

CIIS Human Research Review Committee

BEFORE COMPLETING THE APPLICATION, you must have:

- A complete research proposal reviewed by your chair*
- Guidance from your chair in completing the HRRC application and her/his permission to submit it
- Please be aware that the HRRC will not approve face-to-face research until further notice in response to the public health directive and the CIIS COVID-19 campus response.

* "Chair" means the person overseeing your research (e.g., dissertation chair, thesis advisor, or staff supervisor)

WHEN TO SUBMIT THE APPLICATION:

- By the 1st of any month.**
HRRC DECISIONS are emailed by the end of the month (except in January and August when the committee does not meet). Revisions may be required before the final approval letter is issued.

REQUIRED SIGNATURES*:

- Make sure you secure signatures (dissertation chair and program or department director) on the application where noted.
- The dissertation chair signature is needed for HRRC submission.
- The program/department director signature is needed for HRRC submission.

*Not needed for faculty submissions

HOW TO SUBMIT THE APPLICATION:

- Email** the application as one Word document or PDF to hrrcoffice@ciis.edu.
- Submit the application as **one document only**. One way to do this is to print all application documents, then scan for upload once the Coversheet is filled out.
- Please **do not** include your proposal, the HRRC application packet, or this page.
- Look for an **email confirmation** that your application has been received. If you do not receive confirmation within three business days, your application has not been received.

TIMELINE:

- Please expect a response to your application around the end of the submission month.
- Revisions may be required before the final approval letter is issued.
 - For low risk applications, the average time to receive approval including the time to make revisions is 39 days after the first business day of the submission month.
 - For high risk applications, the average time to receive approval including the time to make revisions is 53 days after the first business day of the submission month.
- If the application is not complete or is not adequately resourced for the high-risk nature of your study, the application will need to be re-submitted as a new application and go through the full HRRC process again.

HRRC APPLICATION PACKET

Dear Applicant:

Enclosed herein are the instructions and forms for completing and submitting an application for Human Research Review Committee (HRRC) approval.

What is the difference between your dissertation proposal and the HRRC application?

- Your application should focus on a brief description of the overall project, then a more extended description based on the categories outlined in this handbook. The application should be no longer than 15 pages not including appendices.
- Do not include your literature review or an extended description of your methods.
- The HRRC committee reviews your research protocols for protecting human participants' anonymity, confidentiality, and physical and mental safety in accordance with Federal guidelines. *Approval from the HRRC is required before you can begin your research.*

Who should apply?

- CIIS students, faculty, and staff whose research project involves human participants
- In addition to qualitative methods such as narrative, case study, ethnography, and autoethnography, HRRC approval is required for quantitative, theoretical, meta-analysis, or other literature-based research that uses narrative data from participants (as is often done to enliven theory or to offer lived experience as examples of concepts).
- Researchers who will use archived data (e.g., records, transcripts, field notes, correspondence, and recordings)

If you are unsure if HRRC review is required, consult with your chair. If there is still some doubt, apply for **request for exempt status** to get a cursory review from the committee. When in doubt it is always better to err on the side of caution with respect to the protection of human participants. Instructions are included in this application.

When can I begin my research?

- When your Proposal has been approved by your committee, the person overseeing your research, and Program Chair, and when your HRRC application has been approved by the HRRC.

For how long is an HRRC approval good for?

- 3 years

Apply for an extension if you have not completed the data gathering phase within 3 years. Send an email to hrrcoffice@ciis.edu requesting extension and stating that no unapproved changes have been made to your study.

What if I need to make changes to my study?

Send an email to hrrcoffice@ciis.edu in advance of making any changes to your study. Indicate all changes requested, rationale for making the changes, and your research supervisor/chair's approval of these changes. (Cc the chair/person overseeing your research to this email.)

Documents included in the HRRC application (Forms and detailed Instructions for these documents follow.)

Your HRRC application will include a completed:

- Coversheet completed in legible writing or typed, including all signatures
- Application fully answering the 14 criteria
- Appendix

Coversheet instructions (See form on next page)

Fill in the Coversheet. Categorize your research as *High* or *Low Risk* or *Request for Exempt Status*. Secure chair and program chair/department director signatures.

