Siena College Institutional Review Board (IRB) Handbook

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Introduction

Role of the IRB

The role of the Institutional Review Board (IRB) is to protect the rights and welfare of people participating as subjects in research while facilitating and promoting ethical research by Siena College faculty, staff, and students. The IRB follows a federally-mandated process to review research proposals that involve human subjects.

Purpose of the Handbook

The Siena College IRB Handbook is designed to provide information about the IRB process and the roles and responsibilities of both the IRB, faculty supervisors, and research investigators (principal investigators and co-principal investigators).

Additional information including templates may be found on the IRB website. Please feel free to consult the IRB (irb@siena.edu) at any point in the process of determining if IRB involvement is required or during the completion of an IRB application. The IRB welcomes the opportunity to assist members of the Siena community in the completion and submission of thorough and accurate applications.

Scope

The IRB process pertains only to research involving human beings as subjects, and the Siena College IRB is required by the U.S. Department of Health & Human Services (HHS), Office for Human Research Protections (OHRP) to review and approve all research conducted by any Siena College constituent or affiliate that involves human subjects. As prescribed by the Code of Federal Regulations (45 CFR Part 46) -- also known as the Common Rule -- the IRB helps to protect the rights and welfare of these subjects. The IRB has the authority to approve, require modifications, or disapprove all research activities that fall within its jurisdiction as specified by HHS. Research must be approved by the IRB prior to initiating any activities associated with the research, on or off campus.

On January 19, 2017 HHS released a new version of the Common Rule, which is scheduled to go into effect in January 2018. Until the new regulations take effect, Siena College will continue to comply with the existing Common Rule.

Please note: Research involving vertebrate animals must be reviewed and approved or exempted by the Siena College Institutional Animal Care and Use Committee (IACUC).
Policies and Procedures

I. IRB Review Categories

Siena College students, faculty, administrators, staff, and other Siena College constituents conducting research (see 1 below) with human subjects (see 2 below) will be required to submit an IRB application unless a project is not defined as research by OHRP.

1) OHRP defines "research" as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities."

2) A "human subject" is a living individual about whom an investigator (whether professional or student) conducting research obtains
   ○ data through intervention or interaction with the individual or
   ○ identifiable private information.

OHRP has a helpful decision chart to assist with determining if a project qualifies as research with human subjects.

If the research project meets both of these federal definitions, an IRB application will need to be submitted and reviewed by the Siena College IRB. There are three types of IRB reviews: Exempt, Expedited, and Full, all of which require submission of an application. Consult the National Institutes of Health (NIH) questionnaire to determine which review category is appropriate for your project. A brief description of each review type is given below.

IRB Review Type 1: Exempt: Due to the potential for conflict of interest if an investigator is allowed to determine that a research study is exempt, OHRPs long-standing recommendation is that investigators not be given the authority to make an independent determination of the project’s review category. Please note that data collection using voice, video, digital, or image recordings may be considered to be IRB Review Type 2, Expedited Review category #6. To be deemed exempt, research activities must be reviewed by the IRB and determined to fall within one or more of the exemption categories outlined by federal regulations:

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
(i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if:

(i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

(4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. Note: This category encompasses publically available secondary datasets.

(5) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:

(i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

(6) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

For guidance in determining the appropriate category for your project, please consult OHRP Chart 2.

Exempt status does not, however, lessen the ethical obligations to subjects as articulated in the Belmont Report and in disciplinary codes of professional conduct. Thus, depending on the circumstances, researchers performing exempt studies may need to make provisions to obtain informed consent, protect confidentiality, minimize risks, and address problems or complaints.

**IRB Review Type 2: Expedited:** Research deemed to be expedited requires the project to be reviewed by at least one member of the IRB. Expedited review is required for activities that meet the following criteria (see OHRP Chart 8):

1. Clinical studies of drugs and medical devices;
2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture;
3. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or...
microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves.

