IRB Researcher Manual

Revised March 2026

Office of the Institutional Review Board

Cummings Graduate Institute

FWA Number: FWA00034328 | Expires: 4/11/2029
IRB Registration Number: IRB00013947 | Expires: 7/10/2029

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About This Manual

This manual guides CGI researchers conducting Human Participants Research (HPR). It explains federal regulations and CGI policies to help you understand your responsibilities and navigate the IRB process. This manual should be read alongside the CGI IRB Submission Package, which provides practical, step-by-step guidance for completing IRB submissions.

This manual and the CGI IRB Submission Package are companion documents; understanding which document covers what will save you time.

CGI Researcher Manual (this document)	CGI IRB Submission Package
Policy framework and federal regulations	Step-by-step submission instructions
Definitions and key concepts	Protocol preparation guidance
Researcher responsibilities and obligations	Forms, templates, and submission checklists
Types of review and review outcomes	
Special considerations and compliance requirements	

> **Two things to know before you begin:** CGI reviews only minimal-risk, non-federally funded research internally. Projects involving greater-than-minimal risk or federal funding are referred to the University of New Mexico (UNM) IRB. For step-by-step guidance on preparing your protocol, drafting consent forms, and completing your submission, see the CGI IRB Submission Package.

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1. Role of the IRB

The CGI Institutional Review Board (IRB) protects the safety, rights, and welfare of research participants. It reviews Human Participants Research (HPR) at initial submission and monitors approved projects. The IRB also ensures CGI complies with federal HPR regulations.

CGI received initial IRB registration from the U.S. Department of Health and Human Services (HHS) in 2023 and renewed its registration in 2026. The IRB is registered with the Office for Human Research Protections (OHRP #IORG0011777) and assigned the number IRB00013947.

Ethical Principles (The Belmont Report)

The Belmont Report (1978) establishes three core principles for conducting HPR:

- Respect for Persons: Treat individuals as autonomous agents. Participants must understand what will be done, what data will be collected, and the risks and benefits. Consent must be given freely without coercion. Those with diminished autonomy require additional protections.
- Beneficence: Do no harm; maximize benefits and minimize risks. Research must balance potential benefits to participants and society against the risks individuals assume.
- Justice: Fairly distribute the burdens and benefits of research. No individual or group should bear an unfair burden or be unfairly excluded from research benefits.

Federal Regulations

The HHS Common Rule (45 CFR Part 46) governs federally funded HPR. Institutions receiving federal research funding must hold a Federalwide Assurance (FWA) and comply with the Common Rule. CGI holds an FWA and is fully compliant.

CGI also applies Equivalent Protections (EP) for minimal risk, non-federally funded research, allowing reduced IRB requirements when appropriate. During initial review, the IRB determines which projects meet EP criteria.

Relevant regulatory references:

Department of Health and Human Services (DHHS)

Food and Drug Administration (FDA)

International Compilation of Human Research Standards

2. IRB Authority and Composition

The IRB has the authority to approve, require modifications to, or disapprove all HPR activities. It conducts a continuing review of approved projects and may suspend or terminate any project that does not meet its requirements or causes unexpected harm.

IRB Members

- IRB Chair: Enforces consistent application of Belmont principles, federal regulations, and IRB policies. Manages IRB meetings and holds standard voting privileges.
- IRB Coordinator: Manages administrative operations, communicates with investigators about submission requirements and IRB determinations, and votes as an IRB member.
- Consultants: Subject-matter experts are invited as needed when the IRB lacks specific knowledge. Consultants serve in an advisory role only and do not vote.

Office of the IRB (OIRB)

The OIRB is the administrative support office for the IRB. It serves researchers, study personnel, and participants. Responsibilities include:

- Conducting intake on all submissions and verifying training and annual COI disclosures
- Assigning IRB numbers to new projects and entering them into the review queue.
- Pre-reviewing submissions to confirm that the required documents are present and consistent
- Making initial determinations on whether a project is HPR and its risk level
- Returning submissions to the PI with a list of issues to address within 10 days
- Providing educational outreach, post-approval monitoring, and continuous quality improvement
- Serving as the point of contact for participant questions, concerns, and complaints

3. What Is Human Participants Research?

Before submitting to the IRB, researchers must understand whether their planned activity qualifies as Human Participants Research (HPR). This determination drives whether and what kind of IRB review is required.