High Risk, Low Risk, or Request for Exempt Status?

- Choose *High Risk* if:
 - Research participants are more vulnerable than the general population (e.g., children; incarcerated participants, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons).
 - Research participants are engaged in illegal activities that constitute the focus of your research (e.g., illegal immigrants; drug users; users of psychedelics, gang members; sex workers)
 - The research methodology has above average risk in causing participants significant distress (e.g., triggering trauma)
 - Participants are to engage in strenuous physical activity or are subject to challenging physical settings
 - The *researcher* is put at risk (e.g., research conducted in politically unstable countries, in high-crime neighborhoods, where psychedelics or other drugs are illegally used)
- Choose *Request for Exempt Status* if:
 - Your study does not use participant data and you and your chair are unsure if your research should have HRRC review.
 - See page 5 for *Request for Exempt Status Application* instructions (abbreviated application).
- Choose *Low Risk* for all other research.

HRRC COVERSHEET TO ACCOMPANY ALL APPLICATIONS

CALIFORNIA INSTITUTE OF INTEGRAL STUDIES HUMAN RESEARCH REVIEW COMMITTEE APPLICATION

Researcher's Last Name _____ First Name _____

CIIS Program (_____) _____
Researcher's Telephone Researcher's E-mail

Researcher's Street Address City

State Country Zip Code

Signature of Researcher Date this application was emailed

Printed name of Chair of Thesis/Dissertation Telephone E-mail

Committee (or Supervisor of Research)

Your signature as Thesis/Dissertation Chair (or Supervisor of Research) indicates that you have considered all risks involved, accept responsibility for the research described, and that you are fully aware of all procedures to be followed, will monitor the research, and will ensure that the HRRC is notified of any significant problems or changes.

Signature of Chair of Thesis/Dissertation Committee Date
(or Supervisor of Research)

This application may be submitted just before committee approval of the thesis/dissertation proposal.

Program Chair/Director Date

Your signature as Program/Department Chair/Director indicates that you have considered all risks involved, accept responsibility for the research described, and that you are fully aware of all procedures to be followed,

Title of Research Project typed or written clearly:

(typed or written clearly) _____

REVIEW CATEGORY REQUESTED:

_____ High Risk (see special instructions on page 6)

_____ Low Risk

_____ Request for EXEMPTION

Request for Exempt Status Application

Abbreviated Application:

Complete the coversheet and attach it to the abbreviated application.

In 1-2 pages, describe your proposed research covering the following points:

- One-paragraph description of the research focus
- Method to be used
- Explanation of human participant data that will be collected
- All possible risks to anonymity, confidentiality, and safety
- How risks are minimized

High Risk Application Special Instructions

All High Risk Studies

All High Risk studies are required to have at least one dissertation committee member or consultant who has the experience and training appropriate to supervise risks involving the population in question and phenomena in question.

Clinical High Risk Studies

High Risk studies exploring a clinical phenomenon are required to have at least one dissertation committee member who is a mental health professional with training and licensure appropriate to supervise the development of the research proposal for the population in question and clinical phenomena in question.

Supervisor Qualifications

A description of the dissertation chair's qualifications related to the study and CV must be included in the application. If the chair lacks the qualifications to supervise the risks associated with this specific population and phenomena, a qualified consultant or committee member is needed. This supervisor must oversee risks involved in the development of the study from its initial planning stages. Include the supervisor's name, qualifications, and CV in this application.

Mental Health Referrals

Research in which participants may become stressed, anxious, or in other ways psychologically impacted in a negative manner needs a referral path to a mental health professional. Please provide license numbers, addresses, and phone numbers for all referrals. Indicate that referral professionals have been directly contacted by you, are aware of the study and its risks, have agreed to accept participants should referral be needed, and are able to conduct remote sessions. Include this information in the application and in the *Informed Consent*. In the event you are conducting research in multiple locations and cannot reasonably identify particular individuals, consider identifying a referral source that is national and a clinician or service who will act in the

role of facilitating referrals. Cost of mental health referrals should be taken into consideration and disclosed to participants.

