HUMAN RESEARCH PROTECTIONS PROGRAM

Frequently Asked Questions

A Guide for Researchers, Instructors, and Graduate Students

Office of Research Integrity and Protections (ORIP) | Syracuse University | Version 1.0 | June 2026

This FAQ addresses the questions HRPP staff hear most often from researchers, instructors, and students at Syracuse University. Answers reflect current federal regulations (45 CFR 46, the revised Common Rule), SU institutional policy, and ORIP practice.

For questions not addressed here: attend ORIP virtual office hours, email orip@syr.edu, or visit researchintegrity.syr.edu.

Important: Only the IRB can make official determinations about review type, exempt status, or whether your activity constitutes human subjects research. This document provides general guidance only.

Topics in This Guide

Section 1 Getting Started: Does My Study Need IRB Review?

01 Q How do I know if my project involves human subjects research?

A A project meets the federal definition of human subjects research when it is:

(1) a **systematic investigation** designed to develop or **contribute to generalizable knowledge (both must be true)**

Systematic Investigation	Generalizable Knowledge
• Poses a research question or hypothesis • Collects data through an organized, consistent method • Analyzes that data (quantitatively or qualitatively) • Draws conclusions from the results	• The findings contribute to an established theoretical framework or body of literature • The primary audience is other researchers, scholars, or practitioners in the field • Results are intended for publication, presentation, or professional distribution • Findings are expected to apply to populations or settings beyond where data was collected • The study is designed to be replicated in other contexts • Results will be published online for professional or academic purposes, including student work showcases

(2) Human Subjects involve obtaining information about living individuals through intervention or interaction with them, or by using their identifiable private information.

Information about Living Individuals	Intervention or Interaction
• Information or biospecimens obtained are about living individuals • Information or biospecimens are collected through intervention or interaction with individuals and will be used, studied, or analyzed • The researcher will obtain, use, study, analyze, or generate identifiable private information or identifiable biospecimens	• **Intervention** — physical procedures used to gather information or biospecimens (e.g., venipuncture), or any manipulation of a participant or their environment conducted for research purposes • **Interaction** — any communication or interpersonal contact between the researcher and a participant • **Private information** — information about behavior occurring where a person reasonably expects no observation or recording, or information shared by an individual for a specific purpose with a reasonable expectation it will not be made public • **Identifiable private information** — information or biospecimens from which a participant's identity is or could readily be determined by the researcher

Both conditions (it is research and uses human subjects') must be present. Class assignments, journalism, oral history projects intended solely for preservation, and quality improvement activities often do not meet this definition, but context matters.

Note: *When in doubt, contact ORIP before you begin. Conducting research without IRB review when it is required is a serious compliance violation.*

Regulatory reference: *45 CFR 46.102(e), (l)*

02 Q Can I self-determine that my study is exempt and begin without contacting the IRB?

A No. Even if you believe your research falls into an exempt category, only the IRB can make an official exemption determination. Starting data collection before receiving written IRB confirmation of exemption is a protocol violation.

Submit an application describing your study and ORIP will review and issue a written determination. This protects both participants and you as the researcher.

Regulatory reference: *45 CFR 46.101; SU HRPP Policy*

03 Q Is my thesis, dissertation, or class project considered human subjects research?

A It may be. A student project that involves collecting data from or about people — through surveys, interviews, observation, or secondary data — may constitute human subjects research requiring IRB review, regardless of whether it is for a class or a dissertation.

Key factors the IRB considers:

- Is the work designed to contribute to generalizable knowledge (beyond meeting a course requirement)?
- Does it involve interaction with people or use of their private identifiable information?
- Will findings be presented publicly (conference, journal, poster)?

Note: *Undergraduate Honors theses and graduate dissertations that involve human subjects research generally do require IRB review. Talk with your advisor and contact ORIP early.*

04 Q Do activities like program evaluations, needs assessments, or quality improvement projects require IRB review?

A Not necessarily but the line between research and non-research can be blurry. Quality improvement (QI) projects and program evaluations are generally not considered research if the primary intent is to improve local processes rather than to generate generalizable knowledge.

However, if you plan to publish or present findings beyond your institution, the activity may cross into research territory. ORIP can help you think through the distinction with a brief consultation.