Definitions

For purposes of this Manual, HPR is any activity that meets the federal definitions of both research and human subject as outlined in the Common Rule (45 CFR 46.102).

Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities intended to benefit only a specific program or population, such as quality improvement projects or program evaluations, may not meet this definition, depending on how the activity is designed and whether findings will be disseminated (45 CFR 46.102(l)).

Human Participant means a living individual about whom an investigator conducting research obtains information or biospecimens through intervention or interaction, or obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. This includes information that could be linked back to an individual even if names are not collected (45 CFR 46.102(e)).

An activity must satisfy both definitions to qualify as HPR and trigger IRB review requirements.

Activities That Are Not HPR

Not all activities involving people or data qualify as HPR under federal regulations. The following are generally not considered HPR:

- Oral history, journalism, biography, or literary criticism
- Quality improvement or program evaluation is not intended to produce generalizable knowledge
- Analysis of fully de-identified data with no possibility of re-identification
- Coursework or training exercises not intended for dissemination

> 📌 When in doubt, consult the IRB before beginning. A determination of whether an activity qualifies as HPR must be made by the IRB, not by the researcher. Beginning an activity that turns out to be HPR without prior IRB review is a protocol violation regardless of intent.

4. Researcher Responsibilities

PI Eligibility

To serve as Principal Investigator (PI) on a CGI IRB project, you must be one of the following:

- A CGI student enrolled in the DBH 9100 course series who has completed OHRP training
- A CGI faculty member who has completed OHRP training
- A PI approved by an external site using CGI IRB services

The PI is responsible for supervising the research, ensuring participant safety, maintaining data security, and complying with all applicable IRB requirements, laws, and regulations.

Required Training

All study personnel who interact with participants, access identifiable data, or serve as PI of record must complete the following:

Every 3 years:

- Human Research Protection Foundational Training (5 lessons via OHRP website)
- Participant-Centered Informed Consent Training (OHRP website)

Annually:

- Conflict of Interest (COI) disclosures

Faculty Responsibility in Student Research

Faculty assigning research involving human participants must take an active role in protecting participants. The CP course instructor and CP Chair are responsible for preparing students to conduct ethical research, assisting with IRB applications, and meeting regularly with students after approval. Faculty are ultimately responsible for participant protection even when a student is the primary researcher.

5. Types of IRB Review Conducted at CGI

All research reviewed by the CGI IRB presents no more than minimal risk. The three review pathways described below reflect procedural distinctions rather than differences in risk level. CGI does not conduct federally funded research and does not approve research presenting more than minimal risk.

Exempt Review

Non-federally funded research that falls within specific low-risk categories defined by federal regulation may be subject to exempt review (45 CFR 46.104). The IRB or OIRB makes this determination; researchers may not self-determine exemption. Examples of research that commonly qualify for exempt review include anonymous surveys on clinician burnout, moral distress, or workplace satisfaction; reviews of existing de-identified case records or treatment outcome data; and secondary analyses of publicly available behavioral health datasets.

Exempt does not mean unreviewed. All research must be submitted to the IRB, which will determine the appropriate review category.

Expedited Review

Non-federally funded research that presents no more than minimal risk and falls within one of the federally defined expedited review categories is eligible for expedited review (45 CFR 46.110). Research involving identifiable data, sensitive topics, or certain vulnerable populations commonly falls into this pathway. A single IRB member conducts expedited review; the full board is not convened.

Minimal Risk Review

Federal regulation defines minimal risk as a level at which the probability and magnitude of harm anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests (45 CFR 46.102(j)). Research that presents no more than minimal risk but does not qualify for exempt or expedited review follows this pathway.

Administrative Review

Minor changes to approved documents, such as grammar corrections, phone number changes, project closures, and HPR determinations, are handled administratively by OIRB staff on a daily, first-come, first-served basis.

> 📌Greater-than-minimal-risk and federally funded projects are referred to the UNM IRB. Contact the OIRB early if your project may require external review.

6. IRB Review Outcomes

IRB review produces two categories of outcomes depending on the stage of the process. Triage outcomes are based on the initial email inquiry. Formal review outcomes result from a review of a formal IRB application.

Stage 1: Triage Outcomes

The following outcomes apply to the initial inquiry submitted by email before a full application is prepared.

