CUMMINGS
GRADUATE INSTITUTE FOR
BEHAVIORAL HEALTH STUDIES

CGI IRB Research Submission Package

DELETE THIS INFO BEFORE SUBMITTING.

1. **MAKE A COPY OF THIS FORM TO YOUR OWN DRIVE**
2. **Make sure you complete all sections. If a section does not apply to you, answer N/A or explain why.**
3. **Ensure your file is named appropriately, according to the CP Assignment File Naming Protocol**
4. **Once complete, share this form with your Course Instructor using the "Share" button in the upper right-hand corner of the form.**
5. **All feedback will be given in this form.**

Part 1 of 2

Submission Checklist

Purpose: This checklist guides researchers through all documents required for a complete CGI IRB submission. All documents with signature lines require a signature before submission. ***All forms can be found at: cgi.edu/irb***

Instructions: Check each box as you confirm the item is complete and included in your submission package. Items may be marked N/A if they do not apply to your study.

☑	Form / File	Description	Notes
☐	**OHRP Training Certificate**	Certificate confirming completion of OHRP Training within 3 years, including: Human Research Protection Foundational Training (5 Lessons), and Participant-Centered Informed Consent Training	After completing OHRP training, upload distinct certificates to your class assignment folder. All 6 certificates must be submitted.
☐	**Protocol Form**	Detailed description of your proposed research project (see Part 1 of this document).	Includes additional required attachments for some projects.
☐	**Consent Form(s)**	Standard (Adult) Consent Form and/or Child Assent Form Consent Form Survey/Interview/Focus Group Additional Elements of Consent (review and include as appropriate) HIPAA Authorization Form HIPAA Waiver Form Translation Certification form (for non-English materials) See LAR Definitions & Policies (reference)	Signed informed consent is required for all projects unless a waiver is requested and justified in the protocol form. If working with children or cognitively impaired individuals, see Part 1, Section 6 for consent guidance.

☐	**Recruitment Materials**	Recruitment Email sample Recruitment Flier 1, Flier 2, Flier 3 samples	Includes flyers, posters, print media, emails, phone recruitment scripts, etc.
☐	**Data Collection Questionnaire / Survey**	PDF files of all data collection tools involved in your research.	Describe tools and your data collection/storage plan in a narrative in the Protocol Form. Attach copies of all assessment tools, surveys, or questionnaires.
☐	**Letter(s) of Support from External Site(s)**	Letter from each external site partner.	Required for all projects utilizing external organizations to conduct recruitment and/or research activities.
☐	**Device and/or Drug Information**	Device and/or Drug Information Form(s), as applicable.	Required for all research involving drugs or devices.
☐	**Mental Health Safety Plan**	Safety plans must align with standard clinical practice. Those developing safety plans should seek guidance from individuals with relevant expertise.	Required if collecting identifiable information about risk of harm to self or others.
☐	**External Personnel List**	Lists all project team members and describes their role in the research.	All project personnel must have completed OHRP Training and a Conflict of Interest (COI) Form.
☐	**Conflict of Interest Form**	Indicates and documents review of COI policy and notes any conflict of interest for researchers and external personnel.	
☐	**Scientific Validity Review Form**	Must be completed by your Culminating Project Chair for the IRB-required documentation.	
☐	**Closure Form**	Submit this form and supporting documents as soon as the data are de-identified, or no later than 30 days before the expiration date on the approval letter.	

Researcher Certification

By submitting this checklist, I certify that all applicable materials have been reviewed, completed, and included in this IRB submission package, and that the proposed research will be conducted in accordance with CGI IRB policies and federal regulations governing the protection of human subjects.

Researcher Signature _____ Date _____

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Part 2 of 2

IRB Protocol Form

Complete all applicable sections. Sections that do not apply to your study may be marked N/A. Once complete, share this document with your Course Instructor. All feedback will be provided within this form.