Regulatory reference: *45 CFR 46.102(l)*

05 Q Does secondary analysis of existing datasets require IRB review?

A It depends on whether the data is identifiable. Secondary analysis of publicly available, fully de-identified data typically does not constitute human subjects research. However, if the dataset contains any information that could be used to identify individuals, directly or indirectly, an IRB review is likely required.

Common scenarios:

- Publicly available, de-identified data (e.g., census, ICPSR datasets): may be non-human subjects research but submit an application to be sure.
- Institutional records with student or patient identifiers do require IRB review
- Coded datasets where the key linking code is held by someone else: may qualify for exempt review under Category 4

Note: *Even if your analysis is deemed non-human subjects research, you may still need to address data use agreements or FERPA/HIPAA requirements.*

Regulatory reference: *45 CFR 46.102(e)(1), 46.104(d)(4)*

Section 2 Submitting a Protocol

06 Q How do I submit an IRB application at Syracuse University?

A All IRB applications are available on the researchintegrity.syr.edu website. Because application updates are sometimes necessary, always download a new application directly from the website.

General steps:

- Complete your CITI training and ensure it is current before submitting
- Go to the www.researchintegrity.syr.edu website
- Complete all applicable sections of the application, including study description, participant information, recruitment materials, and consent documents
- Add all key personnel to the study record
- Submit application for IRB review through the orip@syr.edu email and you will receive an email confirmation

Note: *All application materials must be finalized before submission. Incomplete applications will be returned without review.*

07 Q What information do I need to have ready before I can submit?

A Before submitting your application, you should have the following ready:

- Completed CITI training certification (all key personnel)
- Study description: purpose, design, and research questions
- Description of participants: who they are, how many, and how you will recruit them
- Recruitment materials: scripts, flyers, emails, or social media posts
- Data collection instruments: surveys, interview guides, observation protocols
- Consent/assent documents (if applicable)
- Data management plan: how data will be stored, protected, and retained
- If applicable: sponsor agreements, data use agreements, or site permission letters

> ***Note:*** *Do not contact participants, advertise the study, or begin data collection before receiving written IRB approval or exemption confirmation.*

08 Q How long does IRB review take?

A Review timelines vary by review type:

- Exempt review: typically, 5–10 business days from submission of a complete application
- Expedited review: typically, 10–15 business days
- Full board review requires submission before the IRB meeting deadline; review occurs at the next scheduled convened meeting (monthly). See the ORIP website for the current meeting schedule and submission deadlines.

Review timelines begin when ORIP receives a complete compliant application. Applications missing required documents, incomplete consent forms, or unclear study descriptions will be returned, which resets the clock.

09 Q Can I add or change key personnel after the protocol is approved?

A Yes, but this requires an amendment. Any change to key personnel which includes, adding a co-investigator, adding a student researcher, or removing someone from the study team, must be submitted as an amendment sent to orip@syr.edu and approved before the new person begins working on the study.

All new key personnel must have current CITI training before they can be added. ORIP will verify this as part of the amendment review.

10 Q What is a co-investigator versus key personnel? Does everyone need CITI training?

A Co-investigators are individuals who share responsibility for the scientific and ethical conduct of the research. Key personnel is a broader term that includes anyone who contributes substantially to the design, conduct, or reporting of the research and interacts with participants or has access to identifiable data.

Yes, all key personnel must have current CITI training appropriate to their role and the type of research. This includes graduate student researchers, research coordinators, and anyone involved in data collection or analysis involving identifiable information.

Note: *Undergraduate research assistants who only perform clerical tasks and have no contact with participants or identifiable data may not require CITI training — contact ORIP to confirm.*

11 Q My study involves a site outside of Syracuse University (another institution, school, or community organization). What do I need?

A Research conducted at an external site often requires additional documentation. Depending on the situation, you may need:

- A letter of permission or cooperation from the external site (e.g., a school principal, community organization director)
- A data use agreement (DUA) if you will receive data collected by the other institution
- A reliance agreement if the other institution has its own IRB and you wish to use their IRB as the IRB of record (sIRB arrangement)

Start the conversation with ORIP early because some external site approvals take time to obtain and cannot be finalized until after IRB approval is granted.