Research Involving Psychedelics

- CIIS student researchers, faculty, and staff, in their capacity as researchers, cannot be present, be a participant observer, or be a participant where they know substances that are illegal in that jurisdiction are being used, stored, or distributed.
- You may be asked to provide the relevant information about what substances are legal in specific jurisdictions and how you qualify under the above policy for being present, being a participant observer, or being a participant where substances are being used legally under that jurisdiction. For example, you may be asked to provide a letter or membership card for membership of Santo Daime, UDV, or Native American Church or provide evidence that the substance is indeed legal under the Religious Freedom and Restoration Act (RFRA), for clinical trial purposes or other provisions within that jurisdiction.

Requirements for Submission

1. Study:

___ Purpose, inquiry question, and discipline.

2. Methodology:

___ Methodology and method.

___ Relationship between researcher and participants the methodology supports.

3. For High Risk Studies, Supervisor Qualifications:

___ Description of the dissertation chair or consultant's qualifications related to the study and CV. CV at end of the Appendix.

___ Describe role of consultant who has agreed to oversee risks involved in the development of the study from its initial planning stages.

4. Participant Inclusion/Exclusion Criteria:

___ How many participants included in study.

___ Concisely list inclusion and exclusion criteria.

___ Pertinent demographics: age, gender, ethnicity, etc.

___ Specify that participants are above the age of 18 if study does not involve children.

___ Geographic location.

___ Other characteristics to exclude would-be participants (e.g., current mental health, non-English speaking).

___ Protocol to assess for exclusionary characteristics.

___ Professional and/or personal background if relevant to assessing exclusion criteria.

___ If high risk, describe protocols you and your supervisor will use together to assess for exclusionary characteristics.

5. Recruitment Protocols:

___ How you will contact potential participants.

___ If you use referrals or snowball method, specify that participants will be given your contact information to contact you if interested in study.

___ Samples of all recruitment material.

___ How you will screen participants. (Detailed and thorough screening protocols for high risk.)

___ How you will contact accepted participants to convey next steps.

___ How you will contact excluded participants and what rationale you will give for exclusion. (Sensitive in language)

6. Data Gathering Protocols:

Interactions with participants

___ Relationship to the participant community.

___ Presentation of *Informed Consent* and *Participant Bill of Rights*.

___ Designate neutral, safe space to work with participants that ensures confidentiality, privacy, anonymity, and safety.

- ___ Describe each interaction with participants in data collection.
- ___ How you will put the participant at ease.
- ___ For questionnaires, pilot to confirm they can be completed in the timeframe estimate with a break after 60 minutes.
- ___ Confidentiality protocols if conducting group interviews.

Data handling

- ___ Information about co-facilitators and confidentiality.
- ___ Information about use of transcriber and confidentiality.
- ___ How data will be collected, (e.g., notes, audio tape, video recording, participant artwork) stored, and identifiable data destroyed.
- ___ Secure online data storage protocols.
- ___ Specify use of video or audio recordings.
- ___ Personal information removed from data and stored separate.
- ___ Hardcopy data stored in locked area accessible only by the Principle Investigator.
- ___ Personal, identifiable information destroyed within seven years of completion of research project.
- ___ Statement that either nonidentifiable data could be used or distributed to another investigator for future research studies or will not be used or distributed for future research studies.
- ___ Return participant artwork, journals, or other materials if these were collected.

7. Risks:

- ___ Describe in detail all the potential psychological and physical risks to participants and how you intend to minimize them.
- ___ Describe risks to confidentiality for group interviews, co-facilitators, and transcribers and how you intend to minimize them.
- ___ Include appropriate discussion of risk for online data collection and storage.
- ___ If high risk, provide the license numbers, addresses, and phone numbers for all referrals. Remote sessions an option.
Indicate that referral professionals have been directly contacted by you, are aware of the study and its risks, have agreed to accept participants should referral be needed, and can conduct remote sessions.

8. Benefits:

- ___ Name any monetary or material compensation and indirect benefits to participants, the academic discipline, or to society. Indicate that there can be no guarantee of direct benefit from this study.