5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

6. Collection of data from voice, video, digital, or image recordings made for research purposes.

7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

8. Continuing review of research previously approved by the convened IRB as follows:
   - where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
   - where no subjects have been enrolled and no additional risks have been identified; or
   - where the remaining research activities are limited to data analysis.

9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

**IRB Review Type 3: Full:** Research that does not qualify for exempt or expedited levels of review must undergo a full IRB review by a quorum of IRB members at a convened meeting (see OHRP Chart 1). Research activities that may require a full review include:

- research placing humans at psychological or physiological risk that is greater than minimal risk (due to the inclusion of highly sensitive topics or deception)
- research that involves interaction with minors (under the age of 18) or other potential vulnerable populations (e.g., prisoners, pregnant women, children)

A full review involves a convened meeting at which the majority of the membership of the IRB are present, including at least one IRB member whose primary concerns are in nonscientific areas.
II. Principal Investigators

Only Siena College employees, current students, staff, and administrators can be listed as the principal investigator (PI) on the IRB application. Regardless of an external investigator’s role in the research (e.g., PI on a grant proposal, supervisor, lead researcher), he or she cannot serve as the primary PI on the Siena College IRB application.

IRB approval is valid only as a student or employee of the College. Given the IRB oversight responsibilities, individuals who separate from Siena College will no longer have IRB approval to continue data collection or be eligible to submit an application as an affiliate of Siena College.

The principal investigator, Co-PIs, and faculty supervisor listed on the application must have successfully completed the NIH Protecting Human Research Participants training or equivalent (e.g., Collaborative Institutional Training Initiative - CITI). The IRB cannot approve any IRB application without proof of NIH or CITI certification for each PI, co-PI, and faculty supervisor.

Training must have been completed within four years of the end date of the application. Current NIH or CITI certification completed at another institution is valid.

All individuals who will have access to the data must be listed as either the PI or a co-PI on the project.

Within 48 hours, investigators are required to report to the IRB:

- noncompliance
- risk that was greater than proposed
- unanticipated problems that occur during the research.

III. Multi-Institutional Collaborations and Agreements

Siena College 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 Siena’s IRB. Principal investigators of such research are required to submit their IRB approval to Siena’s IRB. Individuals unaffiliated with Siena who will be listed as members of a Siena study team but who are at an institution or organization without an IRB must have an Individual Investigator Agreement in order to perform work on the project.

Unaffiliated investigators who wish to conduct research that takes place on the Siena campus or that involves Siena College faculty, students, or staff should submit a copy of the application to and approval letter from their institution’s IRB to Siena’s IRB by e-mail.

For some collaborations an IRB Authorization Agreement (IAA) is appropriate between two institutions whose faculty are engaged in human subjects research. An IAA allows an institution with a Federalwide Assurance (FWA) to extend the applicability of its FWA to cover another
institution or organization for a project, particularly when the relying institution lacks an IRB. Investigators in such collaborations should consult Siena's IRB on how to proceed.

IV. Protecting Privacy of Human Subjects and Securing Data

Privacy

PIs are responsible for protecting the privacy of the participants involved in his/her research. The PI must make a determination of whether the project can guarantee anonymity (absolutely no identifying information is available to the PIs and cannot be linked to the participants based on their responses) or if confidentiality is all that can be expected. When possible, personally identifiable information should be removed from the data records (e.g., respondent's responses). Signed Informed Consent forms should be kept in a separate location from the data records. Any document or recorded data (audio/video/digital images) that can identify the subject should be kept separate from the informed consent document. During the informed consent process, explicit permission should be obtained from a participant if you plan to publish or publicly present any information or image(s) that can be directly connected with a participant.