Section 3 Review Types: Exempt, Expedited & Full Board

12 Q What are the three types of IRB review and how are they different?

A Federal regulations establish three review levels based on the degree of risk to participants:

- **Exempt review**: for research that fits specific low-risk categories defined in 45 CFR 46.104. Despite the name, the IRB must still make the exemption determination — it is not self-certifying. Examples: surveys of adults on non-sensitive topics, observation of public behavior, analysis of de-identified data.
- **Expedited review:** for research that involves no more than minimal risk and fits one of 9 federally defined expedited categories. Review is conducted by the IRB Chair or a designated reviewer rather than the full board. Examples: non-invasive physiological measurements, focus groups, interviews on moderate-risk topics.
- **Full board review:** required when research involves greater-than-minimal risk, involves vulnerable populations in ways that cannot qualify for expedited review, or involves deception without a waiver. The full IRB board reviews the study at a convened meeting.

Note: *The IRB assigns review type based on the study as described in the application — not based on the researcher's preference.*

Regulatory reference: *45 CFR 46.104, 46.110, 46.111*

13 Q What does 'minimal risk' mean?

A Minimal risk means 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.

In practice, this includes things like completing a survey about experiences at work, participating in a brief interview about educational practices, or providing a blood sample of the kind taken in a routine medical exam.

Research involving sensitive topics (trauma, substance use, illegal activity, mental health), potentially stigmatizing data, or physical procedures beyond routine measures generally exceeds minimal risk and will require expedited or full board review.

Regulatory reference: *45 CFR 46.102(j)*

14 Q My study was initially determined to be exempt, but I want to change the study design. Do I need to notify the IRB?

A Yes. Any modification to a study, including studies determined to be exempt, must be reviewed by ORIP before implementation if the change could affect the basis for the original determination. This includes adding new questions, changing the participant population, adding new data collection methods, or collecting identifiable information that was not originally planned.

Submit a modification request through the ORIP email describing the changes. IRB reviewers will determine whether the original exempt status still applies or whether a new review level is required.

15 Q When is full board review required? What happens at a convened meeting?

A Full board review is required when a study involves greater-than-minimal risk and does not qualify for expedited review. Common examples:

- Studies involving vulnerable populations (prisoners, pregnant women, children) with more than minimal risk
- Clinical trials involving investigational drugs, devices, or biologics
- Research involving significant psychological stress, sensitive personal disclosures, or potential for deception
- Studies where a waiver or alteration of informed consent is sought

At a convened meeting, a quorum of IRB members (including at least one non-scientist and one non-affiliated member) review the study and vote to approve, request modifications, or disapprove. ORIP will notify you of the outcome following the meeting.

Note: *Check the ORIP website for current submission deadlines and materials must be submitted several weeks before the meeting date to allow time for member review.*

Regulatory reference: *45 CFR 46.108, 46.111*

16 Q Can the IRB waive the requirement for informed consent? When?

A Yes, under specific circumstances. The IRB may waive or alter the requirement for informed consent if all four of the following criteria are met:

- The research involves no more than minimal risk
- The waiver or alteration will not adversely affect the rights and welfare of subjects
- The research could not practicably be conducted without the waiver or alteration
- When appropriate, subjects will be provided with additional pertinent information after participation (debriefing)

Common situations where a waiver is appropriate: surveys where anonymous response is the protective mechanism, retrospective record reviews, and certain naturalistic observation studies.

Note: *You must specifically request a waiver of informed consent in your IRB application and provide justification for each criterion above.*

Regulatory reference: *45 CFR 46.116(f)*

Section 4 Informed Consent

17 Q What must be included in an informed consent form?

A Federal regulations require that informed consent includes eight basic elements and six additional elements when applicable. At a minimum, a consent document must include:

- A statement that the study involves research and an explanation of its purpose
- A description of the procedures to be followed and identification of any that are experimental
- A description of any reasonably foreseeable risks or discomforts
- A description of any benefits to the subject or others
- A disclosure of alternative procedures or courses of treatment, if applicable
- A statement describing how confidentiality of records will be maintained
- Contact information for questions about the research and participant rights
- A statement that participation is voluntary and refusal or withdrawal will not result in penalty

SU's consent form templates are available on the ORIP website and incorporate all required elements. Use of the template is strongly encouraged.

Regulatory reference: *45 CFR 46.116(b)*

18 Q Do I need a written consent form, or can consent be obtained verbally?

A Written consent is the default requirement. However, the IRB may waive the requirement for a written signature when:

- The only record linking the subject to the research would be the consent document itself, and the principal risk is a breach of confidentiality (anonymous survey scenario)
- The research presents no more than minimal risk and involves no procedures that would normally require written consent outside the research context

When written signatures are waived, you must still provide participants with an information sheet summarizing key study details (a written summary of what a consent form would have covered), unless the IRB also waives this requirement.

Note: *Verbal consent scripts and information sheets must be submitted with your IRB application and approved before use.*

Regulatory reference: *45 CFR 46.117(c)*

19 Q My study involves participants who do not speak English. How do I handle consent?

A You must ensure that consent is provided in a language understandable to the participant. Options include:

- Translating the full consent form into the participant's language (requires IRB approval of the translated document)
- Using a short-form consent document in the participant's language, read aloud, with a witness present (requires an IRB-approved short form and an English-language summary)

Translation should be done by a qualified translator. Machine-translation alone is generally not acceptable for IRB purposes. Include the translation process and credentials of the translator in your application.

Note: *If you are recruiting non-English-speaking participants, plan for this in your initial application and do not begin recruitment and then seek approval for translated materials after the fact.*

Regulatory reference: *45 CFR 46.116, 46.117*

20 Q Can I recruit and consent participants online or via email?

A Yes, with appropriate safeguards in place. Online and email-based recruitment and consent are common and acceptable. Key considerations:

- Recruitment emails, social media posts, and online flyers must all be submitted to and approved by the IRB before use
- Online consent can be implemented through a web-based platform (e.g., Qualtrics) with a consent acknowledgment checkbox (ensure the platform meets data security requirements).
- Consider whether email-based contact could compromise confidentiality if messages are forwarded or viewed by others
- Confirm that your data collection platform stores responses securely and that data will not be accessible to third parties

21 Q What is the difference between anonymity and confidentiality?

A These terms are often confusing but have distinct meanings in research:

- Anonymity means there is no way (even for the researcher) to link a response to a specific individual. Truly anonymous data collection requires that no identifying information be collected at all (no name, email, IP address, or other identifier).
- Confidentiality means the researcher can identify participants but takes steps to protect that information from unauthorized disclosure. Most research is confidential, not anonymous.

You must accurately represent the level of privacy protection in your consent form and study materials. Describing a study as 'anonymous' when you collect email addresses for follow-up is inaccurate and can be a consent violation.

Note: *If you collect responses through Qualtrics or a similar platform, check whether IP addresses or metadata are collected by default as these may constitute identifiable information.*

Section 5 Working with Special Populations

22 Q My study involves children. What additional requirements apply?

A Research involving children (defined as persons who have not attained the legal age of consent, typically under 18) requires additional protections under Subpart D of 45 CFR 46. Key requirements:

- Parental permission: one or both parents must provide written permission for their child to participate, depending on the level of risk
- Child assent: children who are capable of understanding the research must also provide assent (agreement to participate), typically in writing for older children and verbally for younger children. IRB determines the appropriate age threshold.
- Risk-level restrictions: certain categories of research involving children require additional IRB findings before approval

Include parental permission and child assent forms in your application. ORIP can provide templates.

Note: *School-based research may additionally require FERPA compliance and permission from the school or district — plan for this in advance.*

Regulatory reference: *45 CFR 46 Subpart D (46.401–46.409)*

23 Q Can students in my own course participate in my research?

A Yes, but the IRB will carefully evaluate the potential for undue influence or coercion given the inherent power differential between instructor and student. You must demonstrate that:

- Participation is genuinely voluntary and refusal will have no consequence on grades, standing, or the student's relationship with you
- Consent procedures are designed to minimize the perception of pressure (e.g., consent is obtained after grades are submitted, or through a neutral third party)
- The research offers equivalent non-research alternatives for students who choose not to participate

If you are recruiting students from courses, you are not teaching, the concerns are lower but still present. Describe your approach to managing coercion in your application.

