Ursinus College

Institutional Review Board (IRB)
Standard Operating Procedures
Last Revised 6/2021

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General Information

Why does Human Subjects Research matter at Ursinus College?

Ursinus College is committed to safeguarding the welfare, rights, and privacy of all persons who participate as subjects in research projects conducted under its auspices, and to ensuring that the subjects of such research are aware of their rights and the protections available to them.

Moreover, the College is required to assure the federal government that such safeguards are being provided and enforced. These safeguards derive from the following ethical principles, which were first articulated in the Belmont Report issued by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in 1979:

- *Respect for persons:* Recognition of the personal dignity and autonomy of individuals and special protection of those persons with diminished autonomy or particular vulnerabilities, including prisoners, children, those who are mentally or cognitively disabled, pregnant women, or economically or educationally disadvantaged persons. Human subjects should enter into research voluntarily and with adequate information.
- *Beneficence:* The obligation to protect persons from harm by maximizing anticipated benefits and minimizing possible risks. Possible risks to human subjects should be weighed against possible benefits to the subjects, and the possible advancement of knowledge.
- *Justice:* Fairness in the distribution of research benefits and burdens. In selecting human subjects for research, investigators should ensure that no group of participants is either consistently selected to participate in research, or consistently deprived of the opportunity to do so.

What is the role of the Ursinus College IRB in the ethical framework of the Belmont Report?

The primary role of the Ursinus College Institutional Review Board is to protect human subjects, through application of the Common Rule (45CFR46), the ethical principles of the Belmont Report, and its own policies and procedures.

The goal of this document is to allow for the conduct of responsible research involving human subjects, and to protect the health and welfare of those individuals who are subject to such research. While this Policy covers all research on human subjects and intends to safeguard those subjects' rights, researchers themselves also bear responsibility for safeguarding those rights. Thus, they should adhere to the following Statement of Principles and Ethics.

Researchers plan and conduct research with human participants in a manner consistent with federal and state law and regulations, as well as professional disciplinary standards governing the conduct of research. As required by this Policy, researchers obtain institutional approval prior to conducting research. The following ethnical principles, following from the Belmont Report, apply to research at Ursinus College:

- *Informed Consent to Participate:* Prior to conducting research (except research involving only anonymous surveys, naturalistic observations, or similar research), researchers enter into an agreement with participants that clarifies the nature of the research. Researchers inform participants of all features of the research that might influence their willingness to participate. Further, researchers respect each participant's freedom to decline to participate in research or discontinue participation at any time for any reason and without penalty.
- *Minimization of Invasiveness and Harm:* Researchers protect participants from physical and mental discomfort, harm, and danger. Risks to participants are minimized and explained to the participant before she or he agrees to participate. If the research procedure has undesirable effects on participants, the researcher should remedy these effects.
- *Deception in Research:* Researchers do not conduct an investigation involving deception unless they have determined that the use of deceptive techniques is justified by the prospective scientific or educational value and that equally effective alternative procedures that do not use deception are not feasible.
- *Confidentiality and Privacy:* All personally identifiable information obtained from participants is confidential. When the possibility exists that others may obtain this information, researchers inform

participants of this before they consent to participate. All information and data are handled, stored, and discarded in a manner that insures the confidentiality of each participant.

What is the federal definition of research?

The Common Rule (45 CFR 46) defines research as *a systematic investigation designed to develop or contribute to generalizable results*.

What is the definition of a human subject?

Under the Common Rule, a human subject is a living individual about whom an investigator conducting research (faculty or student or staff) obtains information or biospecimens, whether through intervention or interaction, and if data is identifiable and private.

Who must apply?

Any Principal Investigator related to Ursinus College (as defined below) who engages in scholarly research involving human subjects, either on- or off-campus, must apply to the Institutional Review Board for approval of the research.

- Ursinus College faculty and staff;
- Ursinus College faculty who are on leave, and who are conducting research involving human subjects either at Ursinus College, with grant funds administered by Ursinus College, or with Ursinus College students;
- Those representing Ursinus College in an official capacity;
- Researchers not affiliated with Ursinus College who are conducting primary research with human subjects on campus, who are covered by the section below titled "What if I am an outside investigator that wants to use Ursinus College Students, Faculty or Staff as Subjects, including on-campus work?"

All researchers including faculty and students collecting data or those who have access to the resulting data, must complete training in human subjects protection prior to submission of a proposal to the Board.

Researchers must obtain approval **before** undertaking the research. Individuals who meet the definition of a "principal investigator/faculty member" must apply for approval from Ursinus' Board even if another institution's or organization's Institutional Review Board has approved their research.

How do I know if I am doing human subjects research?

Research projects involving human subjects require either review and approval by an IRB, or a determination that the research is exempt. The first question a researcher should consider with respect to IRB review is whether the research project fits the federal regulatory definition of research, and if so, whether it also involves human subjects. In light of the responsibility to protect human subjects and the potential regulatory consequences of not obtaining IRB review and approval, the investigator should err on the side of caution and consult with the IRB when uncertain whether a study constitutes human subjects research. Certain categories of human subject research (for instance: non-sensitive and anonymous survey and some pedagogical research) are exempt from federal human subject research regulations. Those wishing to undertake such exempt research should still obtain confirmation of the exempt status by submitting the **Exemption Request Form**

What is considered a student project? What requires approval?

There is often confusion as to what student projects the Institutional Review Board must consider. Generally, student research involving human subjects falls into one of two categories:

- **Research Practica** - the goal of which is to provide research training
- **Research Projects**, either directed or independent, which employ systematic data collection with the intent to contribute to generalizable knowledge

A **"Research Practicum"** is a course of study that involves the supervised practical application of previously studied theories of research method. A number of departments offer courses that require students to interview or observe other people. The purpose of these courses is to train students and give them an opportunity to practice various research methods. **Such projects do not require review by the Board.**

Examples of Research Practicum can include:

- A class assignment involving the interview of participants using a research protocol, where the resulting data is discarded, for the purpose of teaching students how to undertake interview processes.
- A class analyzing a deidentified dataset and answering a prompt in an assignment to produce an interpretive essay about their results.
- A student interviewing a single person and producing a conference proceeding about that person's life.

A **"Research Project"** is any student-initiated and/or student-conducted research that does not fall under the definition of a research practicum, which uses human subjects, and intends to contribute to generalizable knowledge. Dissemination of findings to a scientific audience is a sufficient, but not a necessary, criterion for defining research. Dissemination includes, but is not limited to, honor's theses; presentation at a scientific meeting or conference; submission to or publication, paper or electronic, in a scientific journal; and Internet postings. **If the project falls under this definition of research (as defined in this document), review and approval of a human participant's research protocol by the Institutional Review Board (IRB) is required.**

When does Research Practicum become a Research Project?

As mentioned above, under the Common Rule, research is a *systematic investigation* designed to produce *generalizable results*. Both of these criteria must be met for the research to fall under IRB purview. Generally speaking, a Research Practicum is a systematic investigation that does not produce generalizable results, as results are kept within the confines of an assignment.

Often, if a systematic investigation produces an artifact for public consumption – such as a conference proceeding, Celebration of Student Achievement (CoSA) poster, article, or other presentation – the investigator is engaging in the production of generalizable results. It is possible for systematic investigations not contributing to generalized results to be published, however it is often best to err on the side of caution and submit to the IRB.

Some activities are also "Exempt" from IRB review, as they fall into a special category under federal law. You can find more about these activities under the "Exempt Protocol Review" section.

It is the responsibility of faculty to mentor their students regarding the distinction between practicum and project. Failing to understand the difference could result in research delays for the student as they seek approval for their project.

Please Note

- Instructors are advised to discuss these guidelines with students **before** the instructional assignment/project begins so informed decisions can be made about whether IRB review is needed.
- If even the slimmest likelihood exists that an instructional assignment/project may fall under the definition of research outlined in this document, instructors are advised to submit the appropriate human participants research protocol to the IRB for review and approval.
- Please remember that IRB approval of a research protocol cannot be granted retroactively under any circumstances.
- When overseeing instructional assignments/projects that do not fall under the definition of research outlined in this document, instructors are asked to advise students to identify the project as **a class assignment**. Labeling such projects as research is inaccurate and misleading for the students, as well as for others with whom the students may interact as a necessary component of completing the assignment. When overseeing instructional assignments/projects, instructors are asked to advise students that any data from human participants that are collected or analyzed should not contain personal identifying information when such information is not required for completion of the assignment/project.
- Instructors continue to be responsible for the ethical behavior of their students in conducting instructional assignments/projects.

Guidelines for Oral History/Ethnography

This guidance is for research using oral history and ethnographic methods for data collection to help determine if Institutional Review Board (IRB) review is required. It is based on Title 45 Code of Federal Regulations (CFR) Part 46 and communications between other universities' IRBs and Dr. Michael Carrome, Associate Director for Regulatory Affairs at the Office for Human Research Protections (OHRP). These

communications were designed to clarify statements that OHRP made to the Oral History Association and the American Historical Association in 2003.

Oral history is a method for data collection, and, analogous to the method of sampling blood, the intended purpose (i.e., goal) for using this method dictates whether its use falls under the federal regulations that cover protections of human research subjects and operations of IRBs (i.e., Department of Health and Human Services regulations at 45 CFR 46). Blood samples taken solely for medical reasons do not fall under 45 CFR 46. However, just as when blood sampling methods are used to collect information that will be analyzed to contribute to generalized knowledge, when oral history procedures are used to that end, that research does meet the definition of research under 45 CFR 46.102(d) and must be reviewed by the IRB. The information and examples below further illustrate this point.

Oral History Goals Requiring IRB Review

- Systematic investigations involving open-ended interviews that are designed to develop or contribute to generalizable knowledge (e.g., designed to draw conclusions, inform policy, or generalize findings) would constitute "research" as defined by 45 CFR part 46. **Example:** An open ended interview of surviving Gulf War veterans to document their experiences and to draw conclusions about their experiences, inform policy, or generalize findings.
- Creation of archives by oral historians and qualitative investigators to provide a resource for others to do research. Since the intent of the archive is to create a repository of information for other investigators to conduct research as defined by 45 CFR part 46, the creation of such an archive WOULD constitute "research" under 45 CFR part 46. **Example:** Open ended interviews conducted with surviving Negro League Baseball players in order to create an archive for future research. The creation of such an archive would constitute research under 45 CFR part 46 since the intent is to collect data for future research.

Oral History Goals Excluded from IRB Review

- Oral history activities, such as open ended interviews, that ONLY document a specific historical event or the experiences of individuals with no intent to draw conclusions or generalize findings WOULD NOT constitute research" as defined by 45 CFR part 46. **Example:** An oral history video recording of interviews with holocaust survivors is created for viewing in the Holocaust Museum. The creation of the videotape does NOT intend to draw conclusions, inform policy, or generalize findings. The sole purpose is to create a historical record of specific personal events and experiences related to the Holocaust and provide a venue for Holocaust survivors to tell their stories. However, if a researcher wanted to use Holocaust Museum data which identified individuals, he or she would have to apply to the IRB.

Projects that do not fit any of the above criteria for "research" as defined by 45 CFR part 46 do not need to be submitted to the IRB for human participants protection review. If either generalizable knowledge or archives for others to do research is a possibility, IRB review and approval must be obtained prior to the involvement of human participants. IRB approval of a research protocol cannot be granted retroactively under any circumstances.

If even the slimmest likelihood exists that a project may fall under the definition of research outlined in this document, investigators are advised to submit the appropriate human participants research protocol to the IRB for review and approval.

Please remember that IRB approval of a research protocol cannot be granted retroactively under any circumstances.

What kind of research is governed by the Ursinus College IRB?

There are unlimited types of research, but research governed by the UC IRB falls under strict rules, governed by federal law. We maintain a comprehensive set of up-to-date and compliant guides to human subjects research governed by the IRB on our IRB website: https://www.ursinus.edu/offices/institutional-review-board/

Does the UC IRB govern research conducted outside of the United States?