Recruitment of Participants

During the recruitment and data collection process, PIs have a responsibility to identify prospective participants in a manner that does not compromise expectations of privacy related to membership in, receipt of services from, or employment by an organization. Special consideration must be given to expectations of privacy held by prospective participants who have provided e-mail contact information or other personally identifiable information to someone and/or an organization for a specific, limited use. The IRB will need documentation of permission for e-mail contact information or other personally identifiable information to be released for the purposes of recruitment of participants; this should be included in the organizational support letter provided with your IRB application. Proposed involvement of vulnerable populations may require special consideration and a full review by the IRB.

Security: Data Collection and Storage

PIs have a responsibility to ensure the security of the data collected throughout the project, including consideration of the methods used to gather and store the data. This is particularly important if your project involves the protection of raw, personally identifiable data gathered via any methodology.

The IRB works with ITS to identify appropriate data collection and storage strategies that reduce vulnerability to the loss of privacy or risks of the violation of confidentiality and solutions to address concerns about the secure storage of data. Due to the inherent insecurity of personal smartphones, their use is discouraged. We encourage the use of encrypted portable storage devices. However, if a smartphone must be used, it should be secured (password protected/encrypted) and data should be transferred from the phone to secure storage as quickly as possible. Portable storage devices (flash drives, external hard drives, etc.) and laptops must be properly encrypted. Researchers are encouraged to use Siena provided laptops as a secure
option. If you are using a device not mentioned in this policy, please seek guidance from ITS Instructional Technology about the proper way to secure your research data.

The IRB recommends that hard copies of research materials (e.g., informed consent sheets, surveys, transcripts of interviews, etc.) be kept in a locked cabinet in a secure office on the Siena College campus. Electronic data files saved on a portable storage device or laptop should be password protected, encrypted and transferred to a secured Siena College server or drive as quickly as possible and then deleted from the portable storage device.

Per OHRP requirements, all records relating to the research approved by the IRB should be kept for at least three years after completion of the research. This includes electronic as well as paper records. All records shall be accessible for inspection and duplication by the IRB or other authorized representatives of the department or agency at reasonable times and in a reasonable manner.

V. **Online Surveys**

Although online surveys afford a convenient and easy administration of surveys and other participant inquiries, particular attention to the impact on the subjects should be considered. A few of those considerations are listed below.

- **Anonymity vs. confidentiality** (see Glossary for definitions) - Most online surveys can be administered anonymously; however, the information collected by the online service or software should be carefully considered. Many online surveys collect IP address, time started, time to complete survey, and if the survey was completed. This could be enough information to identify a participant and hence, the subject’s participation is not anonymous. This may particularly be the case for surveys with small samples, low response rates, or when a convenience sample of family and friends is being used, in which case assuring participants of confidentiality may be all that is feasible.

- **Ensuring voluntary participation** - OHRP requires the inclusion of a statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled. In addition to including this language in your informed consent document, online surveys should be programmed to allow participants to skip individual questions, provide a “prefer not to respond” option, or provide strong justification as to why items cannot be skipped.

- **Informed consent template** - Because in-person interaction may not occur during the informed consent process, it is important to describe the timing and the distribution of the informed consent form. Issues that need to be addressed in the IRB application include:
  - Will the informed consent also be administered online? (If so, identifying information does not need to be provided as part of the consent process.)
If the informed consent is collected separately (via hard copy) from the online survey and contains identifying information, how will it be stored to ensure anonymity of responses?

- How will the participant be able to opt out of the survey and not provide consent once he/she has started to take the survey?

- Investigators should be willing to provide access to the online survey to the IRB.

VI. **Process for Application Submission, Review, and Criteria for Approval**

The IRB is now accepting applications via an online submission process (ProcessMaker).

Go to [www.siena.edu/IRBAPP](http://www.siena.edu/IRBAPP) and login with your Siena username and password and complete all relevant sections of the online form. Note that required fields are marked by a red asterisk. If a field requires explanation, a question mark will appear in a blue circle to the right. You can hover over this circle to read the detail.

