# CGI Researcher Handbook

## Office of the Institutional Review Board

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**IRB Registration Number: IRB00013947**

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## Purpose of the Handbook

The purpose of this document is to provide guidance to CGI researchers who conduct human subjects research (HSR). This document provides information on federal regulations, as well as CGI policies that support and interpret research regulations.

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## Role of the IRB: Ethical Human Research Protections at CGI

The primary role of the CGI Institutional Review Board (IRB) is to ensure that the safety, rights, and welfare of research participants are protected. This is done through the initial and continuing review of human subjects research (HSR) and monitoring of approved projects. The IRB also has the responsibility to ensure that CGI remains in compliance with relevant federal regulations regarding HSR.

***All CGI students are required to complete the Human Research Protection Foundational Training and the Participant-Centered Informed Consent Training*** when they first enroll in the DBH 9100 Culminating Project course series. This requirement applies regardless of whether the student intends to conduct HSR as part of their CP, to ensure that all CGI graduates understand ethical HSR protections.

For students who plan to conduct HSR, an application to the IRB is required to ensure the methodology complies with federal and international human research ethics standards.

## Foundations of Human Research Protections

The Belmont Report (1978) provides the foundation of ***three basic ethical principles*** for conducting HSR. These principles are important considerations for researchers, IRBs, institutions, and sponsors involved in human research.

**Respect for persons**: Respect for persons incorporates at least two ethical convictions: first, individuals should be treated as autonomous agents, and second, persons with diminished autonomy are entitled to protection. Research participants should understand as completely as possible what will be done to them, what information will be gathered about them, and the potential risks and benefits of participating in research. Participants must give their consent freely without pressure or coercion.

**Beneficence**: The term "beneficence" is often understood to cover acts of kindness or charity that go beyond strict obligation. Two general rules have been formulated as complementary expressions of beneficent actions in research: first, do no harm; and second, maximize potential benefits and minimize potential harms. An appropriate balance must exist between potential benefits to the participant and/or society and the risks the individual assumes.

**Justice**: The principle of justice holds that particular individuals, groups, or communities neither should bear an unfair share of the direct burdens of participating in research, nor be unfairly excluded from the potential benefits of research participation. Inclusiveness in research and fair distribution of benefits and burdens are important considerations for researchers, IRBs, research institutions, and sponsors. Issues of fair and equitable treatment arise in deciding whether and how to include individuals, groups, or communities in research, and in determining the basis for excluding some.

**Regulations for Federally Funded Human Subjects Research**
The US Department of Health and Human Services (HHS) provides federal regulations (45 CFR part 46), referred to as the “Common Rule”, for the conduct of HSR funded by the federal government. Any institution receiving federal funding for research must have a Federalwide Assurance (FWA) and must adhere to the Common Rule and other relevant federal regulations, as listed below, as they pertain to federally funded research. Through this assurance of compliance, an institution commits to HHS that it will comply with the requirements set forth in 45 CFR part 46 for the protection of human participants. CGI is in full compliance with this requirement and has FWA.

### Codes for Human Subject Research

Cummings Graduate Institute is an American institution, and our enrolled students are bound by US laws and regulations. Links to the relevant regulations are below. Students practicing outside the United States may be subject to international laws and regulations governing human subjects research, and are responsible for discussing these regulations with the Culminating Project team and ensuring compliance with all geographic-specific HSR policies to which they are subject as citizens or residents of any nation.
Department of Health and Human Services (DHHS)
Food and Drug Administration (FDA)
Department of Defense (DOD)
Department of Justice (DOJ)
Department of Education (ED)
International Compilation of Human Research Standards

### Equivalent Protections and Minimal Risk

Federal regulations allow institutions to reduce IRB requirements for minimal risk in non-federally funded research by committing to provide equivalent protections (EP). EP applies only to research that is neither federally funded nor will be submitted for federal funding. CGI IRB policies have incorporated certain EPs for minimal risk research. CGI IRB will determine which projects meet the EP criteria during initial review.

### History of CGI IRB

The U.S. Department of Health and Human Services (HHS) first granted CGI the ability to register its Institutional Review Board (IRB) in 2023. All CGI faculty, students, and staff conducting research with humans and/or protected health information are required to submit human research protocols to the CGI IRB, which is registered with the Office for Human Research Protections (OHRP #IORG0011777), and was assigned the IRB number IRB00013947. This registration is listed on the OHRP website at http://ohrp.cit.nih.gov/search/search.aspx. Funding agencies should use this website to verify that an institutional review board (IRB) is registered.

## Overview of Regulations and IRB Authority

- The IRB shall review and have authority to approve, require modifications (to secure approval), or disapprove all research activities (45 CFR 46.109(a); 21 CFR 56.109(a)).
- The IRB shall conduct continuing review of research covered by the Common Rule (i.e. federally funded) at intervals appropriate to the degree of risk, but no less than once per year for projects that are greater than minimal risk, and shall have the authority to observe or have a third party observe the consent process (45 CFR 46.109(e); 21 CFR 56.109(g)).
- Research covered by the Common Rule approved by the IRB may be subject to further appropriate review, approval, and disapproval by officials of the institution. However, those officials may not approve the research unless it is approved by the IRB (46 CFR 46.112; 21 CFR 56.112).
- The IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to participants (45 CFR 46.113; 21 CFR 56.113).