Outcome	What It Means
Not HPR	The IRB has determined that the described activity does not meet the federal definitions of research or human subjects under 45 CFR 46.102. No further IRB action is required. This response is not an IRB approval and should not be represented as IRB clearance in any publication, presentation, or institutional record. If the project changes in scope, purpose, or methodology, you must contact the IRB before proceeding.
Proceed to Full Application	The IRB has determined that the described activity appears to meet the criteria for HPR and requires formal review. Researchers must submit a complete IRB application before initiating any research-related activities. This response is a triage determination only. It is not an exempt determination, an approval, or an authorization to begin research.

Stage 2: Formal Review Outcomes

The following outcomes apply after a complete IRB application has been submitted and reviewed.

Outcome	What It Means
Exempt Determination	The IRB has reviewed the complete application and confirmed it meets an exempt category under 45 CFR 46.104. The researcher may not begin until the written exemption determination letter is received. Exempt research does not require annual continuing review. Any changes to study procedures must be resubmitted, as modifications may affect exempt status.
Approved	The IRB has reviewed the complete application under Expedited or Minimal Risk Review procedures and determined that all criteria have been met. Research may not begin until the researcher receives a written approval letter.

Outcome	What It Means
	Approval is effective as of the date on the letter and is subject to annual continuing review. Investigators must submit amendments for any substantive changes and promptly report unanticipated problems or participant complaints.
Modifications Required	The IRB has identified changes needed before a determination can be issued. The researcher must revise and resubmit within 30 days. If the researcher does not resubmit within 30 days, the application will be administratively closed and must be resubmitted as a new application with a new protocol number. Researchers who need additional time must contact the IRB Coordinator before the deadline.
Tabled	The submission contains insufficient detail for the IRB to reach a determination. The researcher must provide the additional information specified in the tabling notice before review can continue. If the researcher does not respond within 30 days, the application will be administratively closed and must be resubmitted as a new application.
Disapproved	The research cannot be conducted as submitted. The IRB will provide a written explanation of its concerns. The researcher may respond in writing within 30 days to address those concerns, and the IRB will issue a final determination. If the concerns cannot be resolved, the disapproval is final, and the research may not be conducted. Researchers may not resubmit a disapproved study as a new application without first consulting the IRB Coordinator.
Acknowledged: Administrative	Used for minor administrative corrections to already-reviewed documents only, such as grammar fixes or certified translations. No change to study procedures is involved, and no formal IRB review is required.

7. Appeals Process

If a researcher disagrees with an IRB determination, they may appeal within 10 days of receiving the written decision. Appeals must be submitted in writing to the IRB Chairperson at irb@cgi.edu.

What to Include

A complete appeal must include:

- A letter explaining why the IRB should reconsider, with a point-by-point response to each reason given for the determination
- Any revised documents with changes highlighted using Track Changes

Review Process

The appeal will be reviewed at the next scheduled IRB meeting. The IRB will evaluate the researcher's written response against the original basis for its determination and issue one of the following outcomes:

- Determination upheld: The original determination stands. The researcher will receive a written explanation. No further appeal is available through the CGI IRB process.
- Determination revised: The IRB has accepted some or all of the researcher's response and will issue a revised determination. The researcher must still satisfy any remaining conditions before proceeding.
- Additional information requested: The IRB requires further clarification before issuing a final decision on the appeal. The researcher will be given a specified timeframe to respond.

> **Note:** *Filing an appeal does not authorize the researcher to begin or continue research activities. All research must remain paused until the appeal is resolved and a final determination is issued.*

8. Researcher Obligations After IRB Approval

Once approved, the researcher must:

- Ensure sufficient resources, including time, oversight, equipment, and space, to conduct the research safely
- Verify that all study personnel are trained and their OHRP training is current (renewed within 3 years)
- Maintain current COI disclosures for all team members
- Conduct or supervise research in accordance with the IRB-approved protocol
- Obtain appropriate informed consent from all participants
- Do not change the protocol without prior IRB approval, except to eliminate immediate hazards (notify IRB within 7 days of any such change)
- Submit all required paperwork to the OIRB, including amendments, closures, deviations, and event reports. Continuing review applies only to approved non-exempt research; exempt determinations do not require annual renewal but must be resubmitted if study procedures change.

> 📌Researchers may not begin or modify human research activities until the IRB has granted written approval.