Culminating Project / Study Title Use the exact title as it appears in your CP proposal.	
Researcher / Primary Investigator Name Your full name as the lead researcher	
Is this project grant-funded or federally funded? If your project receives any grant or federal funding, stop here and contact the CGI IRB directly at irb@cgi.edu. This form is for non-federally funded research only	

Section 1: Background Information

1. Rationale (200-word maximum): summarize the key points from your literature review and identify the gap your study addresses. This is not an abstract; write it as a justification for why this study is needed. 2. Research Questions and Hypotheses: List each research question clearly and separately. If your study has hypotheses, state them explicitly. If it is exploratory, indicate that.	

Section 2: Anticipated Data Collection Dates

Provide realistic start and end dates for data collection only, not the full project timeline. The start date cannot precede IRB approval.	

Section 3: Participant Inclusion / Exclusion Criteria

Describe your target participant population with specificity: geographic location, age range, gender, relevant diagnoses, professional role, or other characteristics.	
State your inclusion criteria (who qualifies) and exclusion criteria (who is excluded and why) as separate, clearly defined lists.	

Vulnerable Populations	
Will this study enroll any vulnerable populations (children, prisoners, pregnant women, or cognitively impaired individuals)?	□ **YES** □ **NO**
If YES, identify the vulnerable population(s) and describe the specific protections and safeguards that will be in place to protect their rights and welfare. If NO, state n/a.	

Section 4: Participant Enrollment

1. State the maximum number of participants you intend to enroll. This should match or slightly exceed your target sample size to account for attrition. 2. If you are accessing existing records rather than recruiting individuals, state the maximum	

number of records to be accessed.	

Section 5: Recruitment and Screening Procedures

Identification: Describe when, where, and how you will identify potential participants, including any database or records review.	
Initial Contact and Access: Describe how you will make first contact with potential participants and how you will access the recruitment population to reach your target sample size.	
Advertising and Recruitment Materials: Describe every method you will use and upload copies of all materials as attachments.	
Screening: Describe how you will confirm that participants meet your inclusion/exclusion criteria, what happens with individuals who are screened out, and what you will do with any data collected from excluded participants.	

External Organizations	
Will you work with external organizations to conduct recruitment or research activities? **Important:** A study that recruits participants from a community clinic is not automatically community-engaged. A study where a clinic or advocacy organization is a named partner with defined roles, co-develops the research design, or shares in dissemination would qualify.	□ **YES** □ **NO**
If YES, describe the external organization(s) and their role. Upload a letter of support from each external	

organization as an attachment to this submission. If NO, state n/a.	

Section 6: Informed Consent Process

Section 6 contains several YES/NO subsections. Answer each one, even if the answer is NO. Guidance on preparing each consent document is below.

Standard Informed Consent	
Are you obtaining informed consent?	□ **YES** □ **NO**
If YES, describe: (a) the process for obtaining consent (when, where, how, ensuring a private setting); (b) steps to minimize coercion or undue influence; (c) the method for documenting consent; (d) who, if anyone other than the participant, might provide consent; and (e) any comprehension quizzes used. If NO, state n/a.	
1. Select the correct consent template for your study and copy it to your Drive. a. Adult Consent Form: Standard - for most in-person or individual studies b. Consent Form: Survey / Interview / Focus Group - for remote or group data collection 2. Replace all bracketed placeholders. Study title, PI contact, procedures, and compensation must match the protocol exactly. 3. Verify that all 8 required elements of informed consent	

are present (45 CFR 46.116). Review Additional Elements of Consent and add any applicable elements to your form. 4. Write at an 8th-grade reading level or lower. Describe confidentiality protections specifically: storage, access, de-identification timing, and any third-party platforms used. 5. Version-date the consent form (v1_MMDDYYYY) to match your protocol version date. **Important:** *Never use a consent form from a previous study. Each study requires its own IRB-reviewed consent form.*	

Child Participants	
Does this study involve child participants?	□ **YES** □ **NO**
If YES, prepare a Parental Permission form and the Child Assent Form for participants ages 7-17. Describe the child assent process and how parent or guardian permission will be obtained. ***Upload the Child Assent Form with this submission.*** If no, state n/a.	

Waiver of Informed Consent ***(See the Special Consideration section of the CGI IRB Research Manual for additional information.)***

Answer YES or NO. If standard written consent is not appropriate, determine which waiver applies:

a. Waiver of informed consent: no consent obtained at all. Requires no more than minimal risk, that the waiver will not adversely affect participants' rights, and that research could not practicably be conducted without it.
b. Waiver of documentation: verbal consent obtained, but no written signature. Appropriate when the signed form would be the only record linking the participant to the research.
c. HIPAA waiver: allows access to protected health information without individual authorization when obtaining authorization is not practicable.

1. For consent waivers, justify point-by-point how your study meets each regulatory criterion.
2. For the waiver of documentation, prepare a verbal consent script that includes all 8 required consent elements, written word-for-word. Submit with your application.

3. For HIPAA waivers, complete and include the HIPAA Waiver Form.	
Are you requesting a waiver of informed consent?	☐ **YES** ☐ **NO**
Are you requesting a HIPAA Waiver?	☐ **YES** ☐ **NO**
Are you requesting a Documentation Waiver?	☐ **YES** ☐ **NO**
If YES to any of the above: (a) describe how your project meets the definition of minimal risk. (b) describe how the waiver will not adversely affect the rights and welfare of participants. (c) describe how participants will be provided with additional pertinent information after participation, if appropriate. If NO, state n/a. **Note:** *The IRB decides whether to grant a waiver. Be prepared to use written consent if a waiver is denied.*	

Legally Authorized Representatives (LAR)	
Are you enrolling cognitively impaired adults who require the use of a Legally Authorized Representative (LAR)?	☐ **YES** ☐ **NO**
If YES, describe: (a) the process for determining whether an individual is capable of providing consent; (b) how decisional capacity will be assessed and monitored as the project proceeds; and (c) the process for obtaining assent from the participant and consent from the LAR, and how the authority to provide consent will be confirmed. ***If participants may have impaired decision-making capacity, review LAR Definitions and Policies before drafting your consent materials.***	

If NO, state n/a.	

Non-English Speaking Participants	
Are you enrolling non-English speaking participants?	□ **YES** □ **NO**
If YES, list the primary language(s) of prospective participants, describe: (a) how all materials will be provided in the appropriate language, and (b) upload translated consent forms and a completed Translation Certification Form. If NO, state n/a.	

Section 7: Data Collection Procedures

Sequential Description: provide a step-by-step account of everything that will happen from the participant's perspective, from first contact through data collection completion. Include all procedures, instruments, interventions, and assessments.	
Time Commitment: state how long each procedure takes, and the total time participants will spend on all visits or contacts.	
Existing Data: If you will use existing records or datasets, identify the source, describe what data you will access, and explain how you obtained or will obtain permission.	
Data Capture Method: Describe how information will be recorded (e.g., paper forms, online survey platform, audio recording, note-taking). If using a third-party platform such as Qualtrics or Zoom, name it.	
Upload all data collection instruments (surveys, interview guides,	

assessment tools) as PDF attachments.	

Community-Engaged Research	
Are you conducting a Community-Engaged Project?	□ **YES** □ **NO**
If YES, describe community engagement details, including identification of community partners, how the partnership was formed, and how the community will be involved throughout the project. If NO, state n/a.	
If YES, discuss any literacy issues, and describe the procedures you will use to ensure researcher safety, data/sample safety, data storage and transfer, and how you will communicate and maintain a relationship with the community. If NO, state n/a.	

Section 8: Participant Compensation

Compensation Details	
Will your project provide compensation to participants?	□ **YES** □ **NO**
If YES, describe compensation amounts, form, timing, and payment schedule (class credit, merchandise cards, transportation expenses, cash, check, raffles, etc.). If NO, state n/a.	
If YES, justify how the compensation is proportionate to participant burden. If NO, state n/a.	
NOTE: The consent form and protocol descriptions must match exactly. Do not make compensation contingent on completion in a way that discourages withdrawal. Include	

a statement in the consent form that compensation may be taxable. Consult the IRB if any individual participant may receive $2,000 or more in a calendar year.	

Section 9: Project Resources

Describe what resources and facilities available to conduct the research, including: (a) staffing and personnel availability, number, expertise, and experience; (b) psychological, social, or medical services that may be required; (c) monitoring, ancillary care, and equipment needed to protect participants; and (d) resources for participant communication, such as language interpreter services.	

Section 10: Potential Risks of Harm **Link for:** Assessing Risk of Harm Guidance

In your response below, address each of the following that applies to your study:

- *Confidentiality risks and potential loss of data privacy*
- *Potential for participant distress, emotional stress, or fatigue*
- *Risk of physical harm from any intervention or procedure*
- *Social stigma, legal action, or economic burden resulting from participation*
- *Political, social, or economic context risks relevant to participants*
- *Your plan for preventing or minimizing each identified risk*
- *Additional protections for any vulnerable populations enrolled*
- *Provisions for psychological or medical attention if needed as a result of participation*

Identify all potential risks to participants, including their likelihood and severity, and describe your risk minimization plan. Include additional protections for any vulnerable populations enrolled. If collecting identifiable risk-of-harm data, attach a Mental Health Safety Plan.	

Section 11: Potential Benefits

Describe any potential direct benefit that individual participants may experience. Indicate if there is no direct benefit (e.g., completing a survey).	
Describe the anticipated societal benefit of the research.	

Section 12: Privacy of Participants

Describe where data collection will take place and how participant privacy will be maintained in that setting throughout recruitment, consent, and data collection (e.g., private rooms, closed doors, remote platforms).	

Section 13: Unanticipated Problems / Adverse Events

Describe the process for monitoring and reporting unanticipated problems or adverse events to the IRB and other relevant agencies. *Note: these must be reported to the Office of the IRB within 7 calendar days. Discuss injury compensation, if applicable.	

Section 14: Participant Complaints

Describe procedures for handling participant complaints or requests for information about the research. Procedures should offer a safe, confidential, and reliable channel for current, prospective, or past participants to discuss problems, concerns, and questions, or to obtain information.	

Section 15: Data Management Procedures and Confidentiality

Before completing this section, review the CGI policy on Human Research Data Security Standards. Key requirements include locking paper records; encrypting or password-protecting electronic records; storing identifiers separately from study data; and destroying the linking document between identifiers and study IDs before study conclusion.

Describe data management procedures (electronic, paper, recordings, etc.) from collection through permanent de-identification or destruction.	
Describe who will have access to the data and how data will be handled and maintained securely.	
Provide specific information on where identifiable data and consent forms will be stored. If portable devices are used, describe how data is protected.	
If data will be transferred to collaborators outside CGI, describe the procedures for transferring the data.	
Describe plans for destroying all identifiers prior to project completion.	
Will data from this project be retained for use in future research? If yes, describe the intended use and whether participants will be notified.	
Describe what will be done with any audio, video, or digital records after the project is completed.	
If more than minimal risk, briefly describe the data and safety monitoring plan and upload supporting documents.	

Section 16: Data Analysis / Statistical Considerations

Provide your sample size rationale (statistical power calculation or qualitative sufficiency argument). Describe your analytic approach: what you will do with the data and how it will answer your research questions.	

Section 17: Participant Withdrawal

Describe procedures that will be followed when participants withdraw during data collection.	
Describe the process for participants to withdraw from the project after participation is complete, if applicable.	
Describe conditions under which the researcher might withdraw a participant from the project.	
Describe what will happen to the data obtained from withdrawn participants.	