9. Type of Informed Consent:

- ___ Written consent, assent, or waiver of signed consent.

10. Informed Consent process and documentation:

- ___ If in language other than English, include certified translation.
- ___ **Introduce self** and study.
- ___ State that participation is completely voluntary.
- ___ **Include all details of what participation will involve.**
- ___ Include each interaction with participants: how established, where/how it will take place, what will happen, how long, and who will be there.
- ___ How many participants approximately will be involved in study.

- ___ Private location to ensure confidentiality, privacy, and anonymity.
- ___ Confidentiality protocols if conducting group meetings.
- ___ **Include data security protocols.**
- ___ All information strictly confidential and identity protected within the limits of the law.
- ___ Information about co-facilitators and provide copies of confidentiality forms.
- ___ Information about use of transcriber and provide copies of transcription forms.
- ___ How data will be collected, (e.g., notes, audio tape, video recording, participant artwork) stored, and identifiable data destroyed.
- ___ Secure online data storage protocols.
- ___ Specify use of video or audio recordings.
- ___ Personal information removed from data and stored separate.
- ___ Hardcopy data stored in locked area accessible only by the Principle Investigator.
- ___ Personal, identifiable information destroyed within seven years of completion of research project.
- ___ Statement that either nonidentifiable data could be used or distributed to another investigator for future research studies or will not be used or distributed for future research studies.
- ___ Return participant artwork, journals, or other materials if these were collected.
- ___ **Explain benefits.**
- ___ Indicate if no direct benefit is offered or guaranteed.
- ___ **Include all risks discussed in application.**
- ___ Protocols should participants become distressed.
- ___ High risk require mental health referral relevant experience, license numbers, addresses, phone numbers, directly contacted, aware of study, have agreed to accept participants, and can conduct remote sessions.
- ___ **Include your contact information for general questions only.**
- ___ **Provide HRRC contact information for concerns.**
 - In addition, should you at any time wish to discuss issues related to your contribution to this study, including questions regarding your rights as a participant, suggestions for how to minimize potential risk, or concerns that you have been put at risk, you may share your concerns (anonymously, if you wish) with the Human Research Review Committee at the California Institute of Integral Studies 1453 Mission Street, San Francisco, CA 94103 by email: hrrcoffice@ciis.edu.
- ___ **Include all necessary information with the signature line.**
 - Printed name;
 - *I have read, understood, and received a copy of this Informed Consent form, the Participant Bill of Rights, the Confidentiality Statement, and the Confidentiality Agreement Forms signed by anyone with access to data other than the Principle Investigator and dissertation chair.*
 - *I have had any questions about this research answered to my satisfaction;*
 - *I understand that my confidentiality will be protected within the limits of the law;*
 - *I consent to participate in this study;*
 - *I am willingly and voluntarily participating in this research.*
 - *Signature and date.*
- ___ **Indicate that participants may receive a summary of the results** of the study by providing email or mailing address.

11. Human Participant Bill of Rights:

_____ Orally inform participants of participant rights and provide participants with a written copy.

12. Funding Agency or Sponsor:

_____ If this research is being funded, identify the agency or sponsor and their contact information.

13. Supervision by an Institution Other Than CIIS:

_____ If other institutions are involved in your study, include letter of agreement signed by the appropriate authority.

_____ If using archival data collected by another institution and/or researcher, provide letter giving you permission to use the data.

_____ If the archival data were part of the study that underwent institutional review (IRB), include a copy of the approval letter.

_____ If conducted under the *supervision* of another institution, include copies of their HRRC/IRB review.

14. Samples of Interview Questions and Other Data Collection Materials:

_____ Sample questions, email communications, interview protocols, demographic information forms, and questionnaires included

Further Clarification and Guidelines

- **1-14 not to exceed 15 pages**
- **Use numbers and headings below**
- **Use page numbers**

1. Study, Aim, Background

- *Concisely* (in one-to-two paragraphs) note the purpose of the study, the inquiry question, and the discipline(s) to which relevant literature to the study is associated.