Research conducted outside of the United Sates by Ursinus faculty, students, or staff must be reviewed in accordance with Ursinus College IRB review procedures. **Such research must also conform to the standards for research involving human subjects of the host country**. **The UC IRB cannot approve activity in another country, and only has limited authority to approve the use of data collected in another nation in research at home**. Collaboration with colleagues at a local institution in the host country

often provides a good method for ensuring compliance with host country law and human subject conventions in research.

International studies often require additional safeguards to protect the rights and welfare of research participants. There may be cultural differences that should be considered. For example: local customs or laws that might influence how the research is carried out, and possible risks due to social or political conditions. The UC IRB often cannot advise on local customs or laws.

Investigators who will be conducting research internationally need to be prepared to gather and submit the following information for review:

- Description of where the research will be conducted (including geographic location and specific performance site, where applicable). Note: In some areas, government-issued research visas are required.
- Information about the local research context, including the current social, economic, and political conditions of the area, including a description of the investigator's personal experience conducting research (or studying or residing) in the region
- Any additional risks participants might face as a result of the population being studied and/or the local research context.
- The language(s) in which consent will be sought from participants and the research will be conducted, as well as whether the investigator is fluent in this language or whether a translator will be required. If a translator will be used, it should be clear what limitations or risks, if any, this might present for participants, as well as how these potential problems will be overcome or minimized.
- Names of potential contacts not affiliated with the research who can act as cultural consultants

What if I am an outside investigator that wants to use Ursinus College Students, Faculty or Staff as Subjects, including on-campus work?

Research involving Ursinus College students, faculty, or staff over the age of 18 who are recruited off campus and which takes place off campus should be reviewed by the institution sponsoring the research, and/or, the PI's institution. If the investigator is not affiliated with an institution with an overseeing IRB and the research involves Ursinus as an institution, the research should be submitted to the Ursinus College IRB following the procedures outlined here. A form, **Request for Conducting Research at Ursinus College** exists on the website for outside researchers seeking to work with our students, work on our campus, or working in a related capacity.

What if I am an outside investigator that wants to do research on the UC campus?

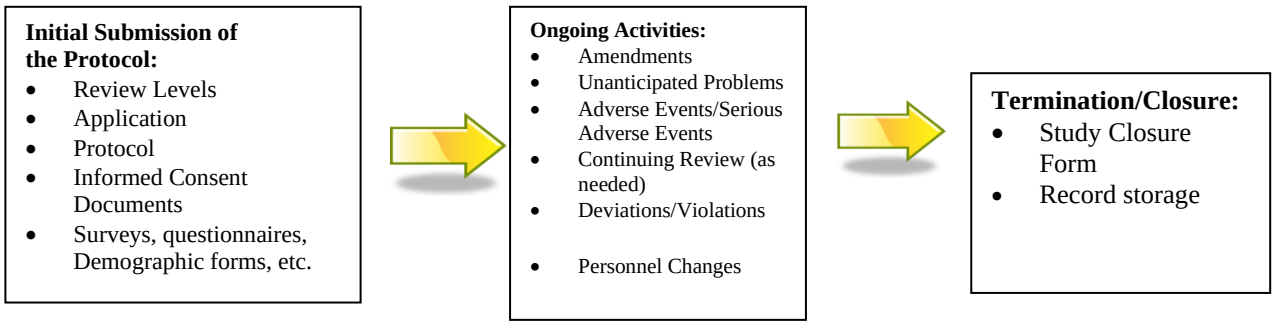
For research involving Ursinus College students, faculty, or staff for research that takes place on the Ursinus College campus, the primary investigator from the home institution must send a copy of the proposal, interview schedules, consent forms, and copies of flyers or advertisements to the Ursinus IRB. This information packet must also include evidence that the research has been reviewed and approved by the investigator's home institution. A form, **Request for Conducting Research at Ursinus College** exists on the website for outside researchers seeking to work with our students, work on our campus, or working in a related capacity.

What about research conducted at off-campus sites with their own Human Subjects Committees?

If some portion of the research is conducted at another institution, that institution may be able to serve as "lead IRB" for purposes of the research. The Ursinus College IRB will normally request some evidence of review and agreement from the home institution.

How does IRB review work at Ursinus College?

The life cycle of a typical proposal is initial approval, amendments, protocol deviations/violations, unanticipated problems, adverse events, serious adverse events, continuing review and completion of the proposal and data analysis. These events must be reported to the IRB by the PI as they occur. Each part of the proposal life cycle is covered below.



What if I am submitting a grant proposal? Do I need IRB approval before my proposal goes out?

Generally, most federal agencies and other grantors do not require submitters to receive IRB approval at the proposal stage. Please advise the IRB if this is not the case with your proposal.

However, upon receipt of award, many grantors and agencies will require written receipt of IRB approval. The IRB and IRB administrator can provide receipt of approval after the protocol has gone through its review. You should work this into your timeline for implementation of your grant.

When will I hear about a protocol?

The IRB may take up to 2 weeks to perform initial review on any proposal, and approval is often a matter of corrections by the PI being reviewed by the IRB, *so plan ahead*!

This two week turnaround time starts from the moment the protocol is accepted for initial review by the IRB Administrator. Incomplete protocols can result in a longer turnaround time, making it important to review human subjects training to create a protocol that can easily make it through the IRB process.

All research proposals are evaluated by the IRB with regard to the degree of "risk", if any, to human subjects. It is expected that most research projects will fall into the Expedited Review category. **THIS DETERMINATION MUST BE MADE BY THE IRB, AND NOT BY THE INDIVIDUAL RESEARCHER.** Full committee review is required when the procedures of the research present more than minimal risk to the subject (see Proposals Requiring Full Review) and/or fall into one or more of the categories specified under Full Committee Review.

If a proposal can be reviewed through the Expedited Review Procedure, the Board will review the proposal following guidelines in *45 CFR 46.110*, and will consult with at least one other member of the Board regarding the proposal. If a proposal is not in a category eligible for Expedited Review, it will be considered under the Full Review procedure.

Any research project that cannot be reviewed using the Expedited Review procedure will be subject to Full Review by the Board. All members of the Board will discuss the proposal. A majority vote of the Board is required for approval of a proposal. Minutes of Full Review discussions will be kept, and a summary of those minutes will be available, on request, to the principal investigator, the human subjects of the research project, and relevant federal, state, or local authorities and funding agencies.

After review of the proposal, a letter will be sent to the investigator by the IRB chair, indicating one of three possible outcomes:

- **Approved** - A protocol which has been approved by the IRB requires no further action from the investigator prior to initiating the study. If the study should extend beyond 12 months, the investigator may be required to submit a **Continuing Review Form** for further IRB review, depending on the nature of the study as determined by the IRB.
- **Revise and Resubmit** - More extensive changes are required before the study may begin. A protocol that has been deferred by the IRB usually requires that additional information be submitted to the IRB prior to approval. A revised application should be submitted to the IRB clarifying the issues involved or providing the requested documentation. Depending on the nature of the concern, the revised proposal will be reviewed by the Chair, the IRB member specifically assigned to the proposal, or the full IRB at its next meeting. Principal Investigators may request the IRB to review its decision, and may write to, or appear before, the committee to discuss the decision.

- **Denied** - The proposed research, because of the level of risk involved, cannot be initiated. Principal Investigators may request the IRB to review its decision, and may write to, or appear before, the committee to discuss the decision.

Board approval of a project is valid for 12 months. If the project closes before the year mark, a **Study Closure Form** should be submitted at that time. Upon the year mark, a Principal Investigator may be required to submit a **Continuing Review Report Form**. Research approved by the IRB that is continuing, may need to be re-reviewed every twelve months by the IRB. The IRB Chair will determine whether a full or expedited review is required. If, during the one year period, the scope of the study changes (for example, if a new experiment is designed and implemented, or if additional human subjects are enrolled in the study) a **Revision Form**, accompanied by a revised protocol, the most recent version of the approved consent form and the revised (if applicable) consent form, must be submitted for Board review. If there are changes made to student investigators, an **Add/Remove/Change Form**, including the student names and years, and the CITI Certificate of Training, must be submitted for Board review. Once the approved research is underway, the investigators will promptly report to the IRB, via an **Adverse Events/Protocol Deviation/Unanticipated Problems Report Form**, any unanticipated problems that pose risks to subjects or others.

How are revisions handled by the UC IRB?

Many proposals initially receive a "Revise and Resubmit" decision. Often the required revisions are very small; sometimes they are quite extensive. The IRB works to respond to revisions as quickly as possible. To resubmit your proposal, please follow these instructions:

- Fill out a new application, checking the "Revised proposal" line in the "Review Status" section
- Write a letter or narrative in which you respond, point by point, to the issues raised in the IRB's decision letter, explaining how you have addressed each issue.
- Submit new or revised documents (consent forms, protocols, etc.) that incorporate the required changes For instance, if the IRB requests clarification about how research participants will be recruited, do not just explain in your letter, but modify the original proposal to incorporate the clarification.
- As with the original proposal, you should submit the revised proposal to **irbadmin@ursinus.edu**

Noncompliance will result in the termination of the study and could result in future submissions being denied. Further, complaints or questions regarding compliance with this Policy should be directed to the Chair of the Board. Such reports will lead to an investigation and may be cause for suspension or termination of IRB approval for the project. Research proposals in need of expedited review may be sent to the Administrator of the IRB at any time. The IRB is available as an advisory board if there are any questions regarding the review process and categories of review.

Training

As part of the College's ongoing efforts to do research ethically, the IRB has implemented the Collaborative Institutional Training Initiative (CITI) Training module for human subjects protections. CITI is the gold standard of human subjects training across higher education. Not only is the training accessible, but UC students continuing on to graduate school or into the healthcare sector will likely encounter the software again.

Starting in fall of 2022, the College will move entire to accepting CITI training certificates as the proper training for human subjects research.

Registering a new account for CITI and beginning training:

1. Go to CITI website: www.citiprogram.org
2. From the home screen, click on Register under "Create an Account"
3. Select Institution/Organization: Enter Ursinus College in the search bar. Click Continue.
4. Personal Information: **Enter your first and last name as you are listed with the College. Under email use your Ursinus email as the email address**. It is recommended that you add another preferred address to the Secondary email address field if you plan to continue in academic human

subjects research after your Ursinus graduation, such as through a job at a medical provider, or in graduate school.
Please note: the email addresses entered here are the ones that any future password requests will be sent to; you are encouraged to use addresses that are stable and make sure to enter them without any typos. Click Continue.

5. Create Your Username and Password: Follow the instructions on the page regarding size and criteria. The username and password can be anything of your choosing that is accepted by the system. Click Continue.
6. Enter your country of residence. Click Continue.
7. Are you interested in the option of receiving Continuing Education Unit (CEU) credit for completed CITI Program courses: You can sign up for these if you choose. CEU's may be required in some programs.
8. Complete the demographic information.
9. Select Curriculum: The next set of screens will guide you through selecting the correct course(s). Select "Social & Behavioral Research" for your course. If you require Biomedical, please contact the IRB.
10. Click on the course name to begin the training. Modules are presented in a linear fashion. There is also an audio slideshow that can be helpful. Proceed through the modules listed on the gradebook. After agreeing to the assurance statement; Click on the name of the Module to start each module.
11. Upon completion of all required modules and achieving 80% overall correct, a link will appear on the Grade Book page with your Completion Report. Keep this report for your records. The IRB will be automatically notified of your successful completion.

Protocol Submission

How does the IRB conduct its review?

There are three levels of IRB review defined in federal regulation (full, expedited, and exempt), determined by the nature of the project, level of potential risk to human subjects, and the subject population. *The type of review applicable to a particular study is determined by the IRB.* However, in order to create a procedure for those studies exempt from IRB review, a researcher can fill out a short Request for Exemption Form for submission to the IRB if they believe their research falls under the Exempt category. The forms can be found on our website.

If you are not sure whether your work is considered research under the regulations, please reach out to the IRB or submit a full IRB application and the IRB will help you with a determination.

Exempt and expedited review can be given to studies that constitute no more than minimal risk to the human subjects, i.e., the risk one experiences in daily living. These reviews are done in the IRB office on a continual basis. Full board review is required for studies that involve greater than minimal risk or vulnerable populations that require special protection by the IRB. These require review by the convened IRB.

What do I submit to the IRB for initial review and approval?

Our two application forms (Request for Exemption and Protocol Application) each list the documents required for submission. The research team is required to keep a copy of these documents, as the IRB approved protocol is the "ethics road map" for how a research study is conducted.

How Long Does the Institutional Routing Usually Take?

On average, the institutional routing for signatures and approvals for expedited and exempt submissions may take up to two weeks and is dependent on the schedules of the department chairpersons and IRB members. The IRB cannot make any guarantees on turnaround time for protocol, as each protocol is different. Full Board reviews are more complicated and involve the coordination of many parties, so researchers should carefully consider how to best work IRB review into their schedule. We advise you to start early!

Can I Start My Study Before I Receive IRB Approval?

No. Research cannot begin until human subjects review is undertaken and the protocol approved.

Can anyone overturn the IRB decision?

The IRB is considered the institutional committee for review of human subjects research and maintains a federally-mandated level of independence from the institution. If an IRB disapproves of a research protocol, there is no institutional authority that can override this decision. If an IRB approves a protocol, the designated institutional authority, usually the Vice President for Academic Affairs, can overturn that decision and disapprove of a protocol. The IRB will work with researchers throughout the process in order to foster a culture of research at the institution, with human subjects protection as its mandate and chief concern.

Full IRB Review

Protocols that require full IRB review, also known as Full Board Review, are those that have a probability for greater than minimal risk. These types of protocols frequently involve special topics and vulnerable groups under federal law.

What are the criteria for Full Board Review?

Under the Common Rule (45CFR46), the IRB reviews protocols as a full committee unless those protocols can, by regulation, fall under Expedited or Exempt review. Any research project that uses vulnerable populations as research subjects, as defined by law and the policies of Ursinus College, must undergo a Full review.

Vulnerable populations are handled in regulation under subpart B (pregnant women, fetuses, and neonates), C (prisoners), and D (children). However, in accordance with its values, Ursinus College further defines

vulnerable populations to include sick persons, elderly persons, mentally disabled persons, and persons who are educationally or economically disadvantaged. The IRB also reserves the ability to identify other vulnerable populations not listed in regulation or in this document, in its effort to protect human subjects.

Any research project that cannot be reviewed using the Expedited review procedure, or that is not eligible for Exempt procedures, will be subject to Full review by the Board.

The IRB has discretion on whether a protocol needs review by its full voting committee.

What Should I Expect After I Submit to the IRB?

The IRB Administrative office staff communicates with the research team members at the time of each submission. The following information will provide additional guidance.

You will receive an email from the IRB administrative office when they accept the protocol for processing, and will also provide the IRB file number for your protocol. You may also receive emails requesting additional information or clarification.

How does the IRB file number work?

Each new protocol is assigned a distinct IRB file number by the IRB administrator. Example: ***AB-PSYC-xxxx-0914F*** (*AB* = PI initials *–PSYC* = Dept. *– xxxx* = protocol reference name *– 0914* = month/year *– F* = Full review). This number, along with the last name of the PI, is used to track all documents and actions related to the study. When requesting information or action for a study, always refer to the IRB file number and the last name of the PI.

When are IRB Meetings?

The IRB aims to meet at least once each semester. If necessary, the committee will hold a meeting for Summer Fellows research projects (depending on the level of review necessary for Summer Fellows submissions). The IRB Administrator will inform the college community of the exact dates of the IRB meetings about a month prior to the meeting. Additional meetings may be convened at the discretion of the Chair. **Principal Investigators may be invited to, or may request to, attend IRB meetings to discuss their proposals.** The full IRB can discuss a protocol without the PI present.

The meeting results of the Committee will be sent to the investigator or designee, initially by email, and then by a hard copy letter signed by the IRB Chairperson or Vice Chairperson. This process may take as long as TWO WEEKS. The Committee will not tell an investigator the status of a proposal prior to the written or emailed notice. **A study may not be started before the receipt of IRB Approval.**

IRB Responses:

The study will be assigned one of the following statuses after the protocol is initially reviewed by the full Committee:

- ***Approval is Deferred*** *(Stipulation request/Changes and clarifications required):* Protocols that fall under this category status indicate that approval is deferred pending a response from the PI to the IRB stipulations (i.e., changes, clarifications) request. The stipulation request will generally pertain to the Protocol, Informed Consent Document (ICD), Children's Assent Document (CAD), survey, etc. The stipulations request is initially sent via email usually within three (3) business days after the meeting date followed by the approval letter signed by the IRB chairperson or administrator. This letter is generally mailed (via campus mail) or scanned and emailed to the PI within five (5) to seven (7) business days after the IRB meeting date. The PI must address each stipulation request promptly in writing as the IRB must receive a response to the stipulations from the PI within 30 days from the date of the letter. The protocol will be administratively withdrawn by the IRB if no response is received by that date. If this occurs, the investigator must resubmit the full review package prior to reconsideration of the protocol. To submit a response, include a memo listing each of the IRB requested changes/modifications/clarifications as well as the response from the research team. For example:
    - The IRB Stipulation Request: Reread for typographical errors.
    - The PI Response: All typographical errors were corrected.
    - The PI must sign all stipulation responses
- ***Protocol is Approved:*** The approval period is for a maximum of one year from the **original** meeting date. This may result in an approval period of less than one full year if the committee requires additional

information and/or depending on their assessment of the risk to benefit ratio. As an example, the protocol is reviewed at a January 21st meeting. The PI adequately addresses all stipulations requested and the Chairperson then approves the protocol on March 1st. The approval period for this protocol will be from March 1st until January 21st. The approval expiration date is noted in the approval letter that is mailed to the PI or his/her designee.

- ***Disapproved:*** Protocols are disapproved if the Committee feels that the risks outweigh the benefits. Only the full convened Committee can disapprove a protocol. Follow submission procedures for new, full review protocols if the research protocol will be submitted once the issues are addressed.
- ***Tabled:*** Protocols may be tabled because the protocol itself was poorly written, the requested/required information was not submitted to the IRB, the submitted protocol was inadequate to address the reviewer's concerns or if the IRB convened meeting fails to maintain a quorum as defined in the IRB Members section. The PI must sign all written responses to a tabled protocol. Follow the submission procedures for new, full review protocols if the research protocol will be submitted once the changes are addressed. Please note that IRB forms are not required to be revised unless the IRB requires changes on the forms. The protocol will be reviewed at the next IRB meeting if required changes are received by the IRB submission date for that meeting. These deadlines are available on the IRB web site. Tabled protocols require a response within 30 days of the date of the letter. The protocol is administratively withdrawn by the IRB if no response is received by that date. If the protocol is administratively withdrawn, the investigator must submit the full review package prior to reconsideration of the protocol.

How Are Stipulation Responses Reviewed?

The stipulation responses from the PI will be reviewed by the:

- Chairperson or his designee if appropriate
- Primary reviewers per their request
- Full committee if requested

An approval letter is generated only if the stipulation responses are adequate. If the responses are not adequate, another request for further clarification may be sent to the PI. The approval by the IRB Chairperson or designee is noted in the agenda and minutes of the next IRB meeting.

When can I start my Full Board Reviewed study?

The protocol may be initiated once all approvals are in place. Institutional Review Boards are forward-looking and cannot retroactively approve and research.

Expedited Review

Proposals which fall into this category may be submitted to the IRB Administrator any time prior to the last two weeks of the semester. They do not have to meet the deadlines established for proposals requiring Full board review. However, the IRB retains discretion in what level of review is required for a proposal, meaning a full board review may be required in some instances.

The regulations allow expedited review procedures for certain kinds of research involving no more than minimal risks (the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests *[45CFR46.102(I)* and *21CFR 56.102(I)),* for minor changes in approved research, and for certain categories of continuing review. These procedures are aligned with initial review of a protocol, review of revisions, and continuing review. Projects reviewed by this procedure require a complete application and are reviewed by the IRB Chairperson, and/or by one or more experienced reviewers who have been voting members for more than one year and who may have expertise in the area being considered. The IRB administrator will designate the individual(s). The Principal Investigator (PI) may request expedited review but the Chairperson or his designee will make this final determination. Approval may be granted, but the Chairperson or his designee may not disapprove the research; only the fully convened Committee can exercise disapproval. Research activity that presents no more than minimal risk to human

subjects and involves procedures listed in one or more of the following categories may be reviewed by the IRB through the expedited review procedure.

If the research involves vulnerable populations, it does not qualify for expedited review.

Who Decides If The Protocol Is Eligible For Expedited Review?

The investigator may request expedited status but the final decision lies with the IRB. If appropriate, the IRB will send the investigator a letter stating that the study was examined and found to be appropriate for expedited review. No studies may be conducted without the letter signed by the IRB Chairperson or his designee. Occasionally a protocol that is submitted for expedited review must be reviewed via the full committee review procedure. If this occurs, the PI and/or research team is notified by an email from the IRB Administrative Office.

Can the IRB Administrative Office Pre-Review My Submission for Expedited Review?

Yes. Contact the IRB administrative office via email to: irbadmin@ursinus.edu.

IRB File Number for Expedited Reviews

Each new protocol is assigned a distinct IRB file number by the IRB administrator. Example: ***AB-PSYC-xxxx-0914x*** (*AB* = PI initials –*PSYC* = Dept. – *xxxx* = protocol reference name – *0914* = month/year – *x* = Expedited review). This number, along with the last name of the PI, is used to track all documents and actions related to the study. When requesting information or action for a study, always refer to the IRB file number and the last name of the PI.

What's the Average Turnaround Time for Expedited Review Studies?

The average turnaround time for expedited review studies, from IRB receipt to IRB approval, is approximately 14 days.

Who reviews Expedited research protocols?

An expedited review procedure consists of a review of research involving human subjects by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB in accordance with the requirements set forth in **45 CFR 46.110**.

How are expedited protocols reviewed? What are the criteria?

Per the federal regulations, research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure. Activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

The categories in this list apply regardless of the age of subjects, except for special populations. The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal. The expedited review procedure may not be used for classified research involving human subjects.

The standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review—expedited or full.

Below categories one (1) through seven (7) pertain to both initial and continuing IRB review.

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
   a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or

decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or

b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

3. Prospective collection of biological specimens for research purposes by noninvasive means.

a) Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

a) **Examples**: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy;

b) weighing or testing sensory acuity;

c) magnetic resonance imaging;

d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;

e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be categorized Exempt. 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:
    a) where (i) the research is permanently closed to the enrollment of new subjects;
    b) (ii) all subjects have completed all research-related interventions;
    c) and (iii) the research remains active only for long-term follow-up of subjects; or (b) where no subjects have been enrolled and no additional risks have been identified; or (c) 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.

Exempt Protocol Review

Some research involving human subjects may be "exempt" from continuing IRB review due to the nature of the research: it must be no more than minimal risk, but also fall under one of the categories spelled out in federal regulations.

All research, including that which the investigator believes falls into the exempt category, must be submitted to the IRB Chair for confirmation of the relevant review category via a **Request for Exemption Form**. It is not the duty of the researcher to determine if the research is exempt –the IRB, must make this determination. This form may be submitted to the IRB administrator at any time on a rolling basis.