## Composition of the IRB

**IRB Members**: Federal regulations require that the IRB have at least five members with varying backgrounds to ensure complete and adequate review of research activities commonly conducted by the institution. The full board composition must include, at a minimum: one member whose primary concerns are scientific areas, one member whose primary concerns are nonscientific areas, and at least one member not affiliated (or whose immediate family member is not affiliated) with CGI. The CGI IRB maintains a modest full board roster responsible for reviewing human research at convened meetings, as well as a roster of minimal risk reviewers.

**IRB Chair and Vice Chair**: Chairs have the knowledge to enforce consistent application of the ethical principles of the Belmont Report, federal regulations, and IRB policies governing human research protections. Chairs are responsible for managing the efficient and effective conduct of IRB meetings and have standard voting privileges as IRB members.

**Consultants**: On occasion, the IRB may request that a topic expert consult on a specific protocol. The consultant is not a replacement for departmental representation on the IRB. Rather, the IRB consults a consultant if its membership lacks knowledge of a specific issue or experience in a particular area, such as a new, specialized technology or a novel participant population. Consultants may be internal or external to CGI and are sought based on their expertise, and must not have a conflict of interest with the protocol under review. Consultants serve an advisory role and do not vote with the IRB.

## Office of the IRB

The OIRB is a support office that serves the IRB, researchers, study personnel, and participants. The OIRB conducts an intake on all submissions, including verification of training and annual conflict of interest disclosure, assigns the submission an IRB number if it is a new project, and enters it in the queue for review. Once entered into the queue, the IRB Chairperson will conduct a preliminary review (pre-review), ensuring that all required documents are present, that information is consistent across all documents, and that critical regulatory and ethical requirements are addressed. The Chairperson will also make an initial determination as to whether the project requires IRB review (i.e., meets the definition of HSR), and the risk level of the project. If any issues are noted, the Chairperson will return the submission to the PI, listing the issues to address prior to IRB review. *Researchers must address issues within 10 days to continue the review process.*

Additionally, the Chairperson will ensure that all required regulatory determinations are properly documented and will communicate the decision to the researcher. OIRB staff are also responsible for educational outreach on HSR protections, post-approval monitoring of approved research, and continuous quality improvement within the OIRB. Regarding research participants, the OIRB serves as an information resource on human research protection requirements and as a contact point for questions, concerns, or complaints about the research participant experience.

## Defining Human Subjects Research

IRB policies define the activities the institution considers HSR. A decision tree and guidance document are available in the DBH 9101 course to help the researcher determine whether their research project meets either the HHS or FDA definition of HSR, keeping in mind that the IRB has the authority to make the ultimate determination if an activity is subject to IRB oversight. The researcher may not conduct HSR without prior IRB approval. If you have questions about whether an activity is HSR, contact the OIRB, which will provide you with a determination.

## Researcher's Responsibilities

**Principal Investigator (PI) Eligibility:** To be eligible to serve as PI on an HSR project submitted to the CGI IRB, an individual must meet one of the following criteria at the time of submission:

- Is a CGI student enrolled in the DBH 9100 course series and has completed the OHRP training.
- Is a PI approved by an external site utilizing CGI IRB services?

The PI is responsible for supervising research to ensure the safety of research procedures and compliance with all relevant IRB requirements, including data security. The PI of Record will assume responsibility for the conduct of the research project in accordance with institutional policy, state and federal laws, and regulations.

### Researcher Training

For the purpose of the IRB, study personnel are those individuals who either interact or intervene with individuals for the purpose of research, who have access to private identifiable information, and/or are the PI of Record for a student project. CGI students and faculty members serving on CP committees are required to complete the OHRP training and have an active completion report every 3 years.

Prior to becoming study personnel, individuals must complete the five lessons in the Human Research Protection Foundational Training and additionally the Participant-Centered Informed Consent Training available at the OHRP website: https://www.hhs.gov/ohrp/index.html

1. Once the lessons have been completed and passed, the Status will read “Passed.” Then you will be taken to a screen where you can download or take a screenshot of a completion certificate. (It will say ‘Congratulations, you’ve completed…' and you must enter your name and date; the OHRP does not collect your data).
2. Students should save the Completion Report as a PDF and upload it to the assignment folder in the DBH 9101 course.

For faculty to serve as a CP Chair or committee member, you must retake the training every 3 years.

### Faculty Responsibility in Student Research

A faculty member assigning research projects involving human participants must take an active role in assuring that the participants in student research are adequately protected. The CGI’s Culminating Project (CP) course instructor and CP Chair will take an active role in preparing students for the role of researcher, instructing them in the ethical conduct of research, and assisting with the preparation of IRB applications. After IRB approval, the CP instructor and CP Chair will meet regularly with the student in order to review their work and progress. While a student serves as the primary researcher for the protocol, the faculty advisor is ultimately responsible for protecting human participants. By completing a new project questionnaire and submitting the protocol, the faculty member indicates their willingness to comply with all administrative and federal regulations. To comply with this policy, the faculty member serving as the Principal Investigator must educate and mentor the research team and maintain research records as required by law and CGI policy.

## Submitting a Project for IRB Approval

The most current versions of the IRB Checklist, IRB submission forms, templates, and research tools are located in the DBH 9100 courses.

All researchers must become familiar with the IRB Submission Checklist, which specifies the documents required to submit new projects, amendments, continuing reviews, closures, modifications, HSR determinations, and IRB deferrals. Researchers must use the current protocol, consent, and recruitment templates when drafting project documents.