If you experience any technical challenges while submitting an application, please contact Heather Dobbin at hodobbin@siena.edu. If you have questions regarding the content of the application, contact the chair of the IRB at irb@siena.edu.

**Submitting your Application**

When you click submit, you will receive alerts if any required sections of the form have not been completed. If you choose to submit the application without saving it first as a draft and reviewing it (this is highly discouraged), you will need to confirm that you want to submit your form to the IRB without saving and reviewing a draft by clicking “Accept” in the pop-up box that appears.

**Saving as Draft**

If you cannot complete the application in one sitting, you can click the “Save as Draft” button. (You are encouraged to save as a draft periodically to prevent the loss of your work.) You will receive an e-mail containing a link which will allow you to access your Draft at a later time. You will be able to edit any information that you have submitted as well as add and delete appendixes that you have uploaded. In addition, you will also be able to review the generated PDF application before it is submitted.

**Certifications**

You are only responsible for submitting your own training certification. If you have previously submitted a certificate and it has not expired (Note: Certificates are good for 4 years), you will see a link to that file and will not be required to upload a new one. After you submit your application, any co-PIs or Faculty Supervisor that you have listed will be notified via e-mail and will be required to submit their own certification while reviewing the application. You will receive an e-mail notification when each of your co-PIs completes their review. After all co-PIs and the Faculty Supervisor (if applicable) have reviewed the application you will be notified and the application will be submitted to the IRB Chair.
Attaching Appendices
When attaching an appendix, please note that only PDF files can be uploaded. To add more than one appendix, click on “Add Additional Documents” and another line will appear with a “Choose File” button which will let you select the file from your computer. The files are not uploaded until you either click “Save as Draft” or “Submit” at the bottom of the form. If you have selected the wrong file and have not clicked either of these buttons you can click “Delete” which will appear in blue to the right of the chosen file to prevent it from being uploaded.

Deleting and Replacing Appendices
When an application is saved as a draft or is sent back to you for revisions, you have the ability to delete and replace appendixes that have already been uploaded. To delete a document, click on the "Delete Documents" button to the right of the documents. This will bring you to a screen that lists all of the documents associated with your account. Each document will have a delete button to the right. Click on the delete button associated with the file you would like to remove. When you are done, click the "Next Step" button. This will bring you back to the application where you can upload any additional files under the appropriate section. The “Choose File” button will let you select the file from your computer. The files are not uploaded until you either click “Save and Close” or “Review and Submit Application” at the bottom of the form.

Submitting your Application
When you click submit you will receive alerts if any required sections of the form have not been completed. If you choose to submit without saving as a draft, you will need to confirm that you want to submit your form to the IRB without saving and reviewing a draft by clicking “Accept” in the pop-up box that appears.

THE APPROVAL PROCESS

An IRB application is approved by the IRB and not any individual member. Approval is granted upon sufficient description, explanation, and/or documentation that the research will be conducted in accordance with OHRP regulations.

Research proposed in an application is approved when the IRB is confident that appropriate steps have been taken to minimize the risks to subjects and that subjects are informed to the fullest extent possible. Criteria for approval include:

- Application is complete and all required supporting documentation is submitted. This includes the submission of current certification for every investigator listed on the application.
- Potential risks to subjects are identified, minimized, and are reasonable in relation to anticipated benefits.
- Selection of subjects is appropriate to the methodology and goals of the project. The investigators should be particularly cognizant of the research challenges involving vulnerable populations.
- Strategies for identifying and contacting prospective subjects are described and appropriate steps have been taken to protect the privacy and confidentiality of these individuals during the recruitment process. Materials used for recruitment must be included in the application (e.g., copy of a flier, text of proposed e-mail or social media
posting, text for Daily Digest posting, etc.). Required in the recruitment correspondence is the following:

- Brief description of the purpose of the research and what is involved in participation
- Indication that participation is voluntary
- Name and contact information for the PI and Faculty Supervisor (if applicable)
- The following statement: “This research project has been approved by the Siena College Institutional Review Board (IRB #**-**-***). If you have any questions about the research or the potential impact of participation, you can contact the chair of the IRB at irb@siena.edu.”
- Link to the online survey (if applicable)

- Description of the informed consent process is included. Informed consent will be sought from each prospective subject or the subject's legally authorized representative (LAR). Information on the informed consent document must correspond to the information provided on the application and include the components required for informed consent (*you are encouraged to use the informed consent template on the IRB website*):
  - Description of the purpose of the research and what is involved in participation;
  - Potential benefits/risks/compensation
  - Voluntary participation
  - Confidentiality
  - Contact information
  - Verification of consent

- There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data (if applicable).
- Additional and appropriate safeguards have been included in the research to protect the rights and welfare of these subjects when some or all of the subjects are likely to be vulnerable to coercion or undue influence.

Note that an IRB application can still be approved even if the research proposal indicates that there could be potential for greater than minimal risk to subjects or sensitive information is required of subjects. However, the PI must:

- Provide a clear and convincing explanation of how the benefit(s) of the research is (are) greater than the risk(s) to subjects.
- Detail how subjects are informed about the risks as well as the conditions in which they consent or refuse to participate.
- Describe the precautions or interventions that will be available to the subjects to mitigate the risk.
- Explain why alternative methodology is not feasible.

The IRB is encouraging the use of inclusive language and response categories that reflect an inclusive range of response options (see the Resource section).
Anticipated Timeframe for Approval

Timeframe for review and approval is influenced by the type of review that is needed.

- **Exempt**: The duration of the review required for an exempt application takes approximately a week. Feedback is generally sent 1-2 weeks after IRB application is submitted.
- **Expedited**: The duration of the review for this application type can be upward of 2 ½ weeks. However, feedback is generally sent 2-3 weeks after IRB application is submitted.
- **Full**: For approval of a full application, the majority of IRB members must vote to approve. As part of the approval process, the IRB will convene to discuss the application. Therefore, feedback is sent to the PI after the next meeting of the IRB. Plan on 1-3 months for feedback depending on the complexity of the research design, instrumentation, and recruitment of subjects.

The review process will be significantly delayed if the application is not clearly written, not thorough, or incomplete (missing attachments), resulting in the need for revision and resubmission of the application.

Process for Resubmission

If revisions are required prior to approval, a detailed description that outlines the necessary changes will be sent to the primary PI and the faculty supervisor (if applicable) via ProcessMaker. The message may also include helpful suggestions for improving the clarity of the application materials and their presentation to potential participants, but those will be separate from the outline of required changes.

The review process may be significantly delayed if the requested revisions are not made and/or if the application remains incomplete.

VII. Revisions after Approval & Renewal

Revisions after Approval

Revisions after approval should be brought to the attention of the IRB Chairperson. Any proposed changes to the research must be approved prior to implementing the change by sending a detailed e-mail (please include the IRB number in the subject header) about the proposed changes to the IRB Chair. Examples of modifications that require the submission of a revised approved application include but is not limited to changes in or additions to:

- recruitment strategies
- subject population(s)
- data collection strategies
- research methodologies
- changes in instrumentation
- storage and securing of participant information and/or data
- investigators
Depending on the type/extent of the proposed changes, approval will remain in place or the PI will be required to submit a revised IRB application that incorporates the changes. Failure to do so may result in termination of approval (see Section VIII - Terminations).

Please note: The purpose for submitting revisions to exempt research is to ensure that the study remains exempt.

Renewals

IRB approval for the data collection phase of an expedited or full-review project is granted for one year. Renewal for ongoing data collection beyond this end date should be requested at least one month before the IRB approval will expire. Certification of PI, all Co-PIs, and faculty supervisor (when applicable) should be current through the renewal end-date.

VIII. Monitoring of Approved Applications

IRB Monitoring

The IRB has the responsibility to ensure that approved research is conducted as proposed. As such, a random sample of investigators that are currently conducting research may be subject to solicitation by the IRB about their research.

Terminations

The IRB has the authority to terminate or suspend their approval of research if the research is not conducted in accordance with the process specified in the approved application, noncompliance with federal (45 CFR §46.113) or state regulations, or has been associated with unexpected serious harm to subjects.

Close-outs

When feasible, the IRB should be informed when:

- the research will not be conducted;
- the research has been discontinued prior to completion; and/or
- collection of data has concluded.

Correspondence should include the primary investigator’s name, IRB #, approval date, and type of review.
IX. **Roles and Responsibilities of Faculty Supervisors and Student Investigators**

**Faculty Supervisor Roles and Responsibilities**

The success of student research hinges on active and informed involvement on the part of the faculty supervisor. Completion of and compliance with the IRB process is the responsibility of the faculty supervisor. Specific roles and responsibilities of the faculty supervisor include:

- Active involvement in the development of the research project and the completion of the IRB application in consultation with the student PI.
- Be familiar with the timeframes required for IRB review and approval and carefully consider these timeframes when incorporating research projects into a course or independent study experience.
- Provide opportunities for students to learn about the protection of subjects and the IRB process, such as:
  - Familiarize students with [Siena College’s IRB website](http://www.siena.edu/irb) and the resources contained on the website.
  - Review important components of subjects protection in conjunction with providing incentive to students to complete the NIH training (e.g., course credit).
  - Invite a [member of the IRB](http://www.siena.edu/irb) to speak to your students during class and/or a group meeting about their research projects and the completion of an IRB proposal.
- Carefully proofread the application for completeness and accuracy. Provide corrective feedback to the students prior to signing the application. Delays are inevitable when an application is submitted prematurely.
- Complete the NIH online training once every four years and provide a copy of your certificate of completion to students for submission.
- Monitor the student's progress with the research and help the student PIs to notify the IRB if any challenges, concerns, or changes arise during implementation of the research.
- Facilitate submission of a renewal request if the timeframe of the research exceeds one year from the date of approval.

**Accountability**

Incomplete IRB applications and inadequate resubmissions may require consultation between the PI, the faculty supervisor and the IRB Chairperson, or a designee. Note that this will substantially delay the approval of the IRB application.

Therefore, it is imperative that faculty supervisors be knowledgeable and keep abreast of current IRB procedures and OHRP regulations. Faculty supervisors who show disregard for the IRB policies and procedures or who fail to adequately review student IRB submissions they are advising will be asked to meet with the IRB to help improve the guidance provided to their student(s). Ongoing neglect in the review of student IRB applications and/or revisions required following initial submissions will result in a meeting with the appropriate dean.
Student Roles and Responsibilities

All students involved in the implementation of research should be involved in the development of the materials that will be used to conduct the research and take part in the completion of the IRB application. Specific roles and responsibilities of each student include:

- An obligation to conduct human subjects research in an ethical manner. Completion of the [NIH online training](https://templates.nih.gov) will facilitate the understanding of this obligation by supplementing and/or reinforcing any information that has been gained in research methods coursework.
- Reviewing templates/examples on the IRB site of informed consent documents.
- Thoroughly completing every section of the IRB application. Indicate “not applicable” if a section is not relevant to the research.
- Contacting your faculty supervisor and/or the IRB Chairperson for assistance if there are questions about a particular section or concept.
- Including all required supplemental materials (see Tips for Success below).
- Allowing adequate time for your faculty supervisor to review your proposal and provide feedback prior to the submission of the application to the IRB. Delays in approval are inevitable if an application is submitted prematurely.
- If you decide to add methods of recruitment other than those identified in your IRB proposal, submit a revised IRB proposal and gain approval for those additional methods BEFORE recruiting additional participants.
- Contacting the IRB and notify your faculty supervisor if any challenges, concerns, or changes arise during implementation of the research.
- Requesting a renewal if the timeframe of the data collection exceeds one year from the date of approval.

Off-Campus Research Opportunities (Study Abroad/Internships/Service)

While participating in a study abroad program, an internship/field placement, or a service experience off campus, a Siena student may have the opportunity to participate as a PI or co-PI in research that involves human subjects. In this type of situation, a student should contact Siena’s IRB one month prior to becoming involved in the research to determine whether or not an IRB application is necessary. Be prepared to answer the following when consulting with the IRB:

- Has the research already undergone human subjects review through another institution or organization? If so, please provide Siena’s IRB with a copy of the application and documentation of the research approval.
- How do you plan to disseminate the findings from the research? Have your dissemination plans been included in the informed consent process?
- How will you ensure confidentiality or anonymity and privacy?
- Are there barriers due to differences in language or dialect?
X. IRB Membership

The IRB will consist of at least one faculty member with a full-time load from each school. There will also be one representative each from Academic Affairs and Student Life. As required by HHS, a member external to the college will be appointed by the Vice President for Academic Affairs (VPAA). All are voting members. The Human Subjects Compliance Officer will also serve on the IRB ex-officio but is not eligible to vote.

Nominations

IRB members can be nominated by one or more of the following:
- IRB Chairperson, Human Subject Compliance Officer, or other current IRB members
- Dean or department chair
- VPAA or Vice President for Student Life
- Self-nomination

Nominations will be approved by the VPAA. Appointment duration is three years. Faculty appointments will be staggered. Members can serve up to two consecutive terms but must be re-appointed for each consecutive term. Exceptions to this term limit may be considered depending upon committee needs.

The committee will review the qualifications of prospective members and make recommendations to the VPAA for appointment.

IRB members should have experience with research involving human subjects and familiarity with the IRB. Ideally, IRB members should have served as a faculty supervisor or mentor for student initiated research.

Current members are expected to:
- hold a current NIH or other certification on the protection of human subjects;
- participate in orientation session and appropriate trainings;
- conduct trainings or workshops as needed;
- attend 75% of meetings (Note: In case of scheduling conflicts, alternative means of facilitating participation in discussions will be arranged.);
- review IRB applications as requested and provide feedback as needed in allotted timeframe;
- participate in full reviews and committee member virtual discussions;
- perform other responsibilities as needed.

A chairperson will be elected by IRB members and approved by the VPAA. The chairperson will serve a two-year term and can serve up to three consecutive terms. Faculty membership is recognized as “sanctioned” service for tenure, promotion, and other relevant faculty recognitions.
Tips for Success

The approval of numerous IRB applications has been needlessly delayed by the premature submission of applications that have been hastily completed and/or are incomplete. Following these tips will facilitate the IRB review process:

- Allow adequate time for careful proofreading of the application. The quality of materials that will be distributed to subjects contributes to the public reputation of Siena’s faculty and students as scholars.
- Provide a thorough description of the research including an explanation of the steps and methods that will be used to recruit subjects and implement the research.
- Be sure that all areas of protection for subjects covered in the NIH certification training that are relevant to the research are thoroughly addressed in your IRB application, paying particular attention to the following:
  - Provide a clear description of the target population and potential sample, noting if any subjects are vulnerable (e.g., minors, institutionalized, or are considered to be at risk).
  - Note any potentially sensitive information that will be gathered or any risk(s)/potential risk(s) to subjects, including psychological or emotional distress and how these risks will be minimized.
  - Describe how informed consent of potential subjects will be obtained.
  - Discuss how you will protect subjects’ privacy/confidentiality, including methods for secure data storage.
- Check that the application is complete and submit all required materials, including:
  - E-mail message(s), flier(s), and/or the text of Daily Digest / social media postings that will be used to recruit subjects.
  - Data collection instrument(s) that will be used (e.g., survey, focus group questions, individual interview questions/prompts).
  - Submit informed consent document(s) - see online checklist for required components.
  - Copy of the NIH certificate for each PI and co-PI that reflects the completion of training to protect subjects within the past four years. Students also need to submit a copy of your faculty supervisor’s NIH certificate.
  - Organizational support letters (if applicable).

Glossary

**Anonymity** - No identifying information that can link the subject to his/her responses, behavior, or facts collected as a result of participating in the research. Not even the investigators could identify a specific subject.

**Belmont Report** - The Belmont Report is a summary of the basic ethical principles identified by the national Commission for the Protection of Human Subjects. It states the basic ethical principles (Respect for Persons, Beneficence, and Justice) and guidelines that should assist in resolving the ethical problems that surround the conduct of research with subjects.
Confidentiality - The investigators can identify a specific subject or could link identifying information to data collected from the participant. However, the attribution of that data to the subject will not be shared with anyone except the investigators.

Generalizable Knowledge - Research that is intended to contribute to the existing knowledge base of a given discipline(s). Activities with the intent to influence behavior, practice, theory, future research designs, and similar are contributing to generalizable knowledge.

Investigations designed to develop or contribute to generalizable knowledge are those designed to draw general conclusions, inform policy, or generalize findings beyond a single individual or an internal program (e.g., publications or presentations). However, research results do not have to be published or presented to qualify the experiment or data gathering as research. The intent to contribute to "generalizable (scholarly) knowledge" makes an experiment or data collection research, regardless of publication. Research that never is published may still be considered research. Subjects in research studies deserve protection whether or not the research is published.

Human Subjects - A living individual about whom an investigator conducting research obtains data through:
   - intervention or interaction with the individual or
   - Identifiable private information (45 CFR Part 46)

Informed Consent - Information must be presented to enable persons to voluntarily decide whether or not to participate as a research subject. It is a fundamental mechanism to ensure respect for persons through provision of thoughtful consent for a voluntary act. Informed consent is an ongoing process, not just a form.

Minimal Risk - The probability and magnitude of harm or discomfort anticipated in the research are not greater than what is ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Privacy - PRIVACY refers to persons; and to their interest in controlling the access of others to themselves. CONFIDENTIALITY refers to data; and to the agreements that are made about ways in which information is restricted to certain people.

Research - Systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge (45 CFR Part 46).

Research Misconduct - A finding of research misconduct requires that:
   - there be a significant departure from accepted practices of the relevant research community including the treatment of subjects. Research misconduct does not include honest error or differences of opinion,
   - the misconduct is committed intentionally, knowingly, or recklessly, and
   - the allegation can be proven by a preponderance of the evidence.

Secondary Data - Data collected by someone other than the investigators.
Secured - Data, research findings, and/or identity of subjects are stored to prevent access by unauthorized investigators and other inappropriate access. Electronic records and documentation associated with the research should be stored in password protected drive owned and maintained by the College.

Vulnerable Populations - Persons not capable of appropriately judging the risks/benefits of their participation in a research due to mental, emotional, or physical impairment. Those who are unable to give consent are also considered vulnerable. OHRP defines vulnerable populations as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

Other examples include individuals:
● with incurable diseases and seriously ill
● persons in nursing homes
● unemployed, impoverished persons, or economically disadvantaged
● ethnic minority groups
● refugees

Other vulnerable persons may include individuals whose willingness to volunteer to participate in a research project may be unduly influenced by the expectation and/or benefits associated with participation, coercion, or of a retaliatory response in case of refusal to participate.

Helpful Links

IRB Application
Informed Consent Form Template
Online Informed Consent Form Template

Sample External Organization Letters

Inclusive Language Resource

Campus Contacts

IRB Chair
Director of Grants and Sponsored Research
Non-human subject research requiring review (IACUC/Biosafety)

Siena Web links
Center for Undergraduate Research and Creative Activity (CURCA)
Grants and Sponsored Research
Siena College Website