9. Types of Submissions

New Projects

Submit a new project to the IRB before beginning any human research. Include the Protocol Form and all relevant documents listed on the IRB Submission Checklist.

Amendments

Before implementing any change to an approved project, submit an amendment and receive IRB approval. Examples of changes requiring amendments include adding or revising questionnaires, increasing enrollment, changing recruitment methods, adjusting compensation, or changing the study population or location.

Continuing Review

Approved non-exempt research is subject to annual continuing review. Submit required paperwork at least 30 days before the expiration date. Exempt research does not require continuing review, but any changes to study procedures must be resubmitted.

Protocol Deviation Reports

Report minor deviations that did not harm participants, such as a missing researcher signature on a consent form or over-enrollment in a minimal-risk project. Complete this report during the approval period and at continuing review or closure if any deviations occurred.

Event Reports

Submit an event report within 7 days of discovering an unanticipated problem or adverse event. Reportable events include:

- Injury, disability, hospitalization, unexpected side effects, or death
- Harm to the safety, rights, or welfare of participants, staff, or others
- Participant complaints indicate an unanticipated risk that cannot be resolved by the research staff
- Privacy, confidentiality, or data security breaches that caused or increased harm
- Loss or destruction of project data not in accordance with IRB-approved procedures

10. Project Closure

Close a project when:

- The project was never initiated
- Enrollment is closed, all data collection is complete, and only analysis of de-identified data with no links to identifiers remains
- The researcher leaves CGI
- A student researcher leaves CGI without notifying the IRB

A project cannot be closed if there is still analyzable identifiable data. To submit a closure, contact the IRB Chairperson.

CGI does not conduct federally funded research. All CGI projects, including those with an exempt determination, require a formal closure submission when qualifying conditions are met.

> 📌Closing a project does not need to wait for the expiration date. Close promptly once qualifying conditions are met.

IRB Approval Expiration

IRB approval for your project covers your time in the DBH program and the remainder of your Culminating Project journey. If approval expires before you submit a renewal, all human research activities, including data analysis, must stop immediately. Failure to renew or close before expiration is a noncompliance violation.

A project may be reactivated up to 6 months after expiration. After 6 months, it must be closed. The IRB may also administratively close a project if the PI does not respond to requested modifications within 30 days or fails to submit required paperwork.

Post-Approval Monitoring (PAM)

Approved projects remain under IRB oversight until closure. The PAM program ensures ongoing compliance and supports researchers in conducting ethical research. The IRB may contact you at any time for a full assessment, self-assessment, consent document review, or review of the consent process.

Records Retention

Retain all project records for at least 3 years after closure. This includes approved IRB documents, signed consent forms, de-identified recordings and transcripts, and all other source documents. Store confidential data securely in both hard copy and electronic formats to prevent breaches.

Longer retention periods apply in certain cases:

- Records involving Protected Health Information (PHI): 6 years minimum, per HIPAA requirements
- Multi-site studies: at least 5 years after closure
- Research subject to other applicable regulations: per those regulations

If you are uncertain how long to retain records for your specific study, contact the OIRB before disposing of any research materials.

11. Noncompliance

Noncompliance occurs when a researcher fails to adhere to IRB-approved procedures, CGI policies, or applicable federal regulations governing Human Participants Research. Noncompliance may be identified by the researcher, the IRB, the OIRB, a participant, or through post-approval monitoring.

Examples of Noncompliance

Common examples of noncompliance include:

- Beginning research before receiving a formal IRB determination
- Implementing changes to study procedures without prior IRB approval
- Failing to submit required amendments, continuing reviews, or event reports
- Using unapproved consent forms or recruitment materials
- Allowing IRB approval to expire without submitting a renewal or closure

- Failing to report an unanticipated problem or adverse event within the required timeframe

Serious vs. Minor Noncompliance

The IRB distinguishes between minor and serious noncompliance based on the risk to participants and the nature of the deviation.

Minor noncompliance involves deviations that did not harm participants and do not reflect a pattern of disregard for IRB requirements. Minor noncompliance is typically addressed through corrective action and education.

Serious noncompliance involves deviations that harmed or placed participants at risk, involved vulnerable populations, or reflected a pattern of disregard for IRB requirements. Serious noncompliance may result in suspension or termination of the research, mandatory training, or referral to CGI administration.