2. Methodology and Method

- *Concisely* (in one-to-two paragraphs) name the methodology and method. Here are some examples of methodology paired with methods:
 - Qualitative: Narrative
 - Qualitative: Ethnography
 - Qualitative: Case study
 - Qualitative: Arts-based research
 - Mixed method: Statistical analysis of empirical data and semi-structured interviews
 - Theoretical: Literature review with excerpts from case notes
- Make clear the relationship between the researcher and participants that the methodology supports. Cite literature where this relationship is discussed.

3. For High Risk Studies, Supervisor Qualifications

- Include a description of the dissertation chair's experience and training appropriate to supervise risks involving the population in question and phenomena in question.
- If the chair lacks the qualifications to supervise the risks associated with this specific population and phenomena, a qualified consultant or committee member is needed. This supervisor must oversee risks involved in the development of the study from its initial planning stages.
- Include the supervisor's name and relevant qualifications in this section. Include the supervisor's CV at the end of the *Appendix*.

4. Participant Inclusion/Exclusion Criteria

- How many participants do you plan to include in your study?
- Concisely list the inclusion criteria and exclusion criteria.
- Describe the following inclusion criteria and rationale if not obvious:
 - Pertinent demographics: age, gender, ethnicity, etc.
 - Specify that participants are above the age of 18 if your study does not involve children
 - Geographic location
 - Other participant characteristics required by the study
- Describe exclusion criteria and rationale:
 - In addition to not fitting the inclusion criteria (not the inverse of the inclusion criteria), what other characteristics will exclude would-be participants (e.g., current mental health, non-English speaking). State your rationale for each exclusion criterion if not obvious.
 - Include the protocol to assess for exclusionary characteristics. (e.g., interview, psychological test)
 - Include your professional and/or personal background if relevant to assessing exclusion criteria (e.g., counselor, therapist, community member, teacher).
 - If your study is high risk, describe the protocols you and your supervisor will use together to assess exclusionary characteristics.

5. Recruitment Protocols

- Describe how you will contact potential participants (e.g., referrals; snowball method, flyers; listserv).
 - In the *Appendix*, provide samples of all recruitment material (e.g., sample e-mail communications, flyers, letters, phone scripts).
 - If you use referrals or snowball method, specify that participants will be given your contact information to contact you if they are interested in the study.
- Describe how you will screen participants (e.g., phone, in person, via Skype). Detailed and thorough screening protocols are needed for studies involving the risk of negatively impacting participants who are not screened out.
- Describe how you will contact accepted participants to convey next steps.
- Describe how you will contact excluded participants and what rationale you will give them for their exclusion. Please be sensitive in language to excluded participants. For example, you may simply want to state that your study has the

number of participants it needs, rather than specify the participant's exclusionary characteristics. Offer psychological resources if appropriate.

6. Data Gathering Protocols

Interactions with participants

- Some research (e.g., anthropological, ethnographic, case study) involves observation and participation with groups and communities and requires relationships with leaders, respected community members, or members formally responsible for a group's welfare (e.g., school principals and instructors). Describe your relationship to the community and how this is included in your protocols for informing participants and receiving their consent.
- As appropriate, indicate that you will present the *Informed Consent* and *Participant Bill of Rights* (see #9 and #10 below) for participants' review prior to their appointment with you. Indicate that you will obtain a signed *Informed Consent* before data collection, first answering any questions they may have.
- Designate a neutral, safe space to work with participants that also ensures confidentiality, privacy, anonymity, and safety for the student researcher. Indicate how the space will meet these standards in your application.
- Describe each interaction with participants in data collection: how the appointment will be established, where it will take place, what will happen during the appointment, how long the appointment will take, and who, if anyone other than researcher and participant will be there (e.g., parent, guardian, support person).
- Describe how you will put the participant at ease.
- **Do not include procedure for analyzing data.**
- For use of questionnaires, pilot to confirm that they can be completed in the timeframe estimate you give to participants. If a survey is predicted to take longer than 60 minutes, include protocols for allowing participants to take a break.
- If a group interview will be conducted, describe how confidentiality will be maintained for individuals sharing personