage College assures compliance with all requirement of the Code of Federal Regulations (45 CFR 46) for all federally sponsored research, and all other human participants research, regardless of source of support.

Russell Sage College (TSC) is guided by the ethical principles set forth in the report of the National Commission for the Protection of Human Participants of Biomedical and Behavioral Research entitled “Ethical Principles and Guidelines for the Protection of Human Subjects of Research” (“The Belmont Report,” see Appendix B).

The policies and procedures in this document apply equally to all research involving human participants conducted under the auspices of Russell Sage College. All faculty members, staff, students and affiliated researchers who conduct or anticipate conducting research projects (either on or off campus) involving human participants are responsible for familiarizing themselves with and complying with these policies.

All studies that involve the use of human subjects in any way must be reviewed by Russell Sage College Institutional Review Board to ascertain that the studies are in compliance with the regulations of the U.S Department of Health and Human Services with which we are certified, and which has granted us a Federal Wide Assurance. **All Principal Investigators must adhere to the policies and procedures of Russell Sage College Institutional Review Board.**

# TWO- Definitions

Russell Sage College (TSC) has accepted all of the definitions included in the federal regulations on the protections of human participants in research (45 CFR 46.102). The following definitions are cited in this document as the ones most applicable to TSC.

1. Legally authorized representativemeans an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject’s participation in the procedures involved in the research.
2. Researchmeans a systematic investigation (including research development, testing and evaluation) designed to contribute to generalizable knowledge. Activities that meet this definition constitute “research” for purpose of this policy, whether or not they are conducted or supported under a program that is considered research for another purpose. For example, some “demonstration” and “service” programs might include research activities.
3. Human participantmeans a living individual about whom an investigator (whether professional or student) conducting research: (i) obtains information or biospecimens through intervention or interaction with the individual and uses, studies, or analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.
4. Interventionincludes both physical procedures by which information or biospecimens are gathered (e.g. venipunctures) and manipulations of the subject or the subject’s environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and participant. Private information includes communication about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public. Private information must be individually identifiable (i.e., the identity of the participant is or may readily be ascertained by the investigator or associated with the information) in order for obtained the information to constitute research involving human participants.
5. IRB Approvalmeans 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.
6. Minimal riskmeans 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.
7. Certificationmeans the official notification by the institution to the supporting department or agency, in accordance with the requirements of this policy, that research project or activity involving human subjects has been reviewed and approved by an IRB in accordance with an approved assurance.

# THREE- Institutional Responsibilities

1. Scope of Responsibility- Responsibilities of Russell Sage College Institutional Review Board
2. Russell Sage College has established one Institutional Review Board (IRB) to review and approve human participants’ research.
3. Russell Sage College acknowledges that it bears full responsibility for the performance of all research involving human participants conducted under its auspices, including compliance with federal, state or local laws as they relate to such research.
4. Russell Sage College and the individual members of its faculty, staff and student body acknowledge and accept their responsibilities for protecting the rights and welfare of human participants in research. This policy applies to all research involving human participants, and all activities which even in part involve such research, regardless of sponsorship, if the research:

* is conducted by or under the direction of Russell Sage College’ faculty, staff or students in connection with the fulfillment of institutional responsibilities or academic requirements; or
* is performed with or involves the use of Russell Sage College’ records, facilities or equipment belonging to Russell Sage College.

1. Russell Sage College encourages and promotes constructive communication among research investigators, the IRB and human participants as a means of maintaining a high level of awareness regarding the safeguarding of the right and welfare of the participants. Russell Sage College assumes responsibility for communicating and explaining these policies to faculty, students and other personnel, and for providing procedural guidelines to ensure their observance.
2. Performance Sites- Russell Sage College is responsible for ensuring that no performance site cooperating in the conduct of federally sponsored research to which Russell Sage College/Federal-wide Assurance applies does so without federal department or agency approval of an appropriate assurance and satisfaction of IRB certification requirements.
3. Protections for Vulnerable Populations- Russell Sage College requires more stringent safeguards for certain research activities and for participants likely to be vulnerable to coercion or undue influence such as: Prisoners; Minors (Under age 18); Individuals with impaired decision-making abilities; Activities involving fetuses and human in vitro fertilization; Other potentially vulnerable groups- includes anyone with a legally authorized representative
4. Provisions of Resources- Russell Sage College will provide the IRB with resources, meeting space, professional staff and support staff to carry out its responsibilities efficiently and effectively.
5. Education and Training- Russell Sage College will ensure that the IRB Chairperson, the IRB members, office staff, human participants, investigators and relevant administrative personnel are prepared to carry out their responsibilities in accordance with the guidelines established in this document.
6. Collaborating Institutions- Russell Sage College will ensure that all collaborating institutions (including subcontractors and subgrantees) engaged in human participants research have appropriate approved assurance on file with OHRP prior to the initiation of research. (See Section VII, Cooperative Research.)
7. Administrative Oversight- The IRB Office of Russell Sage College will exercise the appropriate administrative overview to ensure that the IRB carries out its responsibilities in an efficient manner. A copy of this policy manual will be available in The IRB Office and will be sent to faculty, staff or students requesting copies. It will also be available on our website: <https://www.sage.edu/academics/research/the-institutional-review-board/>

# FOUR- Responsibilities for the Implementation of Policies Regarding Human Participants Research

1. Russell Sage College has assigned compliance with federal regulations and Russell Sage College policy regarding human participant research to the IRB.
2. Russell Sage College Graduate School shall receive from investigators all Applications for Project Review for all research that involves human participants and keep investigators informed of review decisions.
3. The Chair of the IRB shall forward certification of IRB approval of proposed research to the appropriate federal department or agency only after all IRB-required modifications (if any) have been incorporated to the satisfaction of the IRB.
4. The Chair of the IRB shall notify all principal investigators of the approval, or disapproval, of their Applications for Project Review.
5. The Chair of the IRB will inform the IRB of all approved, exempt and expedited reviews.
6. The IRB shall provide advice on the preparation of the Application for Project Review form and other documents and other advice that will facilitate the IRB review process.
7. Russell Sage College Graduate Schools shall maintain all IRB records and arrange access for their inspection, in accordance with 45 CFR 46.115.
8. The IRB is responsible for ensuring constructive communication among research administrators, department heads, research investigators, human participants and institutional officials as a means of maintain a high level of awareness regarding the safeguarding of the rights and welfare of the participants.
9. The Sage College Graduate Schools shall arrange for and document in its records that each individual who conducts or reviews human participants has ready access to this policy manual, copies of 45 CFR 46, regulations of other federal departments or agencies as may apply, the Belmont Report and all other pertinent federal policies and guidelines that relate to the involvement of human participants in research (on our website).

The Chair of the IRB will ensure (a) solicitation (or confirmation where applicable assurances to comply already exist), receipt and management of all assurances of compliance (whatever the appropriate format) and (b) certifications of IRB review (where appropriate) for all performance sites of this institution and subsequent submission of new documents to the proper federal department or Agency authorities as a condition for involvement of each site in human participants research activities sponsored by the Department of Health and Human Services or any other federal department or agency.

# FIVE- The Institutional Review Board (IRB) and Review Process

1. Membership of IRB- Russell Sage College has established its IRB in accordance with the compositional requirements of 45 CFR 46, Section 107.
2. IRB membership requirements
3. The IRB shall be comprised of at least 5 members from diverse backgrounds to promote complete and adequate review of research activities commonly conducted at Russell Sage College.
4. The IRB shall be sufficiently qualified through the experience and expertise of its members and the diversity of its members, including consideration of race, gender and cultural backgrounds and sensitivity to such issues as community attitudes and issues related to vulnerable populations, to promote respect for its advice and counsel safeguarding the rights and welfare of human participants.
5. The IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law and standards of professional conduct and practice and shall, therefore, include persons knowledgeable in these areas.
6. The IRB shall include qualified persons of both sexes so long as no selection is made on the basis of gender.
7. The IRB shall not consist of all members of the same profession.
8. The IRB shall include at least one member whose primary concerns are in a non-scientific area and at least one member whose primary concerns are in a scientific area.
9. The IRB shall include at least one member who is not otherwise affiliated with Russell Sage College now or in the past and who is not part of the immediate family of a person who is affiliated with Russell Sage College.
10. 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.
11. The IRB may, at its discretion, invite individuals with competence in special areas to assist in the review of issues that requires expertise beyond or in addition to that available in the IRB. These individuals may not vote with the IRB.
12. General Principles of IRB Review- IRB Principles of Review include:
13. It is a policy of Russell Sage College that its IRB reviews all research involving human participants. The IRB has the responsibility and authority to review, approve, disapprove, require revisions and/or monitor research activities involving human participants.
14. In accordance with the compositional requirements of 45 CFR 46, Russell Sage College has established the IRB membership listed in the attached roster (Appendix D). Certain research supported by the U.S. Department of Education shall be reviewed in accordance with the requirements of 34 CFR Parts 350 and 356 which require that the IRB include at least one person who is primarily concerned with the welfare of handicapped children or mentally disabled persons.
15. No involvement of human participants in research, including recruitment, is permitted until the IRB has reviewed and approved the research project and informed consent has been obtained. It is the responsibility of the investigator to obtain approval from the IRB prior to the initiation of any research, including pilot or pretest studies, involving the use of human participants.
16. All activities involving humans as research participants must provide for the safety, health and welfare of every individual. Rights, including the right to privacy, must not be infringed. No participant in a research activity shall be exposed to unreasonable risk to health or well-being.
17. An individual does not abdicate any rights by consenting to be a research participant. A participant has the right to withdraw from a research project at any time or can refuse to participate without loss of benefits to which the subject would otherwise be entitled. Further, a participant has the right to receive appropriate professional information and to be free from undue embarrassment, discomfit, anxiety and harassment
18. The direct or potential benefits to the participant, or the importance of the knowledge to be gained, must not preclude consideration of the inherent risks to the individual.
19. The confidentiality of information received from participants in experiments or respondents to questionnaires or surveys shall be fully protected, both during and after the conduct of research activity, within the limits of the law.
20. Participation in projects must be voluntary. Informed consent must be obtained from all participants and must be documented (unless the requirement for documentation of consent is specifically waived by the IRB). Methods in accordance with the requirements of 45 CFR 46.116 and 46.117, appropriate to the risks of the research, must be used to obtain the participants’ informed consent.
21. In research involving more than minimal risk or substantial stress or discomfit, such risk, stress or discomfort shall be carefully explained to the participant before his or her participation and justified by the expected benefits of the research. The investigator shall be satisfied that the explanation has been understood by the participant; and written consent of the participant (unless otherwise waved by the IRB), containing the substance of the explanation, shall be obtained and kept as a matter of record.
22. IRB Responsibilities – Responsibilities of the Institutional Review Board include:
23. The IRB shall follow the written policies and procedures of Russell Sage College for the protection of human participants in research. These policies and procedures are in compliance with federal regulations and state law.
24. Except when an exempt or an expedited review procedure is applicable, the IRB shall review proposed research at convened meetings at which a majority of the members are present, including at least one member whose primary concerns are in non-scientific areas. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting.
25. The IRB shall review and have the authority to approve, require modifications in (to secure approval) or disapprove all research activities, including changes in previously approved human participants research.
26. The IRB shall require that information given to participants as part of the informed consent process is in accordance with 45 CFR 46.116. The IRB may require that information, in addition to those required elements specified in 45 CFR 46.116(A), be given to participants when the IRB’s judgment the information would meaningfully add to the protection of the rights and welfare of the participants.
27. The IRB shall require documentation of informed consent or may waive documentation in accordance with 45 CFR 46.117.
28. The IRB, through its chair, shall notify investigators by email and in writing of its decision to approve or disapprove the proposed research activity or to request modifications required to secure IRB approval of research activity. If the IRB disapproves or requests modifications to the research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.
29. Certification of IRB review and approval for all federally sponsored research involving human participants will be forwarded by the Chair to the appropriate federal department or agency. Compliance will occur within the time and manner prescribed for forwarding certifications or IRB review DHHS or other federal department or agency.
30. The IRB shall designate procedures for the retention of Russell Sage College’ IRB records and documents for at least three (3) years past completion of the research activity.
31. Scope of Review- IRB review and approval is required for any research involving human participants that:
32. Is conducted by or under the direction for Russell Sage College’ faculty, staff or students in connection with the fulfillment of institutional responsibilities or academic requirement; or
33. Is performed with or involves the use of Russell Sage College’ records, facilities or equipment belonging to Russell Sage College; or
34. Is conducted by researchers not affiliated with Russell Sage College who use members of the Sage community as subjects.

### **Who must Apply?**

All faculty, students, and administrators considering any type of research project that involves human subjects must submit an application for project review to the IRB. Researchers CANNOT recruit subjects and/or collect data (including doing ‘pilot studies’ to pretest the procedures) until the IRB has reviewed and approved the project. Please follow the guidelines and instructions below. Projects involving human participants to be reviewed include, but are not limited to, the following:

1. All projects involving research grant applications to funding agencies (new and continuation applications).
2. All administrative, faculty and student (undergraduate and graduate) research, including honors projects, theses, and dissertations, whether participants are from TSC or obtained elsewhere. Course assignments involving research with human participants may also need to be reviewed (see below).
3. All institutional training, research, or demonstration grants, which might include human research.
4. All projects from outside institutions which involve the use of participants who are enrolled at or employed at Russell Sage College.

#### Contact the IRB Chair if you are uncertain about the necessity of an IRB review

1. Levels of Review- Research projects are reviewed at one of three levels, depending on the IRB’s judgment of the project’s risk to the human participants and on the federal guidelines that define the categories of review. The IRB will give special attention to research involving special populations. While the investigator may make the initial determination regarding the appropriate category of review, the IRB or its designee may require review under another category. The three levels are as follows:
2. Projects thatpose **no risk** to the subjects, including children. (Federal regulations list these as exempt from IRB review. Our IRB reviews these projects using the Limited Review Application to determine that they are, in fact, exempt.) These include:
3. One-time anonymous surveys or confidential surveys or interviews on non-sensitive topics.
4. Research involving interviews (not surveys or experiments) or observations of participants, the purpose of which is educational and there is no intention to use the information beyond the classroom assignment.
5. Benign Interventions: Behavioral, not biospecimens, interventions in conjunction with collecting information from an adult subject through oral or written responses or audiovisual recording if the subject prospectively agrees to the intervention and information collection and conditions are met.The investigator has no reason to think the subjects will find the interventions offensive or embarrassing. The intervention is not likely to have a significant adverse lasting effect on the subjects.These studies have little to no risk to subject, are brief in duration, painless, harmless, and not physically invasive.
6. Secondary Data Research Use: Reusing for research purposes, identifiable and non-identifiable information and biospecimens that are collected for some other “primary” activity (including from research studies other than the proposed research study). Includes Records, Archives, Information Systems; Tissue Repositories, Databanks. Records/information/biospecimens does NOT have to be pre-existing at the time that the investigator begins the study. Confidential records covered by HIPAA are excluded.
7. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement) or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human participants can be identified, directly or through identifiers linked to the participants, and (ii) any disclosure of the human participants’ responses outside the research could reasonably place the participants at risk of criminal or civil liability or be damaging to the participants’ financial standing, employability, or reputation.
8. Research studies conducted in established or commonly accepted educational settings involving normal educational practices, such as research on regular and special education instructional strategies, or research on the effectiveness of the comparison among instructional techniques, curricula or classroom management methods.
9. Evaluation projects: See above for details
10. Taste and food quality evaluation and consumer acceptance studies. See the federal manual 45CFR46 for projects that qualify.
11. Information which is gathered by Russell Sage College or an agent of the Colleges from its employees or students for the purpose of providing information to the administration and/or the college community as a whole to support decision-making.

For ‘No Risk’ studies the IRB notifies the researcher by email of approval. The chair sends a formal approval letter. A cover letter or a verbal explanation should be given to the participants to identify the nature of the project, except in the case of the use of public or existing records or anonymous observation. These projects do not a final report to the IRB by the principle investigator.

1. Projects which pose **minimal risk** to the participants. Federal Regulations identify these projects as qualifying for expedited review. To qualify for expedited review, a research activity must incur no more than minimal risk for participants or represent a minor change in previously approved research that involves no additional risks to research participants, in accordance with 45 CFR 46.110. Examples include:
2. Surveys or interviews on sensitive topics. Sensitive topics might include: Issues about sex, gender, race, diseases, disabilities, PTSD, military service, psychological issues. This is not an exhaustive list. Any topic that could potentially cause emotional, physical or psychological upset, trauma, or pain is considered a sensitive topic. Ultimately, the IRB determines if a topic is considered sensitive.
3. Surveys, interviews, observations of public behavior, observations made by audio or videotape, studies using existing records, and studies using educational tests in which:
4. the information is obtained in such a manner that participants can be identified directly or through identifiers linked to the participants, **and**
5. the disclosure of the participants responses outside the research could reasonably place the participants at risk of criminal or civil liability or be damaging to the participant’s financial standing, employability, or reputation, or be stigmatizing.

To qualify for expedited review for these studies, reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and to breach of confidentiality are no greater than minimal.

1. Minor revisions to a previously approved project.
2. Additional categories of research that may qualify for expedited review are listed in the federal document 63 FR 60364-60367, November 9, 1998. Note that not all research in these categories qualifies for expedited review. The categories of research that may qualify for expedited review include:
3. Clinical studies of drugs or medical devices.
4. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture.
5. Prospective collection of biological specimens for research purposes by noninvasive means.
6. Collection of data through noninvasive procedures employed in clinical practice.
7. Existing records research not exempt (not included in the no risk category).
8. Collection of data from voice, video, digital, or image recordings made for research purposes.
9. 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, interviews, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. Some research in this category may be exempt, that is, included in the no-risk category. This listing refers only to research that is not exempt.

All projects qualifying for expedited review require a written explanation of the project, its benefits and risks to the participant (in a cover letter to the subject or a written script of the verbal explanation) and also require participants to sign an Informed Consent form. A final report is due 90 days after completion of this kind of project. An Annual Report including a request for continuation is also required if the project lasts longer than a year. These are due before the one-year anniversary of IRB approval.

1. Projects which pose a **risk** to the subject. (Full Board Review). A risk is defined under federal law as “a possibility of injury, including physical, psychological or social injury, as a consequence of participation as a subject in any research, development or related activity which departs from the application of those established and accepted methods necessary to meet his or her needs or which increase the ordinary risk of daily life, including the recognized risks inherent in a chosen occupation or field of services.” All proposed research deemed by the IRB to present more than minimal risk to human participants must be reviewed by the full IRB.

Examples of research activities that must be reviewed by the full IRB committee include:

1. **Research involving deception.** Projects that involve deception are always considered a “risk” project by the Sage IRB. Definition of Deception: Authorized deception studies would require a prospective agreement by the subject to participate in research where the subject is informed that he or she will be unaware of or misled regarding the nature or purpose of the research.
2. **Vulnerable populations**: Projects that involve vulnerable participants are always considered a “risk” project by the Sage IRB. Vulnerability of subjects in research studies should be considered ONLY as a function of the possibility of coercion or undue influence. Thus, previous categories, such as pregnant women, handicapped, physically-disabled individuals are not considered vulnerable any longer. Vulnerable categories include:

* Individuals with impaired decision-making abilities
* Prisoners
* Minors (Under the age of 18)

1. **Research conducted outside the United States**, regardless of procedures involved.

A final report is due within 90 days of completion of this kind of project. An annual report including a request for a continuation is also required if the project lasts longer than a year. These are due before the one-year anniversary of IRB approval

SIX - Review Procedures - The IRB Application forms and instructions are on our website: <https://www.sage.edu/academics/research/the-institutional-review-board/>

All Primary researchers submitting IRB applications to the Sage IRB must first send an email to [sageirb@sage.edu](mailto:sageirb@sage.edu) to ask for a project number. Next, fill out the application and once it is completed, submit it to the Sage IRB email [sageirb@sage.edu](mailto:sageirb@sage.edu) with the subject line: Submission IRB #XXX-2021-2022.

Projects submitted for review (both Limited Review Projects and Full Review Projects) are submitted electronically to the IRB Email [sageirb@sage.edu](mailto:sageirb@sage.edu) --see details in the document “Instructions for Web Submission of IRB Projects.” Incomplete proposals will not be reviewed. The signature of the Principal Investigator certifies that the application, including that for a student project, is complete and ready to be reviewed by the IRB. Do not sign any applications until you have read them in their final form.

The Chair assigns the project to a reviewer or reviewers. The chair and reviewers determine the level of review (No Risk, Minimal Risk or Risk). If the study is No Risk or Minimal Risk, the reviewers determine whether or not to approve the project or to approve conditionally (with revisions). When the project is approved, the reviewers recommend approval to the IRB Chair and ask the Chair to send the formal letter of approval. If the chair determines that the project is a “Risk” project, the Chair notifies the reviewers and researchers and places the project on the agenda for review at the next Board meeting. The investigators (including students) are expected to attend this meeting to discuss the application and answer any questions the IRB may have. If the project is a student project, the student is expected to respond to the IRB’s questions. Projects must be submitted at least two weeks before this meeting, so that the board members have a chance to read the proposal before the meeting. The Board approves the project, disapproves the project, or approves the project conditionally (with revisions). The Chair, in consultation with the reviewers, determines whether the revisions are acceptable. When approved or disapproved the chair sends notification by email and formal letter to the researcher.

1. The IRB will come to one of four determinations regarding an application:
2. Approval without questions, concerns or requests for modifications;
3. Approved pending clarification and/or modifications. This indicates that approval of the IRB has been withheld pending clarification and/or modification of specific points or components of the protocol. The research activity may not be undertaken until the IRB’s concerns are addressed and submitted to the IRB or designated member(s) for review and approval.
4. Deferred (tabled). This indicated that approval by the Board has been withheld as substantive concerns or significant requests for clarification have been raised and/or the proposed research does not meet Russell Sage College or federal guidelines for the protection of human participants. The research activity may not be undertaken until the IRB’s concerns are addressed and submitted to the full IRB review and approval.
5. Disapproved. While this action is rarely taken, the IRB may disapprove a proposed activity with serious and substantive problems and/or that fails to meet Russell Sage College or federal guidelines for the protection of human participants.
6. All IRB initial review and continuing review applications shall be distributed to all members of the committee prior to the meeting.
7. When it is determined that consultants or experts will be required to advise the IRB in its review of an application, the research application will be distributed to the consultants or experts prior to meeting.
8. A majority of the membership of the relevant IRB constitutes a quorum and is required in order to convene a meeting for the review of research applications.
9. An IRB member whose concerns are primarily in non-scientific areas must be present at the convened a meeting for the review of research applications.
10. For a research project to be approved, it must receive the approval of the majority of those voting members present at the convened meeting.
11. Approval of the proposed research is usually granted for a period of 12 months commencing on the date the approval is granted by the IRB. Based upon the degree of risk to human participants, the IRB may grant special conditions whereby the investigator has a shorter approval period or must report research progress at specific intervals. Continuation of projects past the approval period requires project continuation review and approval by the IRB.
12. Investigators will be notified by email and then in writing of the IRB’s decision by the Chair of the IRB, in accordance with 45 CFR 46.109(d).
13. When the research activity involves an outside agency (e.g., hospital, public school, etc.), the investigator must secure written approval from an appropriate official within the agency prior to conducting the research.
14. The IRB may not have a member participating in the IRB’s initial or continuing review of any project in which member has a conflicting interest, except to provide information requested by the IRB.
    1. Criteria for IRB Approval of Research- The IRB uses the following criteria for approval:
15. **Risk/Benefit:** In order to approve research covered by this policy, the IRB shall determine that the following requirements are satisfied:

* Risks to participants are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose participants to risk.
* 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 from the research.

In evaluating risks and benefits, the IRB will consider only those risks and benefits that may result from the research (as distinguished from risks and benefits that may result from therapies participants would receive even if not participating in the research). The IRB will not consider long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility. The IRB will examine study design or scientific merit of a proposed study only within the context of its risk/benefit analysis.

1. **Equitability of Participant Selection and Recruitment:**

Selection criteria should consider all populations that might potentially benefit from the research. Utilization of populations based solely upon ready availability should be avoided. The IRB will take into account the purposes of the research and the setting in which the research will be conducted. The IRB shall ensure that the recruitment of participants is equitable and free of coercion.

1. **Informed Consent Process:** Informed consent will be sought from each prospective participant or the participant’s legally authorized representative and will be appropriately documented, in accordance with and to the extent required by 45 CFR 46.116 and 46.117.
2. **Privacy and Confidentiality:** The IRB shall determine that adequate provision has been taken to protect the privacy of participants and for ensuring the confidentiality of an individual’s participation and confidentiality of study data, as appropriate.
3. **Special Promotions:** When some or all the participants are likely to be vulnerable to coercion or undue influence (such as children, prisoners, pregnant women, handicapped or mentally disabled persons, or economically or educationally disadvantaged persons), additional safeguards must be included in the study to protect the rights and welfare of these participants.
4. **Review by Russell Sage College:** Research covered by this policy that has been approved by the IRB may be subject to further appropriate review and approval or disapproval by officials of Russell Sage College. However, Russell Sage College officials may not approve the research if it has not been approved by the IRB. (45 CFR 46.112)
5. **Data Monitoring**: When appropriate, the research plan shall *include adequate provision for monitoring the data collected to ensure the safety of participants*.
6. **Suspension or Termination of IRB Approval** of Research

* The IRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB’s requirements or that has been associated with unexpected harm to participants (45 CFR 46.113).
* Any suspension or termination of approval shall include a statement of the reasons for the IRB’s action and shall be reported promptly to the investigator. The Chair of the IRB shall inform other appropriate institutional officials and departments or agency heads, as applicable.

1. **Continuing Review**

* The IRB is required to reevaluate research projects at intervals appropriate to the degree of risk but not less than once a year. For research involving no more than minimal risk, the approval period is generally one year. For research involving greater than minimal risk, the IRB will determine the appropriate approval period. The approval letter from the IRB will indicate the approval period and the date for submitting a request for continuation.
* For research with a one-year approval period, investigators must request a continuation for the approval yearly if the activity lasts more than one year. Only two (2) continuations will be granted for a given project. After three years, the project must be resubmitted, as a new protocol, to the IRB for review and approval.

1. **Modifications-** All modifications to currently approved research are required to have IRB review and approval prior to implementation. Minor changes that do not increase risk to research participants may receive an expedited review. Modifications to approved research projects that may affect risk to participants are forwarded to full IRB for review.
2. **Reviewing Reports of Adverse Events**- The IRB is responsible for reviewing reports of any adverse events to research participants or any unanticipated problems that involve risk to human participants in the course of approved research. Upon the receipt of an adverse event, the IRB will determine whether the study should be modified to reduce the level of risk to participants or whether the consent form should be modified to include a description of activities or procedures that could result in adverse effects.
3. **IRB Policy of Research Conducted Without IRB Approval**- Research activities involving the use of human participants under the auspices of Russell Sage College may not be conducted without prior review and approval of the IRB. Any research activity initiated or completed will be reviewed by the IRB on a case-by-case basis. The IRB will review the project, consider how the project was conducted (i.e., if the investigator has initiated or conducted the research without approval or was unaware of the requirement) and if the procedures used in the research violated any of Russell Sage College’ standards of ethical conduct in research. In these cases, the IRB will decide if the investigator:

* can use the data already collected;
* must provide proof of consent, re-consent participants; or retroactively obtain consent;
* can continue the research (if not already completed); or what, if any, modifications need to be made
* must destroy all data collected to date.
* A letter from the Chair of the IRB will be sent to the investigator indicating the reasons for the IRB’s decision, what actions the IRB is requiring and an opportunity to respond to the Board. A copy of the letter will be sent to the faculty advisor if the researcher is a student. A copy of the letter will be sent to the Chair of the department if the researcher is a faculty member.

1. **Research Lacking Definite Plans for the Involvement of Human Participants**- As required under 45 CFR 46.119, the IRB will review proposed involvement of human participants in federal research activities undertaken without prior intent for such involvement, but will not permit such involvement until certification of the IRB’s review and approval is received by the appropriate federal department or agency.
2. **Research Undertaken Without the Intention of Involving Human Participants**- As required under 45 CFR 46.119, the IRB will review proposed involvement of human participants in federal research activities undertaken without prior intent for such involvement, but will not permit such involvement until certification of the IRB’s review and approval is received by the appropriate federal department or agency.
3. **IRB Records**

* Russell Sage College Graduate Schools or when appropriate, the IRB shall prepare and maintain adequate documentation of IRB activities, in accordance with 45 CFR 46.115, including the following:
* Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposed research, approved sample consent documents, progress reports submitted by investigators and reports of injuries or harm to participants.
* Minutes of IRB meetings which shall be of sufficient detail to show attendance at the meetings; actions taken by the IRB; the votes on these actions 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 controverted issues and their resolution.
* Record of continuing review activities.
* Copies of all correspondence between the IRB and the investigator.
* A list of IRB members in the same detail as described in 45 CFR 46.103 (b).
* Written procedures for the IRB in the same detail as described in 45 CFR 46.103(b) (4) and (5).
* The records required by this policy shall be retained for at least three years and the records related to research that was conducted shall be retained for at least three years after the completion of the research. These records must be appropriately secured. All records shall be accessible for inspection and copying by authorized representatives of supporting departments or agencies at reasonable times and in a reasonable manner.

1. **Appealing an IRB Decision**

* If the IRB makes a decision that an investigator believes to be unfair, unsubstantiated or unduly restrictive on his/her proposed research, the investigator should first discuss the matter with the Chair of the IRB. The investigator should be prepared to present reasons he/she believes that the proposed research is in compliance with Russell Sage College’ policy and federal regulations for the protection of human participants.
* If the issue cannot be resolved satisfactorily by negotiation, the investigator may appeal the decision, in writing, to the IRB.
* In developing his/her appeal, the investigator is encouraged to seek the advice or opinion of an objective, qualified consultant (or consultants) to support the claim that the proposed research is in compliance with human protection of human participants policy and regulations.
* The investigator must appear before the IRB to present his/her appeal and any supportive material or documentation obtained through consultation. Based upon this appeal, the IRB will issue a final recommendation, on the proposed research.

# SEVEN- Research and the Classroom

In an academic institution, such as Russell Sage College, research activities occur in the classroom or involve course assignments. Classes are also used to recruit subjects to participate in research. These activities may create problems regarding the protection of subjects in research. This section of the guidelines is designed to give guidance to faculty and students as to the appropriate procedures to be followed in order to protect faculty and students in their roles as researchers and/or participants in research activities related to coursework

**A. Classroom Assignments**

1. Research (observations, interviews, surveys, experiments, etc.) that is carried out by students in the class as a part of the educational experience and involves only students in the class as participants and researchers, is not subject to IRB review as long as the data are used for the assignment and not made public outside the class through oral or written presentation. If the data are made public, the project must be reviewed by the IRB (whether the decision to present the data outside the classroom occurred before or after the data were collected). Classroom assignments, identified above, which do not require IRB review, may still place students at risk. The instructor needs to be aware of this and is responsible for dealing with this issue.
2. If the data for a class project are collected on participants who are not members of the class, the project must be reviewed by the IRB whether or not the data are made public outside the classroom. Honors projects, theses, dissertations, and research methods courses are some examples of courses to which this applies. Observations or interviews of a single person (for example, interviewing a parent about child-rearing practices by a student in a Child Psychology class) do not require review, as long as the data are not used outside the assignment. A case study completed in an internship but presented outside the class (for example, in Russell Sage College research symposium) is subject to IRB review (whether the decision to present is made before or after the case study was completed).
3. If a class assignment must be reviewed by the IRB (i.e., it does not qualify for the exclusion above) and if it is carried out on a regular basis, the faculty member may apply for a Course Approval for that assignment. A Course Approval continues for 3 years and may be renewed. The Approval applies to the Instructor, not the course. An annual report (giving a brief description of projects completed and identifying IRB issues) is required. Use the Limited Review Application to submit an application for a Course Approval. Contact the IRB chair if you have questions.

**B. Recruitment of Participants from and Conduct of Research in a Class for Research Not Related to that Class**

1. If the faculty member seeks to recruit subjects from or conduct research in his/her own classes, the faculty member must provide assurances of anonymity or participant protection to students. For example, faculty might conduct an anonymous survey using a web-based service where students could participate and not be identified.
2. Whenever a faculty member gives permission to someone to recruit participants or conduct research in their class, the faculty member must not be present during the recruitment or the conduct of research.

**C. Grade Credit for Participation in Research**

A student’s participation in research provides a source of participants which benefits the research activities of faculty or other students. It supports the broader academic community rather than the activities of a specific course. The IRB, in its role of supporting the research program of Russell Sage College, encourages giving grade credit for participation in research with the following stipulations:

1. The credit given may be extra credit or a course requirement.
2. Students MUST be given an opportunity to earn the same extra credit or complete the course requirement by completing an EQUAL alternative assignment. Participation in the research is considered voluntary since the student has a choice.
3. The specifics of the assignment(s) must be stated in the course syllabus.

# EIGHT- Other Research Circumstances

## Program Evaluation

1. Program evaluations (involving observations, interviews, or surveys), including those conducted for TSC, are not subject to IRB review if the information obtained is used by the agency for purposes of evaluation with no intent to make the results public. If the results are made public through oral or written presentations, the program evaluation must be reviewed by the IRB.
2. If the program evaluation involves experimental procedures (e.g., pretests/posttests), it must be reviewed by the IRB even if the results are not to be made public.
3. Program evaluations that are done as class assignments are not subject to IRB review unless the results are made public or involve experimental procedures.
4. Program evaluations that are not anonymous and whose disclosure of participants’ responses could reasonably place them at risk of criminal or civil liability or be damaging to their financial standing, employability, or reputation must be reviewed by the IRB.
5. Program evaluations involving participants in special populations must be reviewed by the IRB.

## **Aggregate Data**

If the data exist in aggregate form only, the project does not need IRB review. Aggregate data are data that do not contain responses of individual subjects: for example, a study involving the comparison of percentages of students who were absent from school over a 10 year period in parochial and public high schools. Note that if the researcher has to compute the percentages by reviewing individual student records, then the study requires IRB review.

Copyright Compliance

Complying with copyright law, including obtaining permission from copyright holders to use instruments, is the responsibility of the researcher. Under current law, copyright protection is automatically given to the authors of materials, whether or not a copyright notice is attached, and even if the instrument is readily available in print or on the web. If you have questions about copyright law requirements, you may ask Regina Vertone ([vertor@sage.edu](mailto:vertor@sage.edu)), in the Russell Sage College library.

## **Retrospective Case Reports**

Russell Sage College’s Institutional Review Board (IRB) does not consider a retrospective case report as human subjects’ research as defined by the Federal Policy for the Protection of Human Subjects since it does not involve the formulation of a hypothesis that is systematically evaluated. Russell Sage College’s IRB defines a case report as a medical/educational activity consisting of one, two, or three clinical cases (more than three cases is considered clinical research). The purpose of a retrospective case report is to describe practice and share information with others.

Authors of case reports which include patient information must comply with HIPAA (Health Insurance Portability and Accountability Act of 1996) regulations regarding Protected Health Information (PHI). HIPAA regulations permit case reports provided that patient confidentiality is maintained. Authors, who remove all HIPAA identifiers prior to receiving or using information from medical reports, do not need permission from patients or their parent/legal guardian/designated surrogate. Authors must assure that the information does not include any of the 18 PHI identifiers noted in HIPPA regulations. This means that the case reports cannot contain any information that could potentially identify the patient and that the medical records on which the case report is based must not contain any information that would identify the patient. The 18 identifiers are as follows:

1. Names;  
2. All geographical subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code, if according to the current publicly available data from the Bureau of the Census: (1) The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and (2) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.  
3. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older;  
4. Phone numbers;  
5. Fax numbers;  
6. Electronic mail addresses;  
7. Social Security numbers;  
8. Medical record numbers;  
9. Health plan beneficiary numbers;  
10. Account numbers;  
11. Certificate/license numbers;  
12. Vehicle identifiers and serial numbers, including license plate numbers;  
13. Device identifiers and serial numbers;  
14. Web Universal Resource Locators (URLs);  
15. Internet Protocol (IP) address numbers;  
16. Biometric identifiers, including finger and voice prints;  
17. Full face photographic images and any comparable images; and  
18. Any other unique identifying number, characteristic, or code. (Note that this does not mean the unique code assigned by the investigator to code the data.)

For case reports, it is important to note #18 on the list which specifically states “any other unique characteristic.” Authors should be sensitive to the “small cell” problem where it is possible for others to identify the individual just based on unique characteristics of the patient.

**Since most retrospective case reports are written about unique cases, all authors must receive approval from Russell Sage College’s IRB committee to use and/or report on information in medical records. For case reports, the role of the IRB is to act as a Privacy Board and is limited to the protection of patient privacy.**

Process: In order to disclose information from a patient’s medical record, authors must receive approval through Russell Sage College’s IRB (acting as a Privacy Board) for waiver of signed release from the patient.

I. When submitting an application to Sage IRB authors must provide a facility consent form, granting permission to use information from the medical records. The consent must be written on facility letterhead and signed by the person responsible for medical records.

II. In order for an IRB to approve a Privacy Board waiver (according to the United States Department of Health and Human Services), it has to make sure that the following criteria have been met:

A. The private health information involves no more than minimal risk to the privacy of individuals based on at least the presence of:

1. An adequate plan presented to the IRB to protect PHI identifiers from improper use and disclosure.

2. An adequate plan to destroy those identifiers at the earliest opportunity and adequate written assurance that the PHI will not be reused or disclosed to any other person or entity except

a. as required by law

b. for authorized oversight of the study or for other research for which the use or disclosure of PHI is permitted by the Privacy Rule.

B. The research could not be practically conducted without the requested waiver.

C. The research could not be practically conducted without access to and use of PHI.

When applying for a waiver from Russell Sage College’s IRB committee, please be sure to address all factors noted above, including a detailed description of all information you plan to disclose (including diagnosis), so the committee can identify whether there is more than minimal risk to the patient when disclosing this information.

III. If photos, videos, or voice recordings are to be used, written consent from the patient is required.

For more information about the HIPAA privacy rules please consult the following document from the United States Department of Health and Human Services:

<http://www.hhs.gov/ocr/privacy/hipaa/understanding/special/research/index.html>

# NINE- Responsibilities of the Investigator

In accordance with the provision of Russell Sage College Federal Wide Assurance, research investigators who conduct human participants research under the auspices of Russell Sage College (faculty, staff, students and affiliated researchers), acknowledge and accept their responsibility for protecting the rights and welfare of human research participants and for the following (see Appendix C):

1. Safeguarding Human Participants- Safeguarding the well-being of and information about an individual is a primary responsibility of the investigator. When the investigator is a student, responsibility for the conduct of the research and for the welfare and supervision of human participants lies with both student and the faculty sponsor. All student research must have a faculty advisor.
2. Preparation of the Application for Project Review Form- Investigators shall prepare the IRB Application for project review that includes the following:

* Research investigators shall prepare the IRB Application for Project Review form that includes a complete description of the research project. In the form, investigators shall make provision for the adequate protection of the rights and welfare of prospective research participants and ensure that pertinent law and regulations are observed. The Application for Project Review form is available by contacting the IRB Chair or on our website: <https://www.sage.edu/academics/research/the-institutional-review-board/>
* Research investigators shall include the proposed informed consent form(s) and copies of all relevant information and documentation (questionnaires, test instruments, recruitment tools, scripts, debriefing statements, contact letters, etc.).

1. Submission of the Application for Project Review Form- It is the responsibility of each investigator to bring all proposed research activity involving to use of human participants or activity involving data collection from or about human participants to the attention of Russell Sage College’ IRB for review and approval.

If it is not clear that a proposed research project involves human participants, the investigator is strongly encouraged to consult the Chair of the IRB on the question. Final authority for making the determination on whether the research is human participants’ research rests with the IRB.

All applications must include signatures of all investigators on the project. Electronic versions of signatures are acceptable as of October 2015. Electronic versions of signatures include scanned original signatures, PDF electronic signatures of investigator names.

1. Reporting Modifications in the Research- Any modifications to research after approval by the IRB involve the following:

* Research investigators are responsible for the promptly reporting any changes in the research project to the IRB.
* Changes in research during the period for which IRB approval has already been given, shall not be initiated by research investigators without IRB review and approval, except where necessary to eliminate immediate hazards to the subject(s).
* In most cases, requests for minor modifications will be reviewed on an expedited basis in accordance with established IRB procedures. A request for a major modification will be considered at an IRB meeting.
* Application for modification includes the submission of all proposed changes with a rationale for each proposed change.

1. Submission of Requests to Continue Research- Approval of a human participants’ project is generally for no more than one year, though the IRB may grant an approval for less than one year, depending upon the nature of the research. One month before the expiration of the approval, the Graduate Office will send the investigator a courtesy reminder that approval for the protocol will soon expire. A “continuation” form will be sent to the investigator for studies that continue beyond one year.
2. Apprising Research Participants of Findings that May Affect Participation- Research investigators are responsible for reporting to both participants and to the IRB significant findings developed in the course of the research that may relate to the willingness to continue participation.
3. Complying with IRB Decisions- Research investigators shall be responsible for complying with all IRB decisions, conditions and requirements.
4. Providing Consent Forms to All Participants- Research investigators are responsible for providing a copy of the IRB-approved and signed informed consent document to each subject at the time of consent, unless the IRB has specifically waived this requirement.
5. Retention of Signed Informed Consent Documents- Research investigators are responsible for retaining the informed consent documents signed by human research participants in a manner approved by the IRB. It is suggested that Principal Investigators keep all records for a minimum of three (3) years following completion of the research activity.
6. Submission of Adverse Event Reports and Reports of Unanticipated Problems Involving Risk- Research investigators are responsible for immediately reporting the IRB any adverse events to research participants or any unanticipated problems that involve risk to human research participants in the course of their participation in approved research.
7. Attending IRB meetings- Research investigators are encouraged to attend IRB meetings in which their human participants’ project or research activities are under review.
8. Education and Training- Prior to the submission of a human participants review form for IRB review, the research investigator and all key personnel listed on the Application for Project Review are responsible for being aware of and understanding the policies and procedures required for human participants review by the IRB.
9. Cooperative Research- Research investigators must fully apprise the IRB of research activities at any collaborating site(s). Any change in a previously approved protocol regarding these activities must be submitted and approved by the IRB as a modification before being implemented.
10. **Data Destruction**- The Sage IRB requires that investigators provide information in the IRB application about when and how identifiable data will be destroyed after the completion of research. Research data must be kept for a minimum of 3 years after the completion of the research project. Some regulations and funding sources require researchers to keep the data longer than three years and researchers should follow those guidelines in that case.

Data destruction language in the IRB application should describe how both printed and electronic data will be destroyed. Federal guidance on how to do this is as follows:

*When the decision has been made to end data storage, data should be*

*thoroughly and completely destroyed. Effective data destruction ensures that*

*information cannot be extracted or reconstructed. Many document storage*

*companies now offer onsite shredding and secure destruction of written and*

*electronic records. For electronic data specifically, software products are available.* (Guidelines for Responsible Data Management in Scientific Research, Office of Research Integrity, US Department of Health and Human Services, 2006)

Other guidance can be found here: [Best Practices for Data Destruction](https://studentprivacy.ed.gov/sites/default/files/resource_document/file/Best%20Practices%20for%20Data%20Destruction%20%282019-3-26%29.pdf) or here: <https://www.wikihow.com/Permanently-Remove-Sensitive-Files-and-Data-from-a-Computer>

# TEN- Cooperative Research

1. Russell Sage College will ensure that any of its collaborating entities [i.e., those engaged in human participants research by virtue of subject accrual, transfer of identifiable information and/or in exchange of something of value, such as material support (i.e., money, drugs or identifiable specimens), co-authorship, intellectual property or credits] materially engaged in the conduct of non-federally sponsored research involving human subjects will possess mechanisms to protect human subjects that are least equivalent to those procedures provided for in the ethical principles to which this institution is committed.
2. Russell Sage College will comply with the requirements set forth in 45 CFR 46.114 regarding cooperative research projects. When research covered by this institution’s Federal Wide Assurance is conducted at or in cooperation with another entity, all provisions of the Federal Wide Assurance remain in effect for that research.
3. Russell Sage College may enter into a joint review arrangement, rely upon the review of another qualified IRB that adheres to similar standards of human participant (s) protections or make similar arrangements for the purpose of meeting the IRB review requirements and obviating duplication of effort. Such arrangements must be (a) in writing, (b) approved and signed by the Institutional Official (or designee) of Russell Sage College and (c) approved and signed by correlative officials of each of the cooperating institutions. These arrangements may be entered into on a case-by-case basis, if arrangement is needed for the review of a single research project. Or, for ongoing cooperative research, a more formal arrangement may be entered into, e.g., a memorandum of understanding detailing the joint review mechanism(s)
4. Russell Sage College’ research studies involving a collaborating institution must include a statement in the consent form indicating the existence of the collaborative relationship. Use of a single, consolidated informed consent form for such studies is strongly encouraged. In addition, copies of all correlative protocols and consent documents required at collaborating institutions must be kept on file at Russell Sage College.

# ELEVEN- Education and Training

In accordance with federal regulations, Russell Sage College will ensure that the IRB Chairperson, the IRB members, investigators, and relevant administrative personnel complete appropriate education related to the protection of human participants before reviewing or conducting human participant (s) research.

1. The Human Protections Administrator, the IRB Chairperson, IRB members and Research Compliance Office staff must complete a training course regarding human participant research. The CITI Program’s Human Subjects Training course is one such course. The link to this is given on our website. The certification must be renewed every five years. IRB members are also required to participate in ongoing educational and training programs as required by the Research Compliance Office. In addition, new IRB members must complete an orientation program to the IRB review process. The IRB chair will provide this orientation and training.
2. Prior to the submission of a human participants review form for IRB review, the research investigator and all key personnel listed on the protocol must complete a training course regarding Human Subjects Research, like the CITI program course mentioned above. Re-certification of the investigator and his/her key personnel is required every five years and will be accomplished through an appropriate continuing education program. If the investigator is a student, the student’s faculty advisor must also complete an appropriate training course.

Appendices (Separate documents found on the IRB website <https://www.sage.edu/academics/research/the-institutional-review-board/>

Appendix A: Federal Regulations and Reports

The Belmont Report

Code of Federal Regulations 45 CFR 46

### Appendix B: For Investigators

IRB Applications and Instructions

Samples of Informed Consent Form and Confidentiality Agreement

Final Report

Annual Report

### Appendix D: IRB Information

IRB Membership

IRB Meeting Schedule

Updated and Approved by the Sage IRB Board August 2021