24 Q My research involves participants with diminished decision-making capacity. What are the consent requirements?

A Research involving individuals with cognitive or psychiatric conditions that may affect decision-making capacity requires careful attention to consent and assent procedures. The IRB will evaluate:

- Whether the individual has the capacity to provide informed consent (this is capacity-specific and may vary by individual and overtime)
- Whether a legally authorized representative (LAR) must provide consent on behalf of the individual

- Whether the individual's assent should also be sought, even if an LAR provides formal consent

Describe in your application how you will assess and document participant capacity. If you plan to use surrogate consent, identify who will serve as the LAR and under what circumstances.

Regulatory reference: *45 CFR 46.116; 45 CFR 46 Subpart B & D*

25 Q My research involves sensitive topics such as trauma, substance use, mental health, or illegal activity. Are there special requirements?

A Research involving sensitive topics generally requires heightened attention to privacy protections and participant welfare. The IRB will look for:

- A compelling justification for collecting sensitive information and a clear explanation of how it serves the research purpose
- Strong privacy and confidentiality protections, including data security measures
- A clear plan for responding if a participant discloses active harm to self or others (know your mandatory reporting obligations)
- A Certificate of Confidentiality, if applicable — these federal certificates protect identifiable research data from compelled disclosure in legal proceedings
- Referral resources available to participants who may be distressed by the research questions

Note: *Research involving illegal activity by participants requires careful attention to how you describe confidentiality limits and what your mandatory reporting obligations are under New York law.*

Section 6 After Approval: Amendments, Renewals & Reporting

26 Q My study has been approved. Can I make changes to my procedures without notifying the IRB?

A No. Any change to an approved study — regardless of how minor it may seem — must be reviewed by the IRB before implementation. This includes:

- Changes to recruitment methods, populations, or sample size
- Changes to data collection instruments (new survey questions, revised interview guide)
- Changes to consent documents
- Adding or removing key personnel
- Changes to data storage or security procedures
- Changes to the study site or geographic scope

Submit an amendment request through the ORIP email describing the proposed changes. Do not implement changes until you receive written IRB approval of the amendment.

Note: *One exception: you may implement a change without prior IRB approval if it is necessary to eliminate an immediate hazard to participants. Report such changes to ORIP immediately afterward.*

27 Q How long is my IRB approval valid? What do I need to do to continue the study?

A IRB approvals are valid for up to one year from the date of approval. For studies that will extend beyond one year, you must submit a continuing review application before the current approval expires.

ORIP will send a reminder approximately 60 days before your approval expiration date. However, it is the PI's responsibility to track expiration dates and submit for renewal on time.

If your approval lapses before renewal is granted, all research activities (including data collection, analysis of identifiable data, and participant contact) must stop immediately.

Note: *Studies that were approved under the pre-2018 Common Rule may still require continuing review. New studies approved under the revised Common Rule may not require continuing review unless they involve greater-than-minimal risk — ORIP will specify this in your approval letter.*

28 Q What is an unanticipated problem, and am I required to report it?

A Yes. Federal regulations and SU policy require prompt reporting of unanticipated problems involving risks to participants or others. An unanticipated problem is one that is:

- Unexpected (not described in the approved protocol or consent form)
- Related or possibly related to participation in the research
- Suggests that participants or others are at greater risk than previously known

Examples requiring reporting: unexpected adverse effects, breaches of confidentiality, protocol deviations that affected participant safety, or a participant experiencing significant psychological distress related to study procedures.

Report unanticipated problems to ORIP as soon as possible and within 5 business days for serious events. Use the reporting form on our website under *Human Research Forms* or contact ORIP directly if the situation is urgent.

Regulatory reference: *45 CFR 46.108(a)(4); OHRP Guidance on Unanticipated Problems*

29 Q What is a protocol deviation and how does it differ from an unanticipated problem?

A A protocol deviation is any departure from the procedures described in the IRB-approved protocol, whether or not harm resulted. Not all deviations are unanticipated problems, but all must be tracked and reported.