## IRB Protocol

The IRB Protocol is the most important document submitted to the IRB. It provides detailed information about the study, enabling the IRB to review and evaluate it in accordance with federal approval criteria. Use the Protocol Template as a starting point for drafting a new IRB Protocol, and use the bullet points as a guide to what the IRB looks for when reviewing research. Here are some key points to remember when developing a protocol:

- Always keep a version-dated electronic copy. You will need to modify this copy whenever you make changes or updates to the protocol.
- If you believe your activity may not be HSR, talk to your CP course instructor prior to developing your protocol.
- Inclusion Criteria should be specific for any vulnerable populations that may be included in the research. These populations may have regulatory implications and may require additional protections. Provide justification if your project includes any of the vulnerable populations listed in the Protocol Template.

## Informed Consent

It is the researcher's responsibility to educate prospective participants about the purpose of the project and its risks and benefits, to obtain their consent before involving them in research, and to keep them informed as the research proceeds. This is the informed consent process. Information may be provided to the potential participant as a document that may or may not require a signature, a script that is read to the participant prior to proceeding with a telephone survey, a paragraph to be read prior to completing an online survey, or a hybrid of the above.

It is essential that informed consent discussions be conducted and that documents be written in plain language that participants can understand. CGI IRB has specific policies regarding the recruitment and informed consent of non-English-speaking and child participants (see the Special Considerations section below). The consent document(s) should always be revised when there are changes to the project that might affect the participant, or when additional information would improve the consent process. If appropriate, participants who have previously provided informed consent may need to be notified of changes in the protocol and/or consent document(s). **All researchers must evaluate the readability of all consent forms and adjust scientific language to**

**ensure reading comprehension at the public health level (6th grade or below) for adults and at a level appropriate for children participating as participants.**

The consent form(s) should not contain any exculpatory language. Participants should not be asked to waive (or appear to waive) any of their legal rights, nor should they be asked to release the researcher, sponsor, or institution (or its agents) from liability for negligence. Federal regulations and CGI policy also require that researchers seek informed consent only under circumstances that provide the prospective participant (or representative) sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence, defined as any act of persuasion that overcomes the free will and judgment of another.

### Consent Forms

Obtaining a participant's signature and date on a consent form is important, but it is just one step in the continuous process of informed consent. Informed consent is about people's understanding and willingness to participate in your project; signing a form is the most common way to document that participants understand and are willing. Prospective participants in your research must understand the purpose, the procedures, the potential risks and benefits of their involvement, and their alternatives to participation. While a consent document that provides this information and more is a vital part of the process, the opportunity to discuss any questions or concerns with a knowledgeable research team member is also necessary.

Use one of the Consent and/or Assent Form templates in the CGI IRB Library to create a consent form. Note that consent forms must include all required elements of consent as outlined in the template. Template language for additional elements of consent that may be required for various projects can be found in the Additional Elements of Consent. Consent forms that exceed 4 pages must include the key information presented in the consent template. All consent forms should also include a version date. Use only the approved consent form to enroll participants.

Note: If working with children, individuals with cognitive impairment, including those with a Severe Mental Illness (SMI) diagnosis, dementia, or other impairment that diminishes capacity for judgment and reasoning, must review the Legally Authorized Representatives LAR Definitions & Policies and demonstrate what safeguards will be in place to protect the rights and welfare of vulnerable participants in the Protocol form.

### Informed Consent Not Needed for Screening

An IRB may approve a research proposal in which a researcher will obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective participants without the informed consent of the prospective participant (or LAR), if either of the following conditions is met:

1) The researcher will obtain information through oral or written communication with the prospective participant or LAR, or

2) The researcher will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

**Informed Consent and Documentation Waivers**

An IRB may waive the requirement to obtain informed consent or approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent. In most cases, this occurs when the participant is not directly involved in the research procedures (e.g., record review, secondary data analysis), provided the researcher justifies, and the IRB finds and documents that:

1) The research involves no more than minimal risk to the participants.
2) The research could not practicably be carried out without the requested waiver or alteration.
3) 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;
4) The waiver or alteration will not adversely affect the rights and welfare of the participants; and
5) Whenever appropriate, the participants or legally authorized representatives will be provided with additional pertinent information after participation.

In most cases, informed consent must be documented (obtain the participant's signature and date). However, in some cases, waiving the requirement for consent documentation (no signature) is appropriate and allowed.

**In order for the IRB to waive the requirement of a participant’s signature, one of the following conditions must be justified in the IRB protocol:**

1) That the only record linking the participant and the research would be the informed consent form, and the principal risk would be potential harm resulting from a breach of confidentiality. Each participant (or LAR) will be asked whether the participant wants documentation linking the participant with the research, and the participant’s wishes will govern; OR that the research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context; OR
2) If the participants or LARs are members of a distinct cultural group or community in which signing forms is not the norm, the research presents no more than minimal risk of harm to participants, and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

If the documentation requirement is waived, the IRB may require the researcher to provide participants with a written statement regarding the research (i.e., a consent form with no signature lines).

Note: If requesting any type of waiver from the IRB, justifications must be provided in the IRB Protocol with direct reference to the criteria listed above.

## Criteria for IRB Approval of Research

In order to approve an HSR project, the IRB must determine that all of the following requirements are met:

1) Risks to participants are minimized: (i) by using procedures which are consistent with sound research design and which do not unnecessarily expose participants to risk, and (ii) whenever appropriate, by using procedures already being performed on the participants for diagnostic or treatment purposes (such as a blood draw, or diagnostic behavioral interview).
2) Risks to participants are reasonable in relation to both the anticipated benefits, if any, to participants and to the importance of the knowledge that may reasonably result.
3) The selection of participants is equitable. In making this assessment, the IRB will consider the research's purposes and the setting in which it will be conducted. The IRB should be particularly cognizant of the unique problems posed by research involving vulnerable populations.
4) Informed consent is sought from each prospective participant or the participant's legally authorized representative, in accordance with relevant policies or federal regulations (including all required elements, ongoing consent, in a language understandable to participants, etc.).
5) Informed consent is appropriately documented, in accordance with relevant policies and federal regulations, unless there is a credible justification to waive such documentation.
6) When appropriate, the research plan provides adequate monitoring of data collected to ensure participant safety.
7) When appropriate, there are adequate provisions to protect participants' privacy and maintain data confidentiality.

## Types of IRB Review

Activities that meet the definition of HSR require IRB review. Activities that do not meet the definition of HSR (e.g., journalism, creative writing, etc.) do not require IRB review. Tools on the website are available to help researchers with this determination.

## Minimal Risk Review of Non-Federally Funded Research

Research that is not funded by the federal government and that involves no greater than minimal risk can undergo minimal risk review. This is a determination made by the IRB after reviewing the project. Minimal risk review procedures allow an individual IRB member to review and approve projects on behalf of the full IRB. Projects that qualify for minimal-risk review are reviewed weekly.

Although not required, the IRB may determine that these projects require continuing review or post-approval monitoring, depending on the type of research and the participant population.

## Exempt and Expedited Review of Federally Funded Research

Certain categories of federally funded HSR can be exempt from IRB oversight as long as they fall within specified categories and meet prescribed ethical criteria, including informed consent, minimal risk procedures, and considerations for participant privacy and data confidentiality. Any significant changes to an exempt project must be submitted to the IRB to ensure the exempt determination remains in effect. This is a determination made by the OIRB or IRB; researchers are not authorized to make exempt determinations.

Examples of exempt projects include online anonymous surveys, classroom curriculum evaluations, interviews on non-sensitive topics, and the review of existing academic, medical, or other records without recording identifiers.

Certain research that involves no greater than minimal risk and only includes procedures listed in the Federal Register expedited review categories can undergo expedited review. This is the IRB's determination after reviewing the project. Expedited review procedures allow an individual IRB member to review and approve projects on behalf of the full IRB. Projects that qualify for expedited review are reviewed weekly.

Although not required, the IRB may determine that these projects require continuing review or post-approval monitoring, depending on the type of research and the participant population. Some full board projects may eventually qualify for expedited review, for example, once the project is limited to data analysis. Examples of expedited projects include identifiable surveys, interviews, and focus groups on potentially sensitive topics; projects that access identifiable health or educational records; projects that collect biological specimens by noninvasive means, etc.

## Full Board Review

Projects that do not qualify for any of the above and/or present greater than minimal risk to participants must be reviewed at a fully convened IRB meeting. The full board meets at least once per month, and more frequently as needed based on enrollment and the needs of CP students at CGI. Submissions that complete pre-review after the deadline will be reviewed at the following month’s meeting. A majority of the board, including at least one non-scientific member, must be present at the meeting in order for a quorum to be established. If protocols include research with prisoners, then an IRB member with that expertise must be present in full board meetings that review such research. ***Examples of full board projects include research in prisons, projects administering drugs or alcohol, research involving invasive interventions (e.g., biopsies), or high-risk or vulnerable populations (e.g., maximal aerobic capacity testing on frail populations), etc.***

## Administrative Review

Minor changes to already approved documents, such as grammar corrections, changes to the recruitment phone number or format, project closures, and HSR determinations, are reviewed administratively by OIRB staff. Submissions that qualify for administrative review are handled on a daily, first-come, first-served basis.

## IRB Review Outcomes

Upon review of a project, the IRB makes determinations that are consistent with federal criteria for IRB approval of research, whether or not the research has federal funding.

**Approved:** The IRB approves a project when all criteria for approval are met. No further action is required from the researcher, and research may begin. Researchers must not begin research (new proposals) or continue research (amendments or continuing review) until the researcher has received a letter documenting IRB approval.

**Modifications Required:** The protocol and/or supporting documents require specific changes to meet the approval criteria. The modification letter will list the changes and/or modifications required by the IRB. The researcher must revise and submit the changes within 30 days and receive an approval letter from the IRB before the project may begin or continue.

**Tabled:** If the IRB was unable to approve a project because one or more criteria for approval were not met or because the submission lacked sufficient detail to make a determination, the PI will be asked to provide additional information or make modifications. In this case, a tabled letter is sent outlining the additional information or changes that need to be provided. If originally reviewed by the full board, the full board must subsequently review the project at a monthly meeting.

**Disapproved:** A fully convened board determines that it is unable to approve the research and cannot describe modifications that might make the research approvable. When making this determination, the IRB will explain its decision and give the researcher an opportunity to address the IRB's concerns. If disapproved, the research cannot be conducted.

**Acknowledged:** OIRB staff are able to acknowledge certain types of submissions, including but not limited to minor administrative corrections to approved recruitment materials and certified translations of approved documents. These submissions do not require formal review by the IRB.

## Appeals Process

If a researcher is not satisfied with the IRB determination, they may submit an appeal within 10 days of receiving the determination by submitting a written defense to the IRB. The IRB will review the appeal at the next available full board meeting. The following should be included in the appeal:

- A letter elaborating a defense that includes why the IRB should reconsider the determination and a point-by-point response to the listed reasons for the determination, including any information not previously provided or considered.

- Any changes to documents should be highlighted using track changes or a similar method to indicate what changes were made.
- Submit the response and any revised documents to the IRB board. Revisions to documents should be made using track changes.

**Researcher Obligations after IRB Approval**

Ensure there are adequate resources to conduct the research safely. This includes, but is not limited to, sufficient time, oversight, equipment, and space; Ensure that project team members are qualified and trained to perform procedures and duties assigned to them during the project, and retain documentation showing human subjects research training (OHRP) has been completed within the last 3 years for all study personnel.

The PI should also have confirmation of COI disclosures on file for the current year for all team members prior to having them perform research duties; Use monitoring and compliance tools, if needed; Personally conduct or supervise the human research in accordance with the IRB approved protocol including ensuring informed consent or permission is appropriately obtained from participants; Not change the project protocol without prior IRB review and approval unless necessary to eliminate apparent immediate hazards to participants.

The IRB will need to be notified of any changes implemented related to immediate hazards within 7 days and submit all necessary submissions to the OIRB, including amendments, continuing review (if required), closures, deviations, and events.

***Researchers may not start human research activities or implement proposed changes until the IRB has granted approval.***

## Type of Submissions

### New Projects

Researchers should submit a new project for IRB approval before they begin any human research. These submissions should include the protocol, consent form, and any documents used with participants during the research. In addition to researching specific documents, a signed Scientific Validity Review form is also required. Scientific validity review is to be completed prior to submitting to the IRB.

### Amendments

Before implementing any change to a project, an amendment must be submitted to and approved by the IRB. Examples include adding or revising questionnaires or other procedures, increasing enrollment, changes in project location or population, changes in recruitment, compensation, etc.

Amendments to federally funded exempt projects should only be submitted if the proposed change disqualifies the project from exemption status or changes the category of exemption to one that requires limited IRB review.

### Continuing Review

Research that is greater than minimal risk must be reviewed by the IRB at least once per year. Some minimal risk research may also require continuing review (this requirement will be noted in the approval letter). Applicable paperwork as outlined in the IRB Submission Checklist (e.g., abstracts and publications that occurred within the last approval period, protocol deviations if appropriate, etc.) must be submitted no later than 30 days prior to the expiration date to allow adequate time for IRB review.

### Protocol Deviations Report

A protocol deviations report is completed over the course of the approval period when protocol deviations occur, as well as at the time of continuing review or closure if any deviations occurred. This report documents minor deviations that did not harm participants, such as the absence of the researcher's signature on the consent form, over-enrollment in a minimal risk project, etc.

### Event Reports

An unanticipated problem is a significant complication or other unfavorable occurrence related to, or possibly related to, research participation that is not anticipated at the time of protocol review and arises during or after the conduct of a project. Unanticipated problems may occur with the participants or others. Adverse events are harms that occur to research participants or others involved in the research. They range from minor to severe and may be anticipated or unanticipated.

An event report must be submitted to the IRB within 7 days of discovery of an unanticipated problem or adverse event occurring during the project. Additional reporting requirements to federal agencies, sponsors, risk management, legal counsel, police, or other entities may also be required. Examples of reportable events include:

- injury, disability, hospitalization, life-threatening experience, death, unexpected side-effects, aggressive or unusual behavior;
- harm or damage to the safety, rights, or welfare of research participants, research staff, or others;
- any complaint of a participant that indicates an unanticipated risk or which cannot be resolved by the research staff;
- breach of privacy, confidentiality, or data security that caused harm or increased the risk of harm; and/or
- loss or destruction of project data not in accordance with IRB-approved procedures.

## Project Closure

Researchers should understand when to close a project in order to remove it from IRB oversight. Closures do not need to wait until the expiration date and may be submitted even if data analysis is ongoing, provided that identifiers are destroyed. The PI is responsible for promptly closing out an IRB-approved project when:

- the PI never initiated the project;
- participant enrollment is closed, all data collection is complete, and the only remaining activity is analysis of de-identified data with no identifying links or codes;
- the PI plans to leave the University; or
- a student researcher leaves the University without notifying the IRB.

The study cannot be closed if the research team is analyzing identifiable data (including data with codes or links to identifiers). To submit a closure request, contact the IRB Chairperson. Note that closure requests are not required for federally funded projects granted an exemption.

## Expiration of IRB Approval

The PI must submit a renewal request at least 30 days prior to the IRB's expiration date. The expiration date is the last date on which the protocol is approved (i.e., IRB approval expires at midnight on that date). If the PI fails to do so and IRB approval expires, all human research activities, including data analysis, must stop. Failure to have a project approved or closed prior to the IRB approval expiration date is noncompliance. When an IRB-approved project's approval expires, a formal noncompliance determination is issued. If a PI has a pattern of IRB approval expiring for projects under their oversight, compliance training will be required, and a fully convened IRB may review the noncompliance. Even if IRB approval has expired, the PI is still responsible for closing the project. The project may be reactivated up to 6 months after IRB approval has expired; after 6 months, it must be closed.

NOTE: The IRB may withdraw or administratively close a project if the PI fails to respond to the IRB's requested modifications within 30 days, the OIRB has not received a response to clarifications within 30 days, or the PI fails to submit a complete continuing review or closure submission. PIs/responsible faculty also have the authority to file a continuing review, amendment, or closure of a student research project if said student has failed to file required paperwork and/or failed to remain in close contact with their mentor/PI. This includes that students cease communication with the University and the IRB Chairperson or their designee post-graduation and fail to respond to requests to complete Project Closure documentation.

## Post Approval Monitoring (PAM)

Researcher interactions with the IRB are not limited to submitting paperwork for review. Once a project is approved, it remains under IRB oversight as long as participant interactions continue, identifiers are in use, and the project is not closed. The PAM program has two goals: 1) ensure ongoing monitoring and compliance of active projects and 2) serve as a training opportunity for researchers as they conduct their research. The IRB may contact the researcher to assess the project in real time through a full assessment, self-assessment, review of the consent document, review of the consent process, or other activities.

### Records Retention

Researchers are advised to retain all project records for 3 years after the project's closure and to take measures to prevent accidental or premature destruction of these documents, unless specified in the IRB protocol and approved by the IRB. This includes approved IRB documents, signed consent documents, de-identified recordings, tapes, or transcripts (unless destroyed earlier in accordance with approved protocol), and all other de-identified data collection instruments and source documents. Confidential data must be stored in a manner that prevents breaches or loss and may be stored in hard copy or electronically. Data may also need to be retained for copyright and intellectual property applications. Researchers must store records in accordance with the IRB-approved plan to prevent breaches of confidentiality.

For research subject to FDA, HIPAA, or other regulatory agency authority, the PI must retain documents and IRB records for the period specified in the applicable regulations, if the requirements exceed 3 years after project closure. For multi-site studies, the PI should consult the sponsor regarding retention requirements, but must retain the records for at least 5 years after closure. There are longer retention periods for certain research records:

- Records involving the generation, disclosure, and/or use of Protected Health Information (PHI) must be retained for six years.
- Record retention for funded research must comply with Sponsor requirements.
- The National Institutes of Health and the National Science Foundation require that grant recipients retain all data for 3 years beyond the final expenditure report.

The PI must ensure that retained records are accessible for confidential inspection and/or copying by authorized representatives of institutional or regulatory agencies.

## Special Considerations

### Assessing Risk of Harm

Assessing risk of harm to individuals who participate in research is one of the IRB's primary responsibilities. Risk is the probability of harm or injury (physical, psychological, social, legal, or economic) occurring as a result of participation in a project. Both the probability and magnitude (severity) of a possible harm may vary from minimal to significant. The magnitude of potential harm is the summative measure of its severity, duration, and reversibility. A research protocol with a low probability of harm occurring, but a high magnitude of harm if it occurs, may be determined to be greater than a minimal risk (e.g., a severe allergic reaction to a new medication, or stigmatization from unintentionally releasing HIV status of participants). Alternatively, a protocol with a high probability of harm but a low magnitude of harm may pose minimal risk to participants (e.g., itchiness after electrode tape removal or distress related to answering sensitive, personal questions).

Federal regulations define minimal risk as 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" (45 CRF46.102(j) and 21 CFR56.102(i)).

The IRB will consider a wide range of risks, including physical, psychological, social, economic, legal, and unknown risks. In most cases, these risks apply to individuals; however, risks can also apply to groups of individuals (e.g., research on alcoholism among Native Americans may be perceived as reinforcing a negative stereotype). The overall project risk is determined by the risk to the most vulnerable known members of the group. IRB reviewers identify anticipated risks associated with participation in the project and classify them as minimal or greater-than-minimal risk.

Reviewers then determine whether the anticipated risks to participants are reasonable in relation to any anticipated benefits to participants and to the importance of the knowledge that may reasonably be expected to result.

Researchers should provide detailed information in the IRB protocol about the potential risks and benefits of the research, including the probability, magnitude, and potential harms associated with each risk. For more information, please see our guidance on Assessing and Minimizing Risk in Human Research.

### Child Assent and Parent Permission

CGI is licensed in the State of Arizona, and our students are required to comply with state law for child assent and parent permission. *Arizona state law requires that, if an individual is under 18 years of age, parental permission be obtained for that child to participate in research, unless the child is married or emancipated by court order.*

Parent permission must be documented in writing unless waived by the IRB. Parent permission may be waived by the IRB if it is not a reasonable requirement to protect the participants (for example, neglected or abused children). However, the PI requesting the waiver must provide justification for the waiver and propose an alternative mechanism to protect the children who will participate in the project. In most cases, when a project involves minimal risk or greater-than-minimal risk but presents the possibility of direct benefit to the child, one parent or guardian's permission is sufficient.

Assent means that a child has given affirmative agreement to participate in research. In determining whether children are capable of assenting, the IRB considers the children's ages, maturity, and psychological state. This judgment may be made for all children to be involved in research under a particular protocol, or for each child, as the IRB deems appropriate. If the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research. In instances where children ages 7-11 are capable of providing assent, the researcher should develop a separate assent form in the language appropriate to the child's educational level. *As a general guideline, children ages 12 and older are considered capable of providing assent and can sign the standard consent form.*

### International Research

CGI researchers who conduct HSR activities at or collaborate with non-U.S. institutions must meet the requirements of U.S. federal laws pertaining to human research as specified in the CGI policies and procedures, as well as any laws that govern research that is conducted in a foreign locality. All researchers must know and comply with relevant laws in the localities where they conduct research, including U.S. tribal, territorial, and foreign localities. In cases of variance between federal laws and state or local laws, or between U.S. and foreign laws and regulations, the more protective standard typically prevails.

If the proposed research will be conducted, in whole or in part, at a site in a foreign country or territory and requires any access to non-public facilities (e.g., local organizations, schools, universities), then authorization to conduct the project must be obtained from the IRB. This is a letter of attestation issued by an appropriate official in the local (foreign) jurisdiction (as determined by that site) that the project complies with local regulations and laws. In many cases, this will involve additional approval of the project by a local IRB or ethics board. If the proposed research will be conducted on tribal land, appropriate authorizations must be obtained, including approval from the Navajo Nation Human Research Review Board (NNHRRB) and/or the tribal council. If there are no relevant regulations or laws in the foreign country pertaining to the proposed research, or no local IRB or ethics board, then a letter of support (translated into English) by an academic administrator or government official from the local jurisdiction may be requested by the IRB (we recommend consulting with the OIRB to determine what is appropriate). In most cases, a letter from a department head or dean at a local academic institution will suffice.

### Non-English Speaking Participants

To ensure prospective participants have sufficient information to provide informed consent to participate in research, researchers must effectively convey information to participants in a language they are comfortable reading, understanding, and speaking. If the project targets a particular group that does not speak and/or read English, the recruitment material(s) (e.g., approach letters, flyers) and informed consent document(s) must be translated into the language understood by the targeted group (45CFR46.116-117 and 21CFR50.20).

### Vulnerable Populations

The CGI IRB gives special consideration to protecting the welfare of research participants who may be particularly vulnerable to the risks of participation, such as children, prisoners, fetuses/neonates, pregnant women, and individuals with impaired capacity to provide informed consent. The IRB also recognizes that additional populations, such as students and disenfranchised groups, may be vulnerable and may need safeguards to protect them during project participation.

It is the researcher’s responsibility to identify the categories of vulnerable participants involved in the research and note the nature of participant vulnerability in the protocol. The protocol should include details regarding the procedures in place to protect vulnerable populations. The IRB submission must include consent/assent forms appropriate to the reading level, language, and cultural sensitivity of the vulnerable population. Additionally, it is the researcher’s responsibility to identify and abide by the applicable state or country (if outside the U.S.) laws governing the use of vulnerable populations.

### Recruitment of Participants

The CGI IRB is charged with evaluating and approving all planned recruitment methods, including appropriateness of materials, inclusion and exclusion criteria, and incentive and compensation components. Researchers and the IRB must ensure that recruitment activities are free of bias, do not exert undue influence on or coerce a potential participant to volunteer, or to imply a guarantee of benefits beyond what is outlined in the IRB approved protocol and consent form. Researchers should make reasonable efforts to ensure open access to research opportunities. However, efforts to be broadly inclusive are only required if there is a potential direct benefit to those participating in the research.

The researcher must carefully consider the targeted research population, research aim(s), participant privacy, and potential for bias and influence when designing recruitment activities for specific protocols. For example, teachers who also serve as researchers and wish to enroll their students in research must ensure that recruitment methods do not exert undue influence or coercion, and that they do not inappropriately promise or suggest classroom or personal benefits beyond what is written in the protocol and consent form. In this example, an acceptable way to address undue influence would be to use a third party to present the project information to potential participants.

Advertisements planned for the recruitment of research participants must be approved by the IRB prior to use. Any changes made after approval must be re-evaluated by the IRB prior to implementation (including exempt research, where new recruitment procedures may substantially change risk levels or participant vulnerability). When developing advertisements, be sure materials clearly state that research participation is being solicited, materials do not contain misleading statements, are written in plain language that participants can understand, potential risks/benefits from participation are accurate, if included, incentives or compensation are not inappropriately emphasized, and communication materials and processes are culturally sensitive and appropriate.

### Compensation of Participants

The IRB will review the amount and schedule of incentives/compensation to assess whether the appearance or reality of undue influence or coercion may lead participants to be overly influenced by their economic insecurity or vulnerability. All information regarding participant compensation should be stated in the IRB protocol and the informed consent document(s), including the amount, method, and timing of disbursement. If compensation is mentioned in the recruitment materials, they must also include a brief description of project procedures.

Payment for purposes of research participation by cash, check, money order, or gift card in the amount of $600 or more per year is taxable income. As such, each participant receiving compensation for participating in a project is required to sign a participant receipt form (for amounts less than $600). Research lotteries and raffles can be utilized under certain specific conditions. Please note that projects receiving federal funding may have additional compensation requirements.

### Family Educational Rights and Privacy Act (FERPA)

FERPA regulates the disclosure of personally identifiable information from education records in all public elementary and secondary schools, school districts, intermediate education agencies, and state education agencies, as well as any public or private agency or institution that uses funds from the U.S. Department of Education. The purpose of FERPA is to protect all student and parent information maintained in an Education Record.

Researchers are responsible for complying with FERPA, IRB, and CGI policies when accessing education records for research purposes. For more guidance on FERPA in human research, review our Guidance on FERPA.

### Health Insurance Portability and Accountability Act (HIPAA)

The CGI IRB serves as the HIPAA Privacy Board for accessing Protected Health Information (PHI) for human research purposes. All other HIPAA issues fall under the jurisdiction of CGI's Privacy Officer. In general, researchers must obtain a HIPAA Authorization or a HIPAA Authorization Waiver for any research use or disclosure of PHI. For further guidance on when HIPAA applies, consult the HIPAA Compliance Policy and/or the Non-Disclosure and Confidentiality Agreement Policy.

### Sponsored Projects

When submitting a new project to the IRB, researchers are required to provide information about acquiring, or the intention to acquire, external funding, as some funding sources require additional scrutiny and the application of additional regulations and policies.

The OIRB suggests that an IRB application be submitted with the proposal for funding, to ensure that IRB review is completed by the time the funding agency needs confirmation of IRB approval. If IRB approval for a funded project expires, it is the researcher's responsibility to contact their sponsor and provide appropriate documentation of the occurrence. Additionally, if an adverse event occurs during the conduct of the project and the IRB determines it to be serious and reportable, the researcher is responsible for reporting it to the funder.

### Additional Requirements for Federally Funded or FDA Regulated Research

When a project is federally funded (e.g., NSF, NIH, DOJ, ED) or falls under FDA regulations, additional human protection requirements may apply. Some federal agencies require the use of a single IRB of record (sIRB) for multi-site projects. In most cases, the IRB at the institution that serves as the prime awardee will function as the sIRB. When participating in a multi-site federally funded project, please contact the IRB Chairperson as soon as possible to discuss the required paperwork. In order to be compliant with federal regulations, IRB Authorization Agreements (IAAs) must be put in place prior to the commencement of the research.

### Research Data Security

Researchers are often entrusted with confidential and privileged human data, whether in paper or electronic form, and must therefore take measures to protect it. Given the wide range of project locations, methods, and electronic devices, researchers should carefully consider confidentiality and data security when collecting and/or storing electronic data, as this data is vulnerable to hacking and other threats. Each member of the campus community is responsible for the security and protection of the information resources under their control. All researchers must be familiar with the information security policies and procedures of their department or unit, CGI, the State of Arizona, and Federal privacy laws (e.g., HIPAA, FERPA), as well as the data confidentiality requirements associated with sponsor funding (e.g., NIH, DOJ, etc.).

In the event that there is a breach or loss of human research data, an event report must be submitted to the IRB within 7 days of the discovery of the occurrence. Additional reporting may be required to the institution and sponsor.

### Certificates of Confidentiality

NIH issues Certificates of Confidentiality (CoCs) to protect identifiable, sensitive research information from forced disclosure. They allow the researcher and others who have access to research records to refuse to disclose all copies of the research record and to prohibit disclosure of names, information, and biospecimens in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level. CoCs are granted for projects collecting information that, if disclosed, could have adverse consequences for participants or damage their financial standing, employability, insurability, or reputation. By protecting researchers and institutions from being compelled to disclose information that would identify research participants, CoCs help achieve research objectives and promote participation by ensuring confidentiality and privacy for participants.

When research is covered by a CoC, researchers:

- May not disclose or provide, in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding, the name of such individual or any such information, document, or biospecimen that contains identifiable, sensitive information about the individual and that was created or compiled for purposes of the research, unless such disclosure or use is made with the consent of the individual to whom the information, document, or biospecimen pertains; or
- May not disclose or provide to any other person not connected with the research the name of such an individual or any information, document, or biospecimen that contains identifiable, sensitive information about such an individual and that was created or compiled for purposes of the research.
- May disclose information only when:
    - Required by Federal, State, or local laws (e.g., as required by the Federal Food, Drug, and Cosmetic Act, or state laws requiring the reporting of communicable diseases to State and local health departments), excluding instances of disclosure in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding;
    - Necessary for the medical treatment of the individual to whom the information, document, or biospecimen pertains and made with the consent of such individual;
    - Made with the consent of the individual to whom the information, document, or biospecimen pertains; or
    - Made for the purposes of other scientific research that follows applicable Federal regulations governing the protection of participants in human research.

## Additional and External IRB Approvals

Some research may require approval by an additional IRB, depending on location or organization. For example, research done on the Navajo Nation requires approval by the Navajo Nation Human Research Review Board. If a site does not use an IRB, approval to conduct research at that site is still required via a Letter of Support (LOS). Researchers are encouraged to consult with OIRB staff to determine whether additional approvals are required for their research.

## Request for Deferral to External IRB

Researchers can request permission to use an external IRB by submitting a Request for External IRB Review form, along with the other documentation listed on the IRB Submission Checklist. In most cases, this request is made for multi-site projects in which another institution is the lead site or for projects in which all human research activities are conducted at a collaborating institution, and does not preclude dual IRB review as noted in the section above. Additionally, the CGI IRB may defer a project to an external IRB if it believes the other IRB is better suited to review it, or if NIH requires single-IRB review. Per CGI policy, the OIRB must decide whether to defer to an external IRB; the researcher cannot make this decision.

Researchers may also request that an external site that is engaged in HSR defer oversight to the CGI IRB. To make such a request, email the IRB office (irb@cgi.edu) and provide the project title and protocol number, the external collaborator's name, and a contact name and phone number for the external site's IRB office. The external collaborator should be listed as a project team member, and the protocol must include details regarding activities being conducted at the external site.