Reporting and Response

Researchers who discover noncompliance in their own study must report it to the OIRB promptly. The IRB will review the circumstances, assess the impact on participants, and determine the appropriate corrective action. Self-reporting is viewed favorably and may reduce the severity of corrective action.

All human research activities must cease immediately upon a finding of serious noncompliance until the IRB issues written authorization to resume.

12. Special Considerations

Assessing Risk of Harm

Risk is the probability of harm, including physical, psychological, social, legal, or economic harm, resulting from research participation. The IRB considers both the probability and magnitude (severity, duration, and reversibility) of potential harm.

Federal regulations define minimal risk as the probability of harm no greater than that ordinarily encountered in daily life or during routine physical or psychological examinations or tests (45 CFR 46.102(j)). The overall project risk is determined by the risk to the most vulnerable known participants.

See the Guidance on Assessing and Minimizing Risk in Human Research

Child Assent and Parental Permission

Arizona law requires written parental permission for any participant under 18 years old, unless the child is married or emancipated by court order. One parent or guardian's

permission is generally sufficient for minimal risk research or research with direct benefit to the child.

For children ages 7 to 11 who are capable of assenting, a separate age-appropriate assent form is required. Children ages 12 and older are generally considered capable of signing a standard consent form. The IRB may waive parental permission in limited circumstances, such as for neglected or abused children, with justification and an alternative protection plan.

International and Tribal Research

Research conducted on tribal land, including the Navajo Nation, requires approval from the Navajo Nation Human Research Review Board (NNHRRB) and/or the tribal council, as applicable, in addition to CGI IRB review.

CGI researchers planning to conduct research outside the United States must consult the OIRB early to determine what additional approvals are required. U.S. federal law applies regardless of where research is conducted, and the more protective standard prevails in cases of conflict with local law.

Non-English Speaking Participants

If your project targets participants who do not speak or read English, all recruitment materials and consent documents must be translated into the participant's language (45 CFR 46.116-117 and 21 CFR 50.20).

Vulnerable Populations

The IRB gives special consideration to participants who may be particularly vulnerable, including children, prisoners, pregnant women, fetuses and neonates, individuals with impaired consent capacity, students, and disenfranchised groups. Researchers must:

- Identify vulnerable populations in the protocol
- Describe protective procedures
- Include consent and assent forms appropriate to the population's reading level, language, and cultural context
- Comply with applicable state and local laws governing vulnerable populations

Dual Relationships

A dual relationship exists when a researcher has a pre-existing relationship with a potential participant outside of the research context. Common examples at CGI include faculty recruiting students, supervisors recruiting employees, and clinicians recruiting patients or clients.

Dual relationships create a risk of undue influence, in which the participant may feel implicit pressure to enroll or remain in the study because of the nature of the existing

relationship. Researchers must identify any dual relationships in the protocol and describe the safeguards they will use to protect participant autonomy, such as having a neutral third-party conduct recruitment or ensuring participants understand that their decision will not affect the existing relationship.

The IRB will evaluate whether the proposed safeguards are adequate. Researchers who are uncertain whether a relationship constitutes a dual relationship should consult the OIRB before submitting.

Informed Consent: Waivers and Modifications

Federal regulations require that researchers obtain informed consent from participants before research begins. In certain circumstances, however, standard written consent is not appropriate or practicable. The IRB may grant one or more of the following waivers or modifications when the regulatory criteria are met. Researchers must request and justify any waiver in the IRB protocol; waivers are not self-determined.

Waiver of Informed Consent

A waiver of informed consent means that no consent is obtained. The IRB may grant this waiver when four conditions are all met:

- The research presents no more than minimal risk
- The waiver will not adversely affect the rights and welfare of participants
- The research could not practicably be conducted without the waiver
- And, when applicable, participants are provided with pertinent information after participation.

Common examples at CGI include secondary analyses of existing de-identified datasets, retrospective reviews of records where contacting participants is not practicable, and studies using administrative or publicly available databases. The practicability requirement is a genuine threshold: if consent could reasonably be obtained, the waiver will not be granted.

Waiver of Documentation of Informed Consent

A waiver of documentation means that full informed consent is still obtained verbally, but no written signature is collected. This modification is appropriate when the signed consent form would be the only record linking the participant to the research, and a breach of confidentiality would present a greater risk than the research itself. It is also appropriate when the research presents minimal risk and involves no procedures that would require written consent outside of the research context.