Types of deviations:

- Minor deviation: does not increase risk or significantly affect the rights and welfare of participants (e.g., a participant completed a survey at a different time than specified). Report on continuing review.
- Major deviation: did or could affect participant safety or the integrity of the research (e.g., consent was not obtained before data collection began). Report promptly to ORIP.

Note: *When in doubt about whether an event requires immediate reporting, contact ORIP. It is always better to over-report than to under-report.*

30 Q My study is complete. Do I need to notify the IRB?

A Yes. When research activities are complete (meaning data collection is finished and you are no longer working with identifiable data) you should close the study by submitting a study closure request.

Closing the study ensures accurate compliance records and relieves you of the obligation to submit continuing review applications. It also documents completion for your grant records if the study was funded.

Note that 'complete' typically means you have finished all data collection with identifiable information. If you are conducting secondary analysis of de-identified data, the study may be considered complete even if analysis is ongoing.

Section 7 Training Requirements (CITI Program)

31 Q Who is required to complete CITI training, and when?

A All investigators and key personnel who will be involved in the design, conduct, or oversight of human subjects research at Syracuse University must complete CITI training before the IRB can approve a protocol. This includes:

- Principal Investigators (PIs) and co-investigators
- Graduate student researchers listed on IRB protocols
- Research coordinators and staff with access to identifiable data or participant contact
- IRB members and IRB administration staff

Training must be completed before submission of an IRB application and must remain current throughout the duration of the approved study.

32 Q Which CITI course do I need to take?

A The course you take depends on your role and your research type:

- Social, behavioral, or educational (SBE) researchers: complete the SBE Basic Course
- Biomedical researchers: complete the Biomedical (Biomed) Basic Course
- Researchers working with data or specimens only (no direct participant contact): complete the Biomed Data/Specimens course or the SBE course, depending on the nature of the data
- IRB members: complete the IRB Members course (Biomed or SBE focus depending on your panel)
- IRB administrators and ORIP staff: complete the IRB Administration course

If you are unsure which course applies to your work, contact ORIP or submit an HSR Training Request Form and ORIP will configure the appropriate pathway for you.

Note: *All courses include the SU-specific module (ID 12605) and the Belmont Report module. These are required for all SU researchers regardless of track.*

33 Q How do I access CITI through Syracuse University?

A Access CITI through your SU institutional account to ensure your completions are linked to Syracuse University's records:

- Go to citiprogram.org
- Click 'Log In Through My Institution'
- Search for and select 'Syracuse University'
- Log in using your SU NetID credentials

Do not create a personal CITI account separate from SU because your completions must be associated with the SU institutional account for ORIP to access your training record for compliance verification.

34 Q How long is CITI training valid?

A CITI certifications at Syracuse University expire on the following schedule:

- Researchers (SBE, Biomed, and related courses): 3 years from the date of completion
- IRB members and IRB administration: 4 years from the date of completion

When your certification approaches expiration, you will complete a refresher course rather than repeating the full basic course. CITI offers staged refresher modules (Stage 1, Stage 2, Stage 3 for Biomed; Stage 1, Stage 2 for SBE) that build on prior knowledge rather than starting from scratch.

Note: *Training must remain current throughout your study. If your certification lapses while a study is active, you must complete refresher training before continuing research activities.*

35 Q I completed CITI training at a previous institution. Does it transfer?

A Generally, no. CITI training completions are associated with a specific institutional account. Training completed under another institution's CITI subscription does not automatically count toward SU's requirements.

In some cases, for example, a researcher joining SU with a very recent completion and ORIP may exercise judgment on a case-by-case basis. Contact ORIP directly with your prior institution, completion date, and the course you completed. ORIP will determine whether any credit can be applied or whether you need to complete SU's required modules.

Key Resources & Contacts

ORIP Website	researchintegrity.syr.edu
Email ORIP	orip@syr.edu
CITI Program Login (SU)	citiprogram.org — log in through your institution (Syracuse University)
Human Research Forms	researchintegrity.syr.edu/human-research/forms/
IRB Meeting Dates & Deadlines	researchintegrity.syr.edu/human-research/deadlines-and-meetings/
ORIP Virtual Office Hours	See ORIP website for current schedule