Please note that an exemption can be invoked only if **all** components of the research fit the category as described. You might find the following decision charts helpful: https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts-2018/index.html

The following are examples of projects which **might** be exempt from Institutional Board Review:

- Data gathered for the purposes of fundraising
- Market research for the purposes of admissions recruiting
- Recruiting efforts for faculty or staff
- Statistical data collected for the management of institutional affairs, including surveys of students, prospective students, and alumnae.

Federal regulation has the following criteria for exempt review:

(1) **Research, conducted in established or commonly accepted educational settings**, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) **Research that only includes interactions involving educational tests** (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

a. (i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; (ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or (iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).

(3) (i) **Research involving benign behavioral interventions** in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

a. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
b. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
c. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).

(ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

(iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

(4) **Secondary research for which consent is not required**: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

(i) The identifiable private information or identifiable biospecimens are publicly available;
(ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;
(iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of “health care operations” or “research” as those terms are defined at 45 CFR 164.501 or for “public health activities and purposes” as described under 45 CFR 164.512(b); or
(iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq.*

(5) **Research and demonstration projects that are conducted or supported by a Federal department or agency**, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

(i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or

demonstration project must be published on this list prior to commencing the research involving human subjects.

(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.

(7) **Storage or maintenance for secondary research for which broad consent is required**: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by §46.111(a)(8).

(8) **Secondary research for which broad consent is required**: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:

(i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with §46.116(a)(1) through (4), (a)(6), and (d);

(ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with §46.117;

(iii) An IRB conducts a limited IRB review and makes the determination required by §46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and

(iv) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

What about research during an academic course?

A "research practicum" is a course of study that involves the supervised practical application of previously studied theories of research method. A number of departments offer courses that require students to interview or observe other people. The purpose of these courses is to train students and give them an opportunity to practice various research methods. Such projects do not require review by the Board. If you are unsure if your study meets this definition, refer to the section on "what is considered a student project" or consult the IRB.

Who Decides If The Protocol Is Exempt From Full Committee Review?

The investigator may request exempt status via a Request for Exemption Form but the decision lies with the IRB Chairperson or designee. If appropriate, the IRB administrative office will send the investigator an approved/signed copy of the Request for Exemption Form indicating that the protocol was found to be exempt from full review. No studies may be conducted without this form being signed by the IRB Chairperson or his designee. Occasionally a protocol that is submitted for exempt review must be reviewed via the expedited review procedure. If this occurs, the PI and/or research team is notified via an email from the IRB administrative office.

When are Exempt Protocols reported to the IRB?

Exempt protocols are reported to the full committee at the earliest regularly scheduled committee meeting via the meeting agenda.

IRB File Number for Exempt Protocols

Each Exempt protocol is assigned a distinct IRB file number. Example: ***AB-PSYC-0914*** (PI's initials – Department – month & year). This number, along with the last name of the PI, is used to track all documents and actions related to the study. When requesting information or action for a study, always refer to the IRB file number and the last name of the PI.

What's the Average Turnaround Time for Exempt from Full Review Studies?

The average turnaround time from IRB receipt to IRB approval for exempt from Full review is approximately 10 business days. These times are dependent on the timely responses and actions of other others involved in the research process including, but not limited to, investigators and research team members. If you do not hear from the IRB administrative office within 5 business days after your submission, contact the IRB administrative office.

Vulnerable Subjects in Human Subjects Research

This section provides information regarding additional protections to vulnerable populations participating in research reviewed by the IRB.

What Is A Vulnerable Subject Or Vulnerable Population?

The Ursinus IRB considers the following to be vulnerable subjects or vulnerable populations. Note that some of these groups are not defined in regulation, but instead constitute Ursinus's serious commitment to protecting human subjects:

- Pregnant Women, Fetuses, or Neonates (as defined in 45CFR46 Subpart B)
- Prisoners or Incarcerated Persons (as defined in 45CFR46 Subpart C)
- Children (as defined in 45CFR46 Subpart D)
- Cognitively impaired
- Non-English Speakers
- Illiterate Subjects
- Others (see below)

Could other vulnerable populations exist that would require IRB review?

The UC IRB believes that there are circumstances in which it must use its judgment on the protection of human subjects above and beyond the regulations, which is its prerogative. The IRB may request additional safeguards to avoid undue influence and coercion of vulnerable subjects. There are specific requirements and exceptions to the consent requirements in specific situations, and the research team should contact the IRB Administrative Office.

Pregnant Women, Fetuses, or Neonates

Can pregnant women participate in research?

Additional protections exist for research protocols involving pregnant women, fetuses, or neonates. The IRB is required to review protocols in accordance with special federal regulations for protocols involving this special population. All protocols involving this special population requires a convened, full board IRB review.

What's the definition of pregnancy, the fetus, and neonates? What other definitions are in place for cases falling under this vulnerable population?

Federal regulations express the following on the definitions of this vulnerable population:

- Dead fetus means a fetus that exhibits neither heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, nor pulsation of the umbilical cord.
- Delivery means complete separation of the fetus from the woman by expulsion or extraction or any other means.
- Fetus means the product of conception from implantation until delivery.
- Neonate means a newborn.
- Nonviable neonate means a neonate after delivery that, although living, is not viable.

- Pregnancy encompasses the period of time from implantation until delivery. A woman shall be assumed to be pregnant if she exhibits any of the pertinent presumptive signs of pregnancy, such as missed menses, until the results of a pregnancy test are negative or until delivery.
- Secretary means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom authority has been delegated.
- Viable, as it pertains to the neonate, means being able, after delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heartbeat and respiration. The Secretary may from time to time, taking into account medical advances, publish in the Federal Register guidelines to assist in determining whether a neonate is viable for purposes of this subpart. If a neonate is viable then it may be included in research only to the extent permitted and in accordance with the requirements of subparts A and D of this part.

What special safeguards are spelled out in regulation for this vulnerable population?

The following is the federal regulations for pregnant women, fetuses, neonates, and potential other research subjects falling under this vulnerable population.

Pregnant women or fetuses may be involved in research if all of the following conditions are met:

1. Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on nonpregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses;
2. The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus; or, if there is no such prospect of benefit, the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means;
3. Any risk is the least possible for achieving the objectives of the research;
4. If the research holds out the prospect of direct benefit to the pregnant woman, the prospect of a direct benefit both to the pregnant woman and the fetus, or no prospect of benefit for the woman nor the fetus when risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means, her consent is obtained in accord with the informed consent provisions of subpart A of this part;
5. If the research holds out the prospect of direct benefit solely to the fetus then the consent of the pregnant woman and the father is obtained in accord with the informed consent provisions of subpart A of this part, except that the father's consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest.
6. Each individual providing consent under paragraph (d) or (e) of this section is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate;
7. For children as defined in §46.402(a) who are pregnant, assent and permission are obtained in accord with the provisions of subpart D of this part;
8. No inducements, monetary or otherwise, will be offered to terminate a pregnancy;
9. Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy; and
10. Individuals engaged in the research will have no part in determining the viability of a neonate.

Research involving neonates.

Neonates of uncertain viability and nonviable neonates may be involved in research if all of the following conditions are met:

1. Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates.
2. Each individual providing consent under paragraph (b)(2) or (c)(5) of this section is fully informed regarding the reasonably foreseeable impact of the research on the neonate.
3. Individuals engaged in the research will have no part in determining the viability of a neonate.
4. The requirements of paragraph (b) or (c) of this section have been met as applicable.

Neonates of uncertain viability. Until it has been ascertained whether or not a neonate is viable, a neonate may not be involved in research covered by this subpart unless the following additional conditions are met:

1. The IRB determines that:
   a. The research holds out the prospect of enhancing the probability of survival of the neonate to the point of viability, and any risk is the least possible for achieving that objective, or (ii) The purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means and there will be no added risk to the neonate resulting from the research; and
2. The legally effective informed consent of either parent of the neonate or, if neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the legally effective informed consent of either parent's legally authorized representative is obtained in accord with subpart A of this part, except that the consent of the father or his legally authorized representative need not be obtained if the pregnancy resulted from rape or incest.

Nonviable neonates. After delivery nonviable neonate may not be involved in research covered by this subpart unless all of the following additional conditions are met:

1. Vital functions of the neonate will not be artificially maintained;
2. The research will not terminate the heartbeat or respiration of the neonate;
3. There will be no added risk to the neonate resulting from the research;
4. The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means; and
5. The legally effective informed consent of both parents of the neonate is obtained in accord with subpart A of this part, except that the waiver and alteration provisions of §46.116(c) and (d) do not apply. However, if either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the informed consent of one parent of a nonviable neonate will suffice to meet the requirements of this paragraph (c)(5), except that the consent of the father need not be obtained if the pregnancy resulted from rape or incest. The consent of a legally authorized representative of either or both of the parents of a nonviable neonate will not suffice to meet the requirements of this paragraph (c)(5).

Viable neonates. A neonate, after delivery, that has been determined to be viable may be included in research only to the extent permitted by and in accord with the requirements of subparts A and D of this part.

Research involving, after delivery, the placenta, the dead fetus or fetal material.

1. Research involving, after delivery, the placenta; the dead fetus; macerated fetal material; or cells, tissue, or organs excised from a dead fetus, shall be conducted only in accord with any applicable Federal, State, or local laws and regulations regarding such activities.
2. If information associated with material described in paragraph (a) of this section is recorded for research purposes in a manner that living individuals can be identified, directly or through identifiers linked to those individuals, those individuals are research subjects and all pertinent subparts of this part are applicable.

Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates.

Children/Pediatric Research

Federal regulations *[21 CFR Parts 201, 312, 314 and 601and 45 CFR46 (OPRR) subpart d .401-409]* stipulate that any research involving children or pediatric subjects, in any manner, must have **specific** approval for their participation.

What Is The Definition Of A Child?

Children are defined in the HHS regulations as "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted". **http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html**

In PA, the age of majority is 18. A child under the age of 18 is considered a minor.

Consent for Research Involving Minors

Under PA law, the following people may consent to participation in research for minors under age eighteen. The consent of only one person is required unless specifically requested by the IRB.

1. Any parent for his/her minor child.
2. Any person temporarily standing "in *loco parentis*," whether formally serving or not, for the minor under his/her care.
3. In the absence of a parent, spouse, legal guardian, or person standing in *loco parentis*, any adult may consent to participate for his/her minor brother or sister; or a grandparent for his/her minor grandchild.

Exceptions to the above rule are as follows:

1. A minor who is a parent may consent to the participation of his/her own child.
2. Married minors may consent to participation for themselves or their spouses.

When obtaining informed consent for participation, investigators should use good judgment and inquire to satisfy themselves that the person purporting to be the guardian or in "*loco parentis*" honestly has that relationship with the minor. Research may require the additional consent of an advocate or other representative of the minor. Each of these instances will be discussed on a case-by-case basis. It is important to confer with the IRB on these issues ahead of time to determine the best methods for the protection of human subjects.

What is the PA state Mandated Reporting law for child abuse? Does this apply to me and my study?

Investigators having reasonable cause to believe that a child under age eighteen (18) has been abused are legally required to report that abuse. Human Subjects research is required to adhere to all applicable laws and the Ursinus College Protection of Minors Policy.

Is a Children's Assent Document Required In Addition To Parental And/Or Legal Guardian Informed Consent Document?

Yes.

May We Label the Children's Assent Document 'A Student's Assent Document' if We Are Working With Children in the School Systems?

Yes.

Can Protocols Involving Children Be Reviewed Using The Expedited Procedure for Initial Review?

Protocols that involve children as research subjects usually require full review for initial review. However, protocols that do not increase any risk to the child may be eligible for expedited review ***after*** the initial review. The review level of amendments, advertisements, continuing review, etc. will be determined by the IRB Chairperson or designee.

What About Waiver Of Consent For Pediatric Subjects?

There are specific requirements and exceptions to the consent requirements in these situations and the research team should contact the IRB Chairperson.

Cognitively Impaired Persons

A cognitively impaired person can be defined as having: a psychiatric disorder (e.g., psychosis, neurosis, personality or behavior disorders), an organic impairment (e.g., dementia), or a developmental disorder (e.g., mental retardation) that affects cognitive or emotional functions to the extent that capacity for judgment and reasoning is significantly diminished. In addition, persons under the influence of or dependent on drugs or alcohol, suffering from degenerative diseases affecting the brain, terminally ill patients, and persons with severely disabling physical handicaps, may also be compromised in their ability to make decisions in their best

interests. The major ethical concern in research involving individuals with these types of disorders or impairments is that their disorders may have an impact on their capacity to understand the information presented as well as their ability to make a truly informed decision about participating in the research. Some individuals with such disabilities may be residents of institutions responsible for the individual's total care and treatment. This dependence on the institution may have an impact on their ability to voluntarily participate in research (e.g., these individuals may agree too readily to requests for their "cooperation" or may be vulnerable to perceived or actual pressures for fear of being denied services.)

The IRB must review several areas and their potential for coercion when reviewing research involving cognitively impaired persons:

- Are these individuals the primary population for this research?
- Are there adequate protections for privacy and confidentiality of information?
- How are issues of consent and competence addressed?

There should be specific evidence of individuals' incapacity to understand and to make a choice before they are deemed unable to consent.

What Should You Do When The Question Of Competency Is Unclear?

Competency is commonly judged by the subject evidencing a choice with regard to research participation, through factual understanding of issues including the rational manipulation of information as well as the appreciation of the nature of the research project. If competency is an issue, it must be acknowledged in the Proposal, and the procedures used to evaluate competency must be described in detail.

What If You Are Considering A Study Where Subjects Will Lose Competency Over Time (e.g., Alzheimer's Disease, Dementia, etc.)?

The Protocol should include how these issues will be addressed, keeping in mind that all human subjects have the right to benefit from the research process.

Non-English Speaking Subjects

Federal regulations stipulate that any research involving non-English speaking subjects, in any manner, must have specific approval for their participation.

If Non-English Speaking Subjects are Part of the Primary Target Pool, do We Have to Explain and Present the Study in a Language that is Understandable to the Subject?

Yes, per the federal regulation *21CFR46 50.20*. All written documents, e.g., informed consent, children's assent, subject diary cards, medication and dosing instructions, etc., must be written in the subject's native language to help ensure that the subject can fully understand the study.

Can Subjects Be Excluded From The Study If They Are Non-English Speakers?

Individuals may not be excluded from the study based on their inability to speak, read or write in English. They must not be enrolled until the IRB has approved an informed consent process that includes translations into their native language. The PI must also document how information will be communicated to these subjects.

What About Documents Used For the Study such as Informed Consent, Questionnaires, Flyers, and Instructions?

The investigator must submit the English language version of all document(s) to the IRB for approval with the initial submission or as an amendment to an approved protocol.

What Forms Must Be Submitted?

After the IRB approves the English language version of the document(s), then the investigator must submit the translated document(s) in the foreign language for IRB approval. A certification statement, by the individual or professional translation service that performed the translation, must be included with the document(s).

What About The Costs Associated With Professional Translators?

The costs associated with the professional translation service are to be borne by the investigator, either through negotiation with the sponsor or other funding source. The investigator's department will be responsible for these costs if the investigator does not have any external funding.

Will The IRB Require Any Additional Safeguards For Non-English Speaking Subjects?

The IRB may require a certified interpreter based on the risk level of the research study.

Illiterate Persons

Can Illiterate Subjects Participate In Research?

Illiterate persons who understand English may have the informed consent document read to them and must then indicate consent to participate by placing an X on the signature line as required by Pennsylvania law. Documentation that the subject cannot read or write must be written on the consent document and in the source documents.

Can Subjects Be Excluded From The Study If They Are Illiterate?

Individuals may not be excluded from the study based on their inability to read or write.

Will The IRB Require Any Additional Safeguards For Illiterate Subjects?

Additional safeguards may be requested by the IRB to avoid undue influence and coercion. This may include requiring an impartial witness for the consent process. There are specific requirements and exceptions to the consent requirements in these situations and the research team should contact the IRB Chairperson.

Prisoner Research

Federal regulations *[45CFR 46 Subpart C .301-.306]* stipulate that any research involving prisoners in any manner must have specific approval for their participation.

What is a Prisoner?

A prisoner is considered to be an individual involuntarily confined or detained in a penal institution. These individuals may be:

- Sentenced under a criminal or civil statute.
- Detained in other facilities by virtue of statutes or commitment procedures that provide alternatives to criminal prosecution or incarceration in a penal institution; and/or
- Detained pending arraignment, trial or sentencing.

What's the composition of the IRB when reviewing prisoner research?

The majority of the IRB shall have no association with the prison, except for the one voting member. This voting member shall be a prisoner representative with appropriate background and experience to speak on behalf of prisoners.

This OHRP guidance on prisoner research is instructive.

What must the IRB document?

The IRB must document that the research protocol meets one of the categories of research that is allowed under the regulations and that the additional duties of the IRB as required under *45 CFR 46.305(2-7)* are met.

Does anyone else have to review the research?

Some human subjects research requires independent OHRP review. If you intend to do human subjects research involving prisoners, it is extremely important to begin a conversation with the IRB early in the process. Safely and ethically conducting research with prisoner subjects is a highly complex area of compliance.

Informed Consent Process and Documentation

What Is The Informed Consent Process?

The Informed Consent process is arguably the most important documented process in an IRB protocol. Informed Consent links directly to the Belmont Report's three ethical principles and as a result, the Ursinus College IRB will closely examine the Informed Consent process of all protocols submitted to the IRB.

The informed consent process is a continual process of communication between the subject, the investigator (s) and the research team. It is not merely the written documentation of the subject's willingness to participate. Open communication of any information that may influence the subject's decision to participate or continue participation in the study must be available and documented.

It is critical that researchers closely attend to the informed consent process.

Who is responsible for making sure that no research begins prior to Informed Consent being obtained?

Federal and institutional regulations specify that the investigator is responsible for ***personally*** assuring that no research begins before obtaining consent, unless the IRB has waived the requirement for written informed consent. Research that occurs before the Informed Consent process is undertaken and completed is in violation of federal law.

When Does Participation In The Research Protocol Begin?

Participation begins when the research subject or legally authorized representative signs the informed consent document.

How Do You Properly Obtain and Document the Informed Consent Process?

To obtain informed consent from a subject, an IRB approved investigator must fully explain the study to the subject and/or their parents, or legally authorized representative. Legally authorized representatives are the following individuals and are listed in their order of priority:

- Legal guardian or special guardian
- Next-of-kin: a close relative of the subject eighteen years of age or older, in the following priority:
- Spouse
- Child
- Parent
- Sibling
- Grandparent
- Grandchild
- Close friend

Consent is to be obtained from the subject or his/her legally authorized representative in circumstances that encourage and preserve the subject's free choice to participate and the investigator communicates in language that is understandable to the subject. Failing to do so is in violation of federal law.

Legally authorized representatives are to be well informed regarding their roles and obligations to protect incompetent participants or persons with impaired decision making capacity. They must also be told their obligation is to try to determine what the prospective participant would do if competent, or if the prospective participant's wishes cannot be determined, what they think is in the incompetent person's best interest. This process must be documented in the research source documents.

How Do You Obtain Informed Consent From Children?

For children under 18, assent of the child, as well as the consent of the parents, must be obtained under Department of Health and Human Services (DHHS) regulations. In determining the capability of the child to give assent for research, the child's age (e.g., typically above 6 years), maturity and emotional state should be considered.

Can the Informed Consent Document (ICD)/Children's Assent Document (CAD) include exculpatory language?

The Informed Consent Document (ICD) and/or Children's Assent Document (CAD) shall not include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights or release or appear to release the research investigator, or the institution or its agents from liability for negligence, except for the extent specifically allowed by law.

What are the readability requirements for the informed consent/children's assent documents?

The ICD should be presented at the eighth-grade reading level and the CAD must be presented at the second grade reading level. Most word processing software allows a readability check. The ICD and/or CAD must be written in language that the subject and/or legal representative can be expected to understand and must clearly present all the information regarding the study in order that the subject and/or legal representative can make a reasonable decision concerning participation.

Researchers should endeavor to create consent documents that are straightforward in their language. If the researcher is in doubt about the reading level of the consent documents, please contact the IRB.

When Should The Subject, Witness And Investigator Sign The ICD And/Or CAD?

The subject must sign and date the ICD and/or CAD in the presence of an approved investigator. The approved investigator must also sign and date the ICD and/or CAD, during this interaction with the subject. In cases where a witness signature is used or required, the IRB requires the witness to be present during the entire consent presentation to attest to the accuracy of the presentation and the apparent understanding by the subject.

Who does the IRB Authorize to obtain Informed Consent?

Only a named Principal Investigator (PI) or Student-Investigator (SI), proposed to and approved by the IRB, may obtain consent or assent. The specific investigators authorized to obtain informed consent must be proposed to and approved by the Committee prior to obtaining informed consent.

How do you determine which Children's Assent document to use?

Typically, studies that involve children aged seven (7) to seventeen (17) years must include a separate assent document for the children to sign. This is a simplified version of the consent, written at a level that the youngest subject can understand. If possible, children under age seven (7) should give verbal agreement. It may be appropriate to have more than one CAD for different age levels (e.g., 7-12 and 13-17 years of age).

No research can be undertaken without parental consent to research.

How Is Informed Consent Obtained From A Cognitively Impaired Subject?

A research subject must be legally and autonomously competent to give informed consent. For subjects that are cognitively impaired, a surrogate whose primary interest is the subject's welfare may give informed consent. Competency is commonly judged by the subject showing a choice with regard to research participation through his/her understanding of the issues, information, and nature of the research project. If competency is an issue, it must be acknowledged in the research proposal and the procedures used to evaluate competency must be described in detail. It is recommended that a physician, not affiliated with the conduct of the study, document the competency of the subject prior to participation. Further guidance on cognitive impairment in research subjects is available through OHRP and should be consulted.

What Is A Legally Authorized Representative?

A legally authorized representative is an individual or body authorized under applicable law to provide permission on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research. For the purposes of this policy and procedure**,** a legally authorized representative includes not only a

person appointed as a health care agent under a Durable Power of Attorney for Health Care (DPAHC), a court appointed guardian of the person, but also next-of-kin in the following order of priority unless otherwise specified by applicable state law: spouse, adult child (18 years of age or older), parent, adult sibling (18 years of age or older), grandparent, or adult grandchild (18 years of age or older). PA State law with regard to legally authorized representatives changes on occasion, making it important for researchers running into this issue to be aware of appropriate state regulations.

Legally authorized representatives are to be well informed regarding their roles and obligations to protect incompetent participants or persons with impaired decision making capacity. They must also be told their obligation is to try to determine what the prospective participant would do if competent, or if the prospective participant's wishes cannot be determined, what they think is in the incompetent person's best interest.

Does The IRB Stamp Each Page Of The ICD And/Or CAD With An Approval Stamp?

Yes. Each page of the ICD and/or CAD must display the IRB stamp of approval that indicates the approval and expiration dates of the study.

Subjects who do not speak English must have an IRB approved ICD translated into the subject's language which can be sent to the subject by facsimile or scanned email attachment. The subject is given a copy of the translated ICD. An interpreter may assist with the discussion but ad hoc translation may not replace the written document. Subject discusses consent with investigator authorized to obtain consent via the telephone, with an identified witness present while the subject is on line. The subject and the witness sign the consent document with the subject retaining a copy of the informed consent document.

Are We Required To Notify Subjects Of Any New Significant Findings During The Course Of The Study?

Yes. Subjects must be informed of any significant new findings that develop during the course of the study, which may relate to their continued willingness to participate. This may require revisions to the ICD and may also require re-consenting of previously enrolled subjects. **NOTE: If a subject is unable to read or write, it must be documented on the informed consent document and visit note.**

How Long Do We Keep Signed Informed Consent Documents For UC?

Signed consent documents must be retained by the investigator for at least three years past the completion of the research activity or at least three years after termination of the last IRB approved period for research activity, whichever is later.

What if the Protocol Changes After a Subject Has Been Consented?

Please see the amendments section in **Section 3** for additional guidance on ICD addendums or revised ICD and/or CAD.

What are the regulations regarding Informed Consent?

The following are a truncated version of regulations for informed consent, pulled from the Common Rule (45 CFR 46). The full text can be found online:

§46.116 General Requirements for Informed Consent.

(a) General: Except as provided elsewhere in this policy:

1. Before involving a human subject in research covered by this policy, an investigator shall obtain the legally effective informed consent of the subject or the subject's legally authorized representative.
2. An investigator shall seek informed consent only under circumstances that provide the prospective subject or the legally authorized representative sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence.
3. The information that is given to the subject or the legally authorized representative shall be in language understandable to the subject or the legally authorized representative.
4. The prospective subject or the legally authorized representative must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.

5. Except for broad consent obtained in accordance with paragraph (d) of this section:

(i) Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.

(ii) Informed consent as a whole must present information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or legally authorized representative's understanding of the reasons why one might or might not want to participate.

6. No informed consent may include any exculpatory language through which the subject or the legally authorized representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

(B) ***Basic elements of informed consent***. Except as provided in paragraph (d), (e), or (f) of this section, in seeking informed consent the following information shall be provided to each subject or the legally authorized representative:

1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures that are experimental;
2. A description of any reasonably foreseeable risks or discomforts to the subject;
3. A description of any benefits to the subject or to others that may reasonably be expected from the research;
4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
6. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
7. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject;
8. 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; and
9. One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:

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

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

(c) ***Additional elements of informed consent***. Except as provided in paragraph (d), (e), or (f) of this section, one or more of the following elements of information, when appropriate, shall also be provided to each subject or the legally authorized representative:

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

4. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
5. A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject;
6. The approximate number of subjects involved in the study;
7. A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;
8. A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and
9. For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

(d) ***Elements of broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens***. Broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens (collected for either research studies other than the proposed research or nonresearch purposes) is permitted as an alternative to the informed consent requirements in paragraphs (b) and (c) of this section. If the subject or the legally authorized representative is asked to provide broad consent, the following shall be provided to each subject or the subject's legally authorized representative:
1. The information required in paragraphs (b)(2), (b)(3), (b)(5), and (b)(8) and, when appropriate, (c)(7) and (9) of this section;
2. A general description of the types of research that may be conducted with the identifiable private information or identifiable biospecimens. This description must include sufficient information such that a reasonable person would expect that the broad consent would permit the types of research conducted;
3. A description of the identifiable private information or identifiable biospecimens that might be used in research, whether sharing of identifiable private information or identifiable biospecimens might occur, and the types of institutions or researchers that might conduct research with the identifiable private information or identifiable biospecimens;
4. A description of the period of time that the identifiable private information or identifiable biospecimens may be stored and maintained (which period of time could be indefinite), and a description of the period of time that the identifiable private information or identifiable biospecimens may be used for research purposes (which period of time could be indefinite);
5. Unless the subject or legally authorized representative will be provided details about specific research studies, a statement that they will not be informed of the details of any specific research studies that might be conducted using the subject's identifiable private information or identifiable biospecimens, including the purposes of the research, and that they might have chosen not to consent to some of those specific research studies;
6. Unless it is known that clinically relevant research results, including individual research results, will be disclosed to the subject in all circumstances, a statement that such results may not be disclosed to the subject; and
7. An explanation of whom to contact for answers to questions about the subject's rights and about storage and use of the subject's identifiable private information or identifiable biospecimens, and whom to contact in the event of a research-related harm.

(e) ***Waiver or alteration of consent in research involving public benefit and service programs conducted by or subject to the approval of state or local officials.***
(1) *Waiver.* An IRB may waive the requirement to obtain informed consent for research under paragraphs (a) through (c) of this section, provided the IRB satisfies the requirements of paragraph (e)(3) of this section. If an individual was asked to provide broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens in accordance with the requirements at paragraph (d) of this section, and refused to consent, an IRB cannot waive consent for the storage, maintenance, or secondary research use of the identifiable private information or identifiable biospecimens.

(2) *Alteration.* An IRB may approve a consent procedure that omits some, or alters some or all, of the elements of informed consent set forth in paragraphs (b) and (c) of this section provided the IRB satisfies the requirements of paragraph (e)(3) of this section. An IRB may not omit or alter any of the requirements described in paragraph (a) of this section. If a broad consent procedure is used, an IRB may not omit or alter any of the elements required under paragraph (d) of this section.

(3) *Requirements for waiver and alteration.* In order for an IRB to waive or alter consent as described in this subsection, the IRB must find and document that:

(i) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:

A. Public benefit or service programs;
B. Procedures for obtaining benefits or services under those programs;
C. Possible changes in or alternatives to those programs or procedures; or
D. Possible changes in methods or levels of payment for benefits or services under those programs; and

(ii) The research could not practicably be carried out without the waiver or alteration.

(f) ***General waiver or alteration of consent.***

(1) *Waiver.* An IRB may waive the requirement to obtain informed consent for research under paragraphs (a) through (c) of this section, provided the IRB satisfies the requirements of paragraph (f)(3) of this section. If an individual was asked to provide broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens in accordance with the requirements at paragraph (d) of this section, and refused to consent, an IRB cannot waive consent for the storage, maintenance, or secondary research use of the identifiable private information or identifiable biospecimens.

(2) *Alteration.* An IRB may approve a consent procedure that omits some, or alters some or all, of the elements of informed consent set forth in paragraphs (b) and (c) of this section provided the IRB satisfies the requirements of paragraph (f)(3) of this section. An IRB may not omit or alter any of the requirements described in paragraph (a) of this section. If a broad consent procedure is used, an IRB may not omit or alter any of the elements required under paragraph (d) of this section.

(3) *Requirements for waiver and alteration.* In order for an IRB to waive or alter consent as described in this subsection, the IRB must find and document that:

(i)The research involves no more than minimal risk to the subjects;
(ii) The research could not practicably be carried out without the requested waiver or alteration;
(iii) If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;
(iv) The waiver or alteration will not adversely affect the rights and welfare of the subjects; and
(v) Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation

(g) *Screening, recruiting, or determining eligibility.* An IRB may approve a research proposal in which an investigator will obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective subjects without the informed consent of the prospective subject or the subject's legally authorized representative, if either of the following conditions are met:

1. The investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative, or
2. The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

Can I request waiver Of written consent?

Yes. Under certain circumstances, the IRB may waive the requirement to obtain informed consent for research or may approve a consent procedure that omits some, or alters some or all, of the elements of informed consent

In order for an IRB to waive or alter consent, the IRB must find and document that:

- The research involves no more than minimal risk to the subjects;

- The research could not practicably be carried out without the requested waiver or alteration;
- If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;
- The waiver or alteration will not adversely affect the rights and welfare of the subjects; and
- Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

Informed consent may also be waived or altered in research involving public benefit and service programs conducted by or subject to the approval of state or local officials under certain circumstances.

What About HIPAA And The Waiver Of Authorization?

The HIPAA Privacy Rule which became effective on April 14, 2003, changed this standard of practice. The Privacy Rule has its own list of criteria that must be met in order to waive a subject's written authorization to use and disclose individually identifiable health information for research. Please consult the IRB for more details on HIPAA waivers.

Can I conduct the consent process verbally/orally?

The IRB has a special procedure for oral consent, including requesting a short form written informed consent form stating that the elements of informed consent required have been presented orally to the subject or the subject's legally authorized representative, and that the key information required was presented first to the subject, before other information, if any, was provided. The IRB shall approve a written summary of what is to be said to the subject or the legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Only the short form itself is to be signed by the subject or the subject's legally authorized representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the subject's legally authorized representative, in addition to a copy of the short form.

If I Request Waiver of Written Informed Consent or Waiver of Authorization, does this Request Automatically Require Review by the Full IRB?

Yes**.** All requests for waiver or alteration of written informed consent must be approved at a legally convened meeting of the IRB. All approvals of waiver of written consent shall be reflected in the Minutes of the IRB meeting. The letter to the investigator authorizing alteration or waiver of written consent will state that the waiver of written informed consent specifically meets the criteria for such a waiver.

What is broad consent?

Broad consent is a new type of informed consent provided under the revised Common Rule pertaining to storage, maintenance, and secondary research with identifiable private information or identifiable biospecimens. Secondary research refers to research use of materials that are collected for either research studies distinct from the current secondary research proposal, or for materials that are collected for nonresearch purposes.

Is broad consent required?

No, broad consent is only an option for conducting secondary research as an alternative to traditional informed consent or a waiver of informed consent. Broad consent is an option only for secondary research use of identifiable private information or identifiable biospecimens.

If identifiable private information or identifiable biospecimens were collected with broad consent, then exemptions 7 and 8 may apply. Exemption 7 may apply for the storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use. Exemption 8 may apply for the secondary research use use of identifiable private information or identifiable biospecimens.

If individuals were asked, and refused, to provide broad consent, the IRB cannot waive informed consent to use the subject's identifiable information or biospecimens in a secondary study. Use of these materials without identifiers is still allowed.

Other options for doing secondary research remain, such as conducting secondary research suing nonidentifiable private information and nonidentifiable biospecimens, using the provisions under exemption 4,

getting an IRB waiver of informed consent, or returning to the subjects and obtaining the standard informed consent.

If you are considering using materials for secondary research use, please use the IRB as a resource to help determine what steps you may need to take.

What are the required elements of broad consent?

Under the revised Common Rule, broad consent includes some of the elements of informed consent that are required in the standard informed consent and additional elements specific to broad consent. All required elements of broad consent include:

- any foreseeable risks to the subjects;
- reasonably expected benefits to subjects or others;
- the extent to which confidentiality will be maintained;
- a statement that participation is voluntary and may be discontinued without penalty;
- when appropriate, a statement about commercial profit and whether subjects will or will not share in it;
- when appropriate, whether research might include whole genome sequencing;
- a description of the types of research that may be done, with sufficient information that a reasonable person would expect the broad consent would permit the types of research conducted;
- a description of the identifiable private information or identifiable biospecimens that might be used, whether they might be shared, and the types of institutions or researchers that may conduct research with that information or biospecimens;
- a description of the period of time the identifiable private information or identifiable biospecimens may be stored, maintained, or used for research purposes;
- a statement, if applicable, that subjects may not be informed about specific research studies that may use their information and that they might have chosen not to consent to some of these studies;
- a statement, if applicable, that clinically relevant research results might not be disclosed to the subject;
- and an explanation of whom to contact for answers to questions about the subject's rights and about storage and use of the subject's identifiable private information or identifiable biospecimens, and whom to contact in the event of a research related harm.

Please note that if broad consent is used, none of these elements can be waived.

Can broad consent for future research be requested at the time of obtaining standard consent for a present study?

Yes, broad consent for secondary use may be obtained when standard informed consent from subjects is obtained for the initial primary research. Investigators who anticipate that they or others may want to use information or biospecimens collected through the primary research for unspecified secondary research may consider this option.

Recruitment Process (Advertisements, Flyers, Brochures, and Recruitment Plans)

Can we advertise for human participants in our research?

Yes. Under Federal Regulations *[21CFR 56]* all announcements and advertisements including email and bulletin board notices, posters, etc., involving research study subjects must be reviewed and approved by the IRB.

What is the Recruitment Process?

The recruitment process includes all aspects of recruiting and retaining subjects in the research study. Examples of recruitment processes that must be approved by the IRB in their dual role as the IRB and the privacy board are:

- Advertisements (e.g., printed ads newspapers, fliers, inserts, bulletin boards notices, etc., or ads for the radio, television and/or web postings).
- Email blasts to the campus community.
- Subject testimonials or experience sharing for a specific study.
- Community organization speaking about a specific study.

Is advertisement part of the recruitment and informed consent process?

Yes. Announcements and/or advertisements may not be utilized until the study, and the individual announcements and/or advertisements have written IRB approval.

Do we have to document where recruitment is done?

Yes. The Protocol must indicate where the advertisements will be used or placed.

What is included in recruitment materials?

The announcement or advertisement should be limited to:

- Principal Investigator's (PI) name, address and telephone number
- Purpose of the study and eligibility criteria
- A truthful description of the benefits (e.g., payments, free treatment, etc.). Deception in research requires additional IRB review.
- Location of research and contact person
- IRB file number

Do you have any suggestions on how to expand our recruitment?

- Use proper grammar.
- Be certain that the advertisement is written so that the target audience can understand it.
- If subjects will be paid for participation or reimbursed for expenses, do not include the actual monetary amount.
- Be certain that the advertisement is not coercive.

Polices for Ongoing Research Activities

What activities are undertaken for ongoing research?

The typical activities involved in the conduct of an ongoing protocol are amendments, protocol deviations/violations, unanticipated problems, adverse events, serious adverse events, continuing review and completion of the protocol and data analysis. These events must be reported to the IRB by the PI as they occur and are covered in the following sections.

Ongoing Activities:

- Amendments
- Unanticipated Problems
- Adverse Events/Serious Adverse Events
- Continuing Review
- Deviations/Violations
- Change of personnel
- Termination/Closure
- Record storage

Revisions/Amendments

The IRB considers any changes to be made in a protocol, whether initiated by the investigator or a study sponsor, to be a revision/amendment.

Examples of revisions/amendments may include a change or revision to any of the following:

- Procedure
- Changes in location
- Changes in focus group interview questions
- Administrative issues

Revisions include changes in investigators (both principal and student), laboratories, sites, etc. or it may be part of an amendment that requires a revised informed consent document. If you are in doubt about whether the change to your protocol requires an amendment, please contact the IRB.

If any member of the research team is no longer involved in the study, the PI must submit a completed Revision Form to remove the research team members from the study. Please follow all policies and note that other forms or documentation may be necessary. The same is true if a new member is added to the study.

Amendments must be submitted with a completed Revision/Addendum/Amendment Form. Other forms or support documentation may be necessary.

An amendment must be approved, in writing by the IRB, prior to its enactment. Conduct of the study under the revised protocol may not proceed until the IRB approval is granted. An exception can only occur when changes to eliminate an apparent immediate hazard to subjects must be implemented for the safety of the subject.

There are no deadlines for amendments, however, if the Chairperson or designee determines that the amendment requires additional review, there may be a delay in amendment approval. The IRB must be informed of any changes that are planned in an approved study prior to their implementation unless the action is taken to reduce the risk to the subject.

The Chairperson or his designee may review the amendments using expedited review. The designee must have at least one year of experience as a member of the IRB.

Do federal regulations require that protocols originally approved as exempt submit amendments to the IRB for review?

No. Although federal regulations do not require IRB review of amendments for studies that meet the criterion for exempt from full review, the IRB ***does*** require submission and approval of all amendments for studies that meet the criterion for exempt from review. This action is taken to provide the maximum protections for the

human subjects and/or human derived materials in the study and the ensure the studies still meet the criterion for exempt from review.

What are some amendments that would fall under expedited review?

The following examples are amendments that would allow expedited review:

- A change in advertisement/recruitment strategy, such as a new form email or poster
- New student investigator(s) added to the project
- Administrative changes such as phone numbers, mailing addresses, etc.
- Typographical error corrections

What are some examples of amendments that require additional review, up to Full Board review?

The following are some examples of amendments that would require additional review by the RB:

- Any increased risk to subject whether the risks involve physical, psychological, social, economic, confidentiality risks, etc. (i.e., increased number of blood draws, more procedures, potential for adverse events, etc.)
- Changes to the consent/assent form of any kind, as this requires a new "stamped" form.
- Protocols involving vulnerable subjects (adding pediatric subjects to an approved protocol is a major change and requires full Committee review).

How can I assist in the review of an amended/revised protocol?

To ensure faster routing and approval, provide a copy of the amendment with all changes noted from the previously approved version. Changes may be noted by using the track changes feature in Microsoft Word or other software or by highlighting, bolding the font or handwriting the changes, additions or deletions. A document listing all changes is strongly encouraged and appreciated.

Unanticipated Problems and Adverse Events

Federal Regulations [45CFR46.103 (a) and 45CFR46.103 (b) require prompt reporting to the IRB of unanticipated problems (as defined below) involving risks to subjects participating in research projects.

What is an Adverse Event?

According to federal law, an adverse event is any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research.

There are two types of adverse events:

1. Internal events that involve our local subjects enrolled by our investigators.
2. External events using subjects enrolled in a clinical trial under an investigator not affiliated with our research site for this study.

What is an Unanticipated Problem Involving Risks to Subjects or Others?

According to DHHS OHRP guidance, an unanticipated problem is any incident, experience, or outcome that meets all of the following criteria:

1. Unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol and related documents, such as the informed consent documents; and (b) the characteristics of the subject population being studied.
2. Related or possibly related to a subject's participation in the research
3. Suggests that the research places subjects or others at a greater risk of harm (including economic, social, physical, or psychological harm) than was previously known or recognized.

Unexpected Problems are not only related to physical events. For example, an unexpected event may be any of the following:

- A researcher's laptop is stolen with protected health information on it
- A researcher's digital camera or memory stick stolen with photographs or identifiable data of subjects
- Increased time off from work resulting in less pay to subjects or parents
- Increased time out of school resulting in lower grades
- Suspected child or domestic abuse

What is An Unexpected Adverse Event?

Any adverse events occurring in one or more subjects, in a research protocol, the nature, severity, or frequency of which is not consistent with either of the following:

- The known or foreseeable risk of adverse events associated with the procedures involved in the research that are described in (a) protocol and related documents, such as the IRB approved informed consent documents; and (b) other relevant sources of information; or
- The expected natural progression of any underlying disease, disorder, or condition of the subject(s) experiencing the adverse event and the subject's predisposing risk factor profile for the adverse event.

How can you determine which adverse events are reportable to the IRB?

If the answer to all three of the following questions is yes, then the adverse event is an unanticipated problem and must be reported to the IRB for reporting to DHHS OHRP:

1. Is the adverse event unexpected?
2. Is the adverse event related or possibly related to participation in the research?
3. Does the adverse event suggest that the research places subjects or others (such as parents, other students, siblings, etc.) at a greater risk of harm (physical, psychological, economic or social) than was previously known or recognized?

If you are unsure about the nature of your adverse event, you should report it to the IRB for review.

What if an event that is expected and listed in the informed consent documents and protocol happens but gets worse or happens more often?

The event does not require reporting to the IRB if the event is listed in the protocol or informed consent/assent documents, unless a study sponsor (such as in a clinical trial) requires reporting the event to them. However, if the event increases in frequency or duration or if any additional measures are needed, it should be reported to the IRB. When in doubt, report to the IRB.

Who reviews these events?

The IRB Chairperson or his designee reviews these events. These reports will be submitted to the full Committee for review. The IRB may request additional guidance from other departments or those with certain expertise to assist in the review process of these events.

What form is required?

All unexpected adverse events, unanticipated problems, or serious adverse events must be reported to the IRB via an Adverse Events/ Protocol Deviation/ Unanticipated Problems Report Form. The IRB file number, the protocol title, the Principal Investigator's name, and the name of the person submitting the report must be included. The report must also provide the subjects age and gender as well as a description of the occurrence. This form must be signed by the PI.

The reports may be emailed to the email address of: irbadmin@ursinus.edu. However, the original report must be mailed to the IRB Administrative Office, Corson Hall 110.

Protocol Deviations/Violations

Elisabeth Clark, Research Ethics Officer/Human Protections Administrator of McGill University Health Center provides the following clarification:

"**Protocol Violation"** - A term broadly used in clinical research to describe any study event whereby the current IRB approved research protocol was not followed, i.e. a change in a research activity. There is a

general acceptance in the biopharmaceutical industry for two categories of protocol violation, protocol exception and protocol deviation.

"**Protocol Deviation"** - A divergence or departure from the expected conduct of an approved study that is not consistent with the current research protocol, consent document or study addenda that had not been anticipated. All protocol deviations must be reported in writing to the IRB immediately upon discovery.

Urgent action to eliminate an immediate hazard to a subject is the only acceptable protocol deviation, and the event must be explained in writing to the sponsor, and to the IRB, as soon as possible.

"Protocol Exception" - A divergence or departure from expected conduct of an approved study that is not consistent with the current research protocol, consent document or addenda, that had been anticipated by the investigator, and for which IRB grants acceptance.

Deviations generally do not have a major impact on subject's welfare or data integrity.

Violations affect a subject's rights, safety or well-being or data integrity. It may also affect primary safety or efficacy endpoints of the study. Examples are:

1. Enrolling subjects who did not meet entry criteria without prior permission of the IRB
2. Failing to obtain informed consent prior to any study-related procedures

All protocol deviations and violations must be reported to the IRB, via a Adverse Events/ Protocol Deviation/ Unanticipated Problems Report Form, within five (5) business days.

Continuing Review

What is Continuing Review?

Continuing review is a report to the IRB on the progress of the study. The UC IRB is interested in the timely completion of approved studies and tracks the progress of studies under its purview in order to maximize human subjects protections.

How do I inform the IRB of the status of my study?

The IRB uses the Continuing Review Form in order to track progress of a study and ensure that human subjects are being protected.

Who has to submit their protocol for continuing review?

The IRB shall conduct continuing review of research requiring review by the convened IRB no less than once per year. This applies to all full board studies. Studies falling outside full board review are handled differently.

How is continuing review understood for studies not under full board review?

Unless otherwise determined, continuing review of research is not required in the following circumstances:

1. Research initially approved under expedited review.
2. Research reviewed in accordance with the limited IRB review (see explanation of limited IRB review).
3. Research that has progressed to the point that it involves only one or both of the following, which are part of the IRB-approved study:
    a) Data analysis, including analysis of identifiable private information or identifiable biospecimens, or
    b) Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.

If your research was originally approved as full board review, but now meets the criterion of category 3 above, you can submit a Removal of Continuing Review Form.

Polices for Termination/Closure of a Study

When is a study closed or terminated?

The typical protocol is closed at the completion of the protocol and data analysis. Requests for study closure must be submitted to the IRB by the PI.

A study may not be closed if research subjects are in follow-up or if data are still being analyzed. However, if all research subjects have completed study participation, and all data has been analyzed, the study may be closed. A Study Closure form must be submitted to close a study. A phone call or e-mail message is inadequate to close a study. The PI is responsible for notifying all other departments, if necessary.

The IRB will also terminate the approval of a protocol because the PI fails to request continuing review, per regulation. Please keep note of your protocol end dates for IRB review.

If a PI will be leaving Ursinus College, and has an open proposal with the IRB, he/she must file a Study Closure form with the IRB. If he/she fails to do so, the **department** Chairperson will be responsible for submitting the form.

At study termination or completion, a timely final report must be submitted to the IRB. The following information should be included in the Study Closure form:

1. the number of enrolled, discontinued and completed subjects, and
2. the number of signed informed consent forms in the investigator's files for the entire project.

How long do I need to store my records?

You are required to keep the information for several reasons including federal regulations, state law, Board of Regents' policies, institutional policies and good clinical practice. All data storage should be explained in your protocol. If your department has storage space you can store them on site. You may also arrange for long term storage off site, if approved.

If access to a closed IRB file is needed, a request must go through the IRB Administrative Office to gain access to those records. The IRB limits access to IRB files to the OHRP staff, IRB members, research team members and others who submit a request in writing to the IRB and the Principal Investigator.

Storage of Active Research Protocols

All active research protocols are maintained in a lockable/fireproof file cabinet in the IRB Administrative Office.

Storage of Terminated Research Protocols

All terminated files are maintained in a lockable storage space in the IRB Administrative Office as space permits. The following table lays out the record retention requirements set out by law:

IRB Records	3 years after study completion
Federal Grants	3 years after expiration of grant period
HIPAA Authorization	6 years after completion of study
HIPAA Waiver	6 years after completion of study
FDA	2 years after last marketing approval

Non-Compliance

Non-compliance means conducting research involving human subjects in a manner that disregards or violates Ursinus College policy or federal regulations governing such research.

Non-compliance can include, but is not limited to the following:

- Failure to obtain IRB approval for research involving human subjects prior to commencing such research
- Failure to satisfy contingencies set by the IRB prior to commencing research
- Failure to conduct research as delineated in the IRB-approved study
- Failure to follow recommendations made by the IRB to ensure the safety of subjects
- Failure to obtain informed consent from each prospective subject according to the IR approved study
- Inadequate supervision of personnel during the conduct of research
- Failure to report promptly adverse events involving harm to subjects
- Failure to obtain approval for modifications to a study prior to implementation
- Failure to provide ongoing progress reports as requested by the IRB

Whenever a non-compliance allegation or complaint is made in regard to an IRB-approved study, the Chair will either investigate the allegation or refer the investigation to another IRB member with appropriate expertise. The Chair will send written notice of the allegation to the researcher and request a response. The Chair (or designated member) will review the allegation of non-compliance, the researcher's response, and any other information necessary to determine whether a full investigation is warranted. At the conclusion of her/his inquiry, the Chair (or designated member) will report findings to the IRB and to the SO (Signatory Official). Recommendations for sanctions, correction, or educational measures will be established by the SO in consultation with the IRB.

The Board may take action to suspend or terminate approval of research. Serious non-compliance may be reported to the Office of Human Research Protection (OHRP). Some examples of serious non-compliance include, but are not limited to the following: conducting human subjects' research without IRB approval, failing to provide accurate reports on adverse events or unanticipated problems in a timely manner, and breaching subject confidentiality. Only the IRB/Executive Committee can make the determination of serious non-compliance. If the IRB suspends or terminates the study, the investigator will be notified of the Board's action. In such circumstances, the IRB has the authority to refuse further research with human subjects by a researcher.

Continuing Non-compliance: Non-compliance that has been previously reported, or pattern of non-compliance that suggests a lack of understanding of human subjects protection requirements that continue after attempts to education the Principal Investigator (PI). Some examples of continuing non-compliance include, but are not limited to the following: repeated failures to renew IRB application ten working days before the protocol expires resulting in lapses of IRB review, inadequate oversight of ongoing research, or failure to respond to a request to resolve an episode of non-compliance within ten business days. Continuing noncompliance may be reported to OHRP. Research misconduct adheres to Ursinus College's Research Misconduct policies.

Membership Policies and Procedures

Who makes up the IRB membership?

This section provides information regarding IRB membership requirements, responsibilities, education and training, regulations, and the information received by the Committee members.

Per federal rules and regulations, the IRB must be composed of the following:

- At least five members
- All members cannot be of the same profession
- All members cannot be of the same sex
- One member must be a non-affiliated member (not affiliated with the institutions served)
- One member must be a non-scientific member

The primary responsibility of the IRB member is to protect the rights and welfare of human research subjects. This obligation is maintained when the proposed research protocol is reviewed for scientific merit. Members are also required to attend training and education sessions.

Terms of service are three years although a term may be less depending on the situation. These are reviewed on a case-by-case basis. There is no limit on numbers of terms that a member may serve. A member may be terminated from service if the member requests termination, if the three-year term expires or if a confirmed issue of non-compliance involves the member.

The Vice President of Academic Affairs appoints the IRB members based upon the recommendation of the IRB Chairperson. Non-affiliated members are selected from the community by word-of-mouth or by contacting the IRB Administrative Office.

A dated and, preferably, signed CV or résumé for IRB members is to be submitted at the time of initial appointment and then at each re-appointment.

Who is the IRB Chairperson?

The Vice President of Academic Affairs appoints the IRB Chairperson on a three-year basis. There is no limit on the numbers of terms that the IRB Chairperson can serve.

The IRB Chairperson may approve research protocols if the protocol qualifies for exempt from full or expedited review. The IRB Chairperson may not disapprove a protocol. All disapprovals, regardless of level of review, must be determined by the full committee.

Who is the IRB Vice-Chairperson?

The Vice President of Academic Affairs may appoint an IRB Vice-Chairperson. There is no limit on numbers of terms that the IRB Vice-Chairperson may serve. The IRB Vice-Chairperson may approve research protocols if the protocol qualifies for exempt from full or expedited review. The IRB Vice-Chairperson may not disapprove a protocol. All disapprovals, regardless of level of review, must be determined by the full committee. The Vice-Chairperson assumes the duties of the Chairperson during the absence of the Chairperson.

When are IRB meetings?

The full Committee meets once a year, at a minimum, but can meet as often as three times a year, depending on the level of review required for each proposal. The IRB meetings are held on campus. The IRB meetings are scheduled at a mutually convenient time for the members. If a change in the meeting or application submission date is required, or a meeting needs to be cancelled, an email message will be sent to campus, as well as posted on the IRB web page.

Attendance at a meeting is acceptable as a training and education opportunity. Guests such as students, new faculty members, staff or community members who wish to observe the IRB meeting in order to learn about research and who are not affiliated with a particular research protocol, or visitors from other Institutional Review Boards may attend the IRB meeting if the following criteria are met:

- If the guests are required to attend by a faculty member as part of their curriculum, then the individual must contact the IRB Administrative Office a week prior to the meeting, to confirm their attendance.
- The Chairperson or his designee, prior to the meeting, must approve each visitor's request to attend.

- Also, any individual may be asked to leave the meeting if the Chair determines a sufficient need. If requesting to attend a meeting, please contact the IRB administrative office by the Wednesday prior to the meeting in order to ensure that:
- Appropriate number of copies of required materials are available.
- The potential for any conflicts of interest is determined.

If requested to attend to present a specific protocol, a window of time will be determined prior to the meeting to avoid an investigator having to miss advising, teaching or research time. Please note that scheduled times are not exact as some protocols may require more or less discussion than others.

Investigator attendance at the IRB meeting is not required, unless specifically requested. Sometimes, meeting attendance by the Principal Investigator (PI) alleviates questions regarding the protocol, informed consent and/or assent document(s). However, no member of the research team may be present in the room for the discussion that follows the informational portion of the review in compliance with federal regulations. They may be asked a question to clarify an earlier response, but cannot be in the room during the discussion and vote.

All information discussed in the IRB meetings is confidential. Official reports or letters to investigators regarding the status of the study must come through, or be approved by, the IRB administrative office.

Members are notified of protocols, amendments and continuations that were approved via the expedited or exempt criteria by the agenda and the minutes of the full committee meeting. The IRB Chair will present the study to the full Committee. The investigator or research team will be given approximately five minutes to answer questions related to the study, if necessary. The IRB members are not limited in their presentation, discussion or deliberation time. After the question and answer period, the investigator and/or research team will be asked to leave the room and wait in the reception area outside of the meeting room. The investigator and/or research team should not leave the area until the discussion and vote are concluded as the Committee may have additional questions for them.

Meetings begin when a quorum arrives and each required element is represented. A quorum is defined as 50% of the committee members plus one and must include at least one non-scientific member and/or non-affiliated member. Items may be discussed before a quorum is established; however, no votes may be taken. If a quorum is lost during the meeting, items can be discussed, but no votes may be taken.

At times, additional or special expertise (either scientific or scholarly) or a consultant will be required for the IRB to adequately review a protocol. The use of special expertise is at the discretion of the IRB Chairperson or his designee. Additional expertise is sought from leaders in the field. This expertise is usually presented in writing to the Committee members. The expert is not allowed to vote on the protocol.

What are Conflicts of Interest and how do they pertain to IRB membership and review?

Conflict of interest may be defined as: “A conflict between the private interests and official responsibilities of a person in a position of trust.” This definition is not limited to financial conflicts of interest. For an IRB member, the conflicts may be any of the following:

- **Financial** – owning stock or receiving payments, gifts, etc., from an individual or sponsor
- **Professional** – bias, whether positive or negative, toward an individual, section, department, and population

The conflicts may also be research-related such as conflicts that arise out of an individual’s participation in the conduct or oversight of clinical research or non-research related if unrelated to clinical research.

If an IRB member feels that a conflict of interest may exist, the reviewers should excuse themselves from the review process. IRB members who may have a conflict of interest are required to recuse themselves from discussing and voting on these protocols.

If an investigator feels that a conflict of interest exists, the investigator may request in writing, prior to IRB member assignment, that an individual member not be assigned to review the protocol in question. The investigator must fully document the perceived conflict of interest.

What do IRB Members look for when reviewing a protocol?

The reviewers are to conduct the following for initial and continuing review:

- Evaluate risks to subjects and others.
- Determine whether risks have been minimized.
- Evaluate the anticipated benefits.
- Determine whether risks to subjects or others are reasonable in relation to expected benefits.
- Determine the level for continuing review based on the level of risk.

How is review of Exempt and Expedited projects handled, outside regular meetings of the IRB?

Projects reviewed by the expedited or exempt procedure require a complete application and are conducted by the IRB Chairperson, or by one or more experienced reviewers who have been voting members for more than one year and have expertise in the area being considered. The IRB Chairperson will designate the individual.

How are IRB Meeting Minutes recorded?

The IRB Chairperson, Vice-Chairperson, and the IRB administrator compile information during the meeting for inclusion in the minutes. If minutes have to be altered or revised, the convened committee must approve the alterations or revisions. The IRB administrative staff strives to make the minutes available for review within 14 business days after the meeting. The minutes are not final until approved by the IRB Chairperson. Attendance is taken and documented in the first section of the meeting minutes. If there are late arrivals or early departures, the agenda items may be shifted as needed to ensure compliance with regulations.

What IRB Member education and training is available?

New members are required to complete the CITI online training for IRB members. Each new member is required to complete an orientation session as conducted by the IRB Office prior to serving. Specific educational topics are presented to Committee members on an "as needed" basis such as when issues arise in the lay press, scientific journals and/or if a members requests the presentations.

How and for how long are IRB records retained?

The records required by this policy shall be retained for at least 3 years, and records relating to research which is conducted shall be retained for at least 3 years after completion of the research.

All records shall be accessible for inspection and copying by authorized representatives of the department or agency at reasonable times and in a reasonable manner.

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

- Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects.
- Minutes of IRB meetings, which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions, including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.
- Records of continuing review activities.
- Copies of all correspondence between the IRB and the investigators.
- A list of IRB members, in the same detail as described in §46.103(b) (3).
- Written procedures for the IRB, in the same detail as described in §46.103(b) (4) and §46.103(b) (5).
- Statements of significant new findings provided to subjects, as required by§46.116(b) (5).

Administrative Office Information

IRB Administrative Office Staff

The IRB administrative office staff is employees of Ursinus College and therefore, UC funds their positions.

The IRB administrator receives all IRB mail. In her absence, the duties are assumed by the IRB Chairperson.

All IRB submissions from new protocols, amendments, continuing review, adverse event reports, serious adverse reports, protocol deviations/violations, terminations, general information, and letters to the IRB are logged in on a regular basis by the IRB Administrator.

Filing System

Active files are kept in the order they are received. Files are assembled and are created as needed. Terminated files are placed numerically by month and year in standard filing cabinets. Files that have been terminated for more than three years are shredded on-site. A database of all files is kept in an excel spreadsheet, and updated regularly by the IRB administrator.