This waiver is most commonly appropriate for qualitative interview studies involving sensitive topics or participants from stigmatized or vulnerable populations, where a signed document creates meaningful confidentiality risk. When the IRB grants this waiver,

researchers typically provide participants with a written information sheet in lieu of a signed form. Verbal consent must still be documented in study records.

HIPAA Authorization Waiver

A HIPAA Authorization Waiver is a distinct instrument that applies specifically when researchers need access to Protected Health Information (PHI) held by a covered entity, and obtaining individual authorization from each patient is not practicable. This is separate from informed consent: a study may have a HIPAA Authorization Waiver while still requiring standard written informed consent for the research itself, or it may have both a HIPAA waiver and a consent waiver, depending on study design.

The CGI IRB serves as the HIPAA Privacy Board and reviews all requests for HIPAA Authorization Waivers. Common scenarios at CGI include retrospective studies that access clinical records from a partner health system when the patient population is large, retrospective, or includes deceased individuals. See Section 14 for additional HIPAA compliance requirements.

Recruitment of Participants

All recruitment methods, including materials, inclusion and exclusion criteria, and compensation, must be approved by the IRB before use. Recruitment must not:

- Exert undue influence or coerce potential participants
- Imply benefits beyond those in the approved protocol
- Include misleading statements

Recruitment materials must be clearly identified as soliciting research participation and must be written in plain language. Any changes after approval require re-evaluation before implementation.

Compensation of Participants

All compensation details, including amount, method, and timing, must be stated in the IRB protocol and consent documents. The IRB reviews compensation to ensure it does not constitute undue influence on participants' decisions to participate. Compensation must be proportionate to the burden of participation and must not be contingent on study completion in a way that would discourage withdrawal.

> **Note:** *Payments for research participation may be taxable income. See the IRS link for guidance on compensation reporting requirements.*

13. Privacy Laws and Compliance

FERPA

FERPA protects personally identifiable information in education records at institutions using U.S. Department of Education funds. Researchers must comply with FERPA, IRB requirements, and CGI policies when accessing education records for research.

See the CGI Guidance on FERPA

HIPAA

The CGI IRB serves as the HIPAA Privacy Board for the research use of Protected Health Information (PHI). Researchers must obtain a HIPAA Authorization or a HIPAA Authorization Waiver for any research use or disclosure of PHI. For guidance on when a HIPAA Authorization Waiver applies and how it relates to informed consent requirements, see the Informed Consent: Waivers and Modifications subsection in Section 13.

See the HIPAA Compliance Policy

See the Non-Disclosure and Confidentiality Agreement Policy

14. Research Data Security

Researchers entrusted with human data must take measures to protect it in all forms, both paper and electronic. You are responsible for understanding and following:

- CGI information security policies
- State of Arizona privacy laws
- Federal privacy laws (HIPAA, FERPA)
- Sponsor data confidentiality requirements (e.g., NIH, DOJ)

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

Certificates of Confidentiality (CoCs)

NIH issues CoCs to protect identifiable, sensitive research information from forced disclosure. A CoC prohibits researchers and institutions from disclosing participant names, information, or biospecimens in any civil, criminal, administrative, or legislative proceeding.

Researchers covered by a CoC may disclose identifiable research information only when:

- Required by federal, state, or local laws, excluding legal proceedings

- Necessary for the medical treatment of the individual, with their consent
- The individual has provided consent for the disclosure
- The disclosure is for other scientific research that follows applicable federal regulations

15. Additional and External IRB Approvals

Some research requires approval from an IRB or oversight body beyond the CGI IRB. For example, research conducted on the Navajo Nation requires approval from the Navajo Nation Human Research Review Board (NNHRRB).

Navajo Nation Human Research Review Board

If a research site does not use an IRB, a Letter of Support (LOS) from that site is still required. Consult the OIRB to determine whether additional approvals apply to your project.

Referral to the University of New Mexico IRB

CGI refers projects to the University of New Mexico (UNM) IRB when a project involves greater-than-minimal risk or federal funding, neither of which CGI reviews internally. If the OIRB determines during triage or full application review that your project requires UNM review, you will be notified and provided with guidance on next steps. Investigators are responsible for the UNM review process and any associated fees.

