Siena College Institutional Review Board (IRB) Handbook

(Revised January 2019 to Reflect Changes to Common Rule)

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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 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 (DHHS), 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 DHHS. Research must be approved by the IRB *prior* to initiating any activities associated with the research, on or off campus.

On January 19, 2017 DHHS released a new version of the Common Rule, effective on or before January 21, 2019. Siena College began complying with the revised Common Rule on January 14, 2019 (beginning of the Spring semester).

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. Human Subjects Research Requiring IRB Review

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. For purposes of this part, the following activities are deemed not to be research:

   (1) Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.

   (2) Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).

   (3) Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.

   (4) Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions."

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.

II. Application (Review) Categories

There are four types of IRB reviews: **Exempt, Exempt Limited, Expedited**, and **Full**, _all of which require submission of an application_. While the researcher is encouraged to identify the level of requested review, the IRB makes the final determination of review category. A brief description of each review type is given below. Please visit the IRB website or click here for a full description of each type of review.

Exempt

Under certain circumstances, human subject research activities subject to the IRB may be granted exempt status. The significance of exempt status is that the research activity is not monitored by the IRB. Assuming the project does not change, it also is not subject to continuing IRB oversight. Exempt status does not 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. To be deemed exempt, research activities must be reviewed by the IRB and determined to fall within one or more of the eight exemption categories outlined by federal regulations:

Informed Consent?	Typically not required
Who Reviews?	IRB chair or one member of the IRB
Expected Time Frame for a Decision?	1-2 weeks

Exempt Limited

A limited IRB review is a type of expedited review process required in the Revised Common Rule. Its purpose is to ensure privacy/confidentiality protections are in place with exempt research that involves the collection or use of sensitive, identifiable data (exemptions 2, 3 and 8) and, for exemption 7, that "broad consent" was obtained and (if appropriate) documented according to an approved protocol. For exempt studies involving access to PHI (e.g., from medical records), the required Privacy Board review may be integrated with Limited IRB Review by the same assigned reviewer.

Informed Consent?	Required
Who Reviews?	IRB chair or one experienced IRB member
Expected Time Frame for a Decision?	2-3 weeks

Expedited

An IRB may use the expedited review procedure to review the following: (1) Some or all of the research appearing on the list described below, unless the reviewer determines

that the study involves more than minimal risk; (2) Minor changes in previously approved research during the period for which approval is authorized; or (3) Research for which limited IRB review is a condition of exemption. 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, heel, or ear 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.

      4. Non-exempt 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).

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

      7. Non-exempt 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.

Informed Consent?	Required
Who Reviews?	IRB chair or one experienced IRB member
Expected Time Frame for a Decision?	2-3 weeks

Full

Research that does not qualify for exempt or expedited levels of review must undergo a full IRB review. Research activities that may require a full review include:
- research placing humans at psychological or physiological risk that is greater than minimal risk
- research involving sensitive topic areas
- research that involves interaction with minors (under the age of 18) or other potential vulnerable populations (e.g., prisoners, pregnant women, children)

Informed Consent?	Required
Who Reviews?	All IRB members. A decision is made at a convened meeting at which a majority of IRB members are present, including at least 1 IRB member whose primary concerns are in non-scientific areas and
Expected Time Frame for a Decision?	1-3 months

III. 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), they 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.

Student PIs are not permitted to conduct research projects that involve greater than minimal risk to participants.

The principal investigator, Co-PIs, and faculty supervisor listed on the application must have successfully completed the National Institute of Health (NIH) *Protecting Human Research Participants Training* or the [Collaborative Institutional Training Initiative - CITI](#) basic training. 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. *(Note: As of 9/27/18, NIH is no longer offering this training and access to previous completion records.)*

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.

IV. Multi-Institutional Collaborations and Agreements

Siena College 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. PI's 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 email.

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 Federal-wide 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.

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V. 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.

VI. 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 - 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.

VII. Process for Application Submission, Review, and Criteria for Approval

SUBMITTING YOUR APPLICATION

The IRB accept applications via an online submission process.

Go to 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.

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 email 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 email and will be required to submit their own certification while reviewing the application. You will receive email 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*: 1-2 weeks
- *Exempt Limited Review* – 2-3 weeks
- *Expedited*: 2-3 weeks
- *Full*: 1-3 months (Requires a convened IRB meeting)

The approval process will be 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. Plan on a minimum of 1 week for every resubmission.

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 Process Maker. 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.

VIII. Revisions (Amendments) after Approval & Renewal

Revisions (Amendments)

Revisions after approval should be brought to the attention of the IRB Chairperson. Any proposed changes (amendments) to the research must be approved prior to implementing the change. This should be done by submitting an "Application for Revision".

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

Prior to implementation of the revised Common Rule, IRB approval for the data collection phase of an expedited or full-review project was granted for <u>one year</u>. After 1/14/19, continuing review will no longer be required for most new studies that qualify for expedited review. The Siena IRB will make the determination of whether continuing review is necessary. Some reasons for maintaining the continuing review requirement include:

- The project is regulated by the Food & Drug Administration (FDA) or by another sponsor that requires continuing review
- The project involves additional regulatory oversight, such as conflict of interest (COI) management
- The research will be conducted internationally or at non-UM sites
- An amendment or incident report reveals new findings that require additional oversight
- The investigator has had previous serious non-compliance or a pattern of non-serious non-compliance

The default for new expedited studies will be that continuing review is *not* necessary. If continuing review is required by the IRB, it will be noted in the acceptance letter and a rationale provided.

Renewal for ongoing data collection beyond the end date should be requested at least one month before the IRB approval will expire by using the "Continuing Renewal" application. Certification of PI, all Co-PIs, and faculty supervisor (when applicable) should be current through the renewal end-date.

IX. 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.

X. 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 IRB's website 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 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 a 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 CITI Training 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, submitting 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's 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?

XI. 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 from Academic Affairs or Student Life. As required by DHHS, 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
- Vice President for Academic Affairs (VPAA) or Vice President for Student Life (VPSL)
- Self-nomination

Nominations will be approved by the VPAA. Appointment duration is three years. Faculty appointments will be staggered. Members can serve up to 2 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 IRB website 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 d*evelop 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

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

HHS Policy for Protection of Human Research Subjects

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

Inclusive Language Resource
    http://williamsinstitute.law.ucla.edu/wp-content/uploads/geniuss-report-sep-2014.pdf