Syracuse University

# Protecting Human Participants in Research

Office of Research Integrity and Protections (ORIP)

researchintegrity.syr.edu

# What is the Institutional Review Board?

The Institutional Review Board (IRB) is a committee designated to protect human participants engaged in research conducted at Syracuse University. The SU IRB is comprised of eight members from relevant and diverse academic disciplines and one non-affiliated community member.

# IRB Research Oversight and Protections

The IRB is responsible for the review and oversight of ALL research involving human participants at Syracuse University to ensure compliance with the Code for Federal Regulations, the basic ethical principles outlined in The Belmont Report, University policies, and state and local laws.

# The Belmont Report Basic Ethical Principles Federal Policy for the Protection of Human Participants
## Common Rule 45 CFR 46 (Part A)

**The Belmont Report Basic Ethical Principles**

1. Respect for Persons - Informed Consent-the autonomy in the decision to participate
2. Beneficence – (1) do not harm and (2) maximize possible benefits and minimize possible harms.
3. Justice – fair and equitable procedures and outcomes in the selection of participants.

**The Common Rule defines:**

- The roles and responsibilities of the IRB
- The definition of research
- Categories for review of research
- Criteria for IRB review/approval of research
- General requirements for informed consent

# Definition of Human Participant Research

Human Participant Research is defined as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge that includes interaction or intervention with a living individual about whom private/identifiable information is obtained, used, studied, and or analyzed.

- Do you have a research question/hypothesis related to the data collection?
- Do you intend to draw conclusions as a result of the data collection?
- Are the results intended to be generalized? Will it inform in the body of knowledge already in existence, be published, shared at a conference/workshop, etc.?

If your research meets this definition, IRB review and oversight is required, and you must submit an IRB application for review. The application you submit is dependent upon the category of your research.

# Categories of IRB Review

There are three categories of IRB Review

- Exempt
- Expedited
- Full Board

The category of research is determined by the level of risk to the participant.

# Exempt Review

- Exempt research studies present the lowest level of risk to participants and must meet one or more of the 8 categories defined by the federal regulations.
- Exempt applications are reviewed by the ORIP Director, Tracy Cromp.
- Turn around time for review is approximately 5-7 business days from the date of receipt.
- There are no deadlines for exempt applications. Allow a minimum of 4 weeks for the review to approval process.
- Exempt studies are authorized for a period of 5 years.
- Exemption must be determined by the IRB, not the investigator.

# Exempt Review Examples

## Exempt research may involve:

- Anonymous surveys.
- Identifiable surveys or interviews-if the data is recorded in such a manner that the identity of the participant cannot be readily ascertained or if disclosure of their responses outside the research would not reasonably place them at risk.
- Research on regular/special educational instructional strategies that do not interfere with students' ability to learn required content or adversely affect the assessment of those providing instruction.
- Secondary research involving the use of identifiable information that is publicly available or is recorded in such a manner that the identity of the participant cannot be ascertained.
- Passive observation of public behaviors without the collection of identifiers.
- Low risk/non-sensitive research involving deception ONLY if the participant is informed they will be misled regarding the purpose of the research prior to engagement. A debriefing script must be provided at the end of the study explaining the true purpose of the research and participants must have the option to withdraw their data.
- Research that involves the interaction/intervention with children/minors, decisionally-impaired individuals, and legally restricted individuals does not qualify for exemption.

# Expedited Review

- Expedited research studies present minimal risks to human participants - no greater harm or discomfort than those encountered in daily activities - and must meet one of the 9 categories defined by the federal regulations.
- Expedited applications are reviewed by the IRB Chair or one of the IRB Co-Chairs and, when deemed necessary, specialists in the field being studied.
- Turn around time for review is approximately 7-10 business days. There are no deadlines for expedited applications. Allow a minimum of 4-6 weeks for the review to approval process.
- Expedited studies are approved until the project is closed. However, an Annual Research Status report is required.

# Expedited Review Examples

## Expedited research may involve:

- Research on individual or group characteristics or behaviors.
- Research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.
- Collection of data through noninvasive procedures routinely employed in clinical practice (moderate exercise, blood pressure screening, muscular strength and flexibility testing, and body composition assessment).
- Research studies that involve the interaction/intervention with legally restricted individuals does not qualify for expedited review.

# Full Board Review

- Full Board research involves greater than minimal risks to participants. Any research that exposes participants to harm or discomfort beyond the level encountered in their daily activities or if disclosure of the participants' responses outside of the research could place them at risk of criminal or civil liability, be damaging to their social or financial standing, employability or reputation requires full board review.
- Full Board applications must be reviewed at a convened IRB meeting with a majority of members present. There is a hard deadline. Applications must be received two weeks prior to the IRB meeting date. Allow a minimum of 8 weeks for the approval process. The IRB meets monthly but does not meet in July. The meeting schedule is on our website.
- Full board applications are approved for up to 365 days from the date of review (unless the IRB determines more frequent review is necessary).
- Annual continuing review at a convened meeting of the full board is required.
- Full board studies are renewable for up to 7 years.

# Full Board Examples

Full Board Research Activities may involve:

- Potential illegal behavior
  - Underage drinking
  - Situations of abuse, harm, or neglect
- Sensitive topics that could be damaging to participants
  - Disclosure of medical status
  - Sexual behavior
  - Job satisfaction
- Legally restricted participants

# Application Content

- Purpose of Research (Rationale or research question) Provide a lay description of the proposed research and the hypothesis to be evaluated.
- Approach/Method –Describe the methods that will be used to gather the data. Define what you will ask participants to do and provide copies of all research instruments.
- The qualifications of the researchers listed in the protocol.
- The characteristics of the participants-including any special populations.
- Any possible participant risks-physical, psychological, financial, etc. and the procedures that will be used to mitigate the risks.
- Any possible participant benefits and how those benefits outweigh the risks.
- How participant privacy and confidentiality of collected data will be maintained.
- How participants will be recruited (learn about participation in the research) and copies of all recruitment tools.
- The type of informed consent that will be obtained and copies of all consent documents.

# Application Information

Student researchers cannot be Principal Investigators on Human Subjects research projects that require IRB review and oversight at SU. It is the policy of the SU IRB that the Principal Investigator be a member of the SU faculty at one of the following positions/levels: Assistant, Associate, Full Professor; Academic, Research, or Professor-of Practice, Department Dean/Chair; or Administrative Staff with the position of Director of higher.

**All applications should be completed under the guidance of the student's faculty advisor and reviewed by the faculty advisor prior to submission.**

# Informed Consent/Assent

Consent is required for **all** human subject participants 18 years of age or older.

Assent is required for **all** human subject participants who are minors (17 years of age or younger) or those considered impaired in their decision making ability.

Although you may request a waiver of the documentation of written consent/assent, i.e. electronic or oral consent/assent, you must obtain consent/assent from **all** participants who will engage in your study.

# Informed Consent

Informed consent is a voluntary agreement to participate in research.

It is not simply a document, but it is a process. The consent process is dialogue between the researcher and the participant that includes a clear description of the study's purpose, duration, procedures, potential risks, and benefits. Circumstances should provide the prospective participant or the legally authorized representative the opportunity to ask questions and allow sufficient time to consider whether they wish to participate.

Because consent is an on-going process, participants should understand that participation is voluntary, and they have the right to withdraw from the study at any time - not just at the time of initial consent.

# Requirements of Informed Consent

General requirements for Written, Oral and/or Electronic Consent must be presented in the following order:

1. An introduction of the researchers so participants understand who is involved in the study.
2. A concise and focused description of the purpose for the research (using language at a reading/comprehension level of the targeted population.
3. Information regarding the procedures.
   - Descriptions of all research activities, including their purpose and duration.
   - Descriptions of the types of measures you will use, including an explanation as to who will administer them.
4. A description of any possible risks and/or discomforts associated with participation and how the risks will be mitigated.
5. A description of any possible benefits associated with participation.
6. A description of how the privacy interests of the participant will be protected.
7. A description of how the confidentiality of the data will be maintained.
8. A description of participant rights including a statement that participation is voluntary.
9. An explanation of who to contact for answers to pertinent questions.

# Additional Requirements for Informed Consent

Additional Requirements for Written, Oral and/or Electronic Consent that should only be included when they are applicable:

- A description of any alternatives to participation.
- A description of any medium of recording (photographs, audio, video, film) which includes the purpose for the recording, how they will be used, who will have access to them, and the disposition of them when the study is complete.
- A description of whether compensation will be offered which includes the method of compensation, how it will be awarded, and how it will be pro-rated if a participant withdraws prior to completion.
- Information regarding situations of abuse, abuse or harm and a description of if/when mandated reporting is indicated.
- Information regarding legal subpoena.
- Information regarding Certificates of Confidentiality.
- Information about whether relevant research results will be returned to the participants.
- Information about possible commercial profit.
- Information about whether research activities will include whole genome sequencing.

# Consent Form Guidance

For all Expedited and Full Board research applications please use the consent form templates on our website.

You are not required to use the headers provided in the template; however, it is imperative that the information presented in the consent form strictly adhere to the order in which it is presented in the template in order to be compliant with current federal regulations.

A consent form template for Exempt research applications and an assent form template are also available on our website.

https://researchintegrity.syr.edu/human-research/forms/

# Complete IRB Application

In order to prevent additional delays in the review process a complete IRB application must include:

- The finalized versions of all research instruments- questionnaires/surveys/interview guide questions/focus group topics, etc.
- All recruitment tools, scripts for direct-face-to-face/telephone/announcements, Internet/social media posts, advertisements, flyers, emails, letters, etc.
- All informed consent/assent documents as appropriate.
- Any additional forms that may be required, letters of cooperation, international research, research conducted in schools, children, prisoners, genetic research, etc.

# Outcomes of Review

Once your application has been submitted and reviewed, the IRB can:

- Approve
- Request modifications or additional information
- Disapprove
- Defer approval due to lack of essential information related to participant risk, methods, privacy and/or confidentiality
- Re-categorize the research as Exempt, Expedited, or Full Board

# Student Projects

Student projects involving human participants that are conducted ***solely*** to fulfill course requirements do not require IRB review.

**However, if data will be shared beyond the classroom/course assignment *(e.g. in any type of publication-including web publication, for presentation at academic conferences/workshops, in thesis/dissertation, etc.)* the project must receive IRB approval prior to initiation.**

All Capstone, SOURCE, Honor's, Master's or doctoral theses, or other projects involving human participants that will lead to generalizable knowledge in some manner **must** be submitted for IRB review.

# Collaborative Institutional Training Initiative (CITI) Education and Required Training

- CITI Training is required for all Expedited and Full Board Applications.
- All persons listed in the protocol application that will have direct contact with participants and/or identifiable human participant data are required to complete the CITI training appropriate to their role in the research.
- No Expedited or Full Board studies will be approved until CITI training requirements are satisfied.

CITI training guidance is provided on our website.

https://researchintegrity.syr.edu/human-research/education-and-required-training/

# Amendments

After your research study is approved by the IRB, it is only approved for what is included in the application the IRB reviewed and authorized. This includes all research instruments, research staff, recruitment materials, consent/assent forms, research sites, and any other changes however minor (i.e.-change in title).

Amendments are required whenever any changes are made to the materials in the original approved protocol.

Changes to the protocol, no matter how minor, cannot be implemented prior to IRB review and formal approval of the changes.

- *Exception*: if the change is essential to protect human participants from harm

# When can I begin conducting my research?

- No aspect of your human participant research can be conducted until your application has been submitted, reviewed and you receive formal notification from the IRB of Exempt authorization or Expedited or Full Board approval.
- This includes recruitment, scheduling appointments for interviews and or conducting interviews, the dissemination of any questionnaires/surveys, data collection, and/or data analysis.
- The IRB review process can take up to two months dependent upon due diligence on the part of the researchers in responding to the IRB when modifications/revisions are required. Because of this, researchers should consider the timeline of the planned research when submitting an IRB application for review.

# IRB Guidance and Contact Information

Please contact the IRB office for guidance regarding IRB policies and procedures.

The Office of Research Integrity and Protections
214 Lyman Hall
Phone Number: 315-443-3013
Email: orip@syr.edu
Web: http://researchintegrity.syr.edu

# QUESTIONS?

Syracuse University

# Thank You


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