Requesting Deferral to an External IRB

You may request to use an external IRB by submitting a Request for External IRB Review form along with the documents listed on the IRB Submission Checklist. This is most common for multi-site projects in which another institution is the lead site, or when all HPR activities occur at a collaborating institution. Per CGI policy, the OIRB makes the final determination on deferral requests; it is not the researcher's decision.

If an external site is engaged in HPR and you want that site to defer oversight to the CGI IRB, email irb@cgi.edu with the project title and protocol number, the external collaborator's name, and a contact name and phone number for the external site's IRB. The external collaborator must be listed as a project team member, and the protocol must describe their activities.

16. Sponsored Projects

CGI researchers may receive non-federal external funding, such as foundation grants or institutional awards, to support their research. If your project has or anticipates external funding, indicate this when submitting your IRB application. Some funding sources impose additional requirements beyond CGI IRB review, and the OIRB recommends submitting

your IRB application alongside any funding proposal so that approval is in place before the funder requires confirmation.

If your project has external funding and the IRB approval expires, contact your sponsor promptly and provide documentation of the lapsed approval. If a reportable adverse event occurs on a funded project, you are responsible for notifying the funder in addition to submitting an event report to the IRB.

> **Note:** *CGI does not conduct federally funded research. Researchers who receive or anticipate federal funding must consult the OIRB before proceeding, as federal funding triggers additional regulatory requirements, including referral to the UNM IRB.*

Glossary

The following terms are used throughout this Manual. Federal regulatory citations are provided where applicable.

Term	Definition
45 CFR 46	The Common Rule. The federal regulation governing Human Participants Research protections at institutions receiving HHS funding.
Amendment	A formal request to modify an IRB-approved study. Required before implementing any change to procedures, population, or risk level.
CGI	Cummings Graduate Institute for Behavioral Health Studies.
COI	Conflict of Interest. Annual disclosure is required of all study personnel.
CoC	Certificate of Confidentiality. Issued by NIH to protect identifiable research data from forced disclosure.
Common Rule	See 45 CFR 46. The primary federal regulation governing HPR protections.
Continuing Review	Annual IRB review is required for approved non-exempt research to ensure ongoing compliance and participant safety.
EP	Equivalent Protections. CGI's framework for applying human subjects protections to minimal risk, non-federally funded research.
Exempt Research	Research that falls within specific low-risk categories under 45 CFR 46.104 and does not require ongoing IRB oversight. The IRB, not the researcher, makes this determination.
Expedited Review	Review by a single IRB member for research that presents no more than minimal risk and falls within a federally defined expedited review category (45 CFR 46.110).
FWA	Federalwide Assurance. CGI's agreement with HHS to comply with federal Human Participants Research protections. FWA number: FWA00034328.
HPR	Human Participants Research. Any systematic investigation designed to contribute to generalizable knowledge that involves obtaining information about living individuals (45 CFR 46.102).
IRB	Institutional Review Board. The committee is responsible for reviewing and approving Human Participants Research at CGI.

Term	Definition
LAR	Legally Authorized Representative. A person authorized to consent on behalf of an individual who lacks decision-making capacity.
LOS	Letter of Support. Required from external research sites that do not have their own IRB.
Minimal Risk	A level of risk at which the probability and magnitude of anticipated harm are no greater than those encountered in daily life or routine examinations (45 CFR 46.102(j)).
Noncompliance	Failure to adhere to IRB-approved procedures, CGI policies, or applicable federal regulations.
OHRP	Office for Human Research Protections. The HHS office that oversees IRB registration and federal HPR regulations.
OIRB	Office of the IRB. CGI's administrative office supports IRB operations.
PAM	Post-Approval Monitoring. Ongoing IRB oversight of approved projects to ensure continued compliance.
PHI	Protected Health Information. Individually identifiable health information is protected under HIPAA.
PI	Principal Investigator. The researcher of record is responsible for the conduct of an IRB-approved study.
Protocol	The foundational document of an IRB submission describes study design, procedures, participant population, and risk management.
UNM IRB	University of New Mexico Institutional Review Board. CGI's external IRB partner for projects involving greater-than-minimal risk or federal funding.

Questions? Contact the Office of the IRB

Email	irb@cgi.edu
Phone	(480) 285-1761
Submissions	All forms and templates are in the DBH 9100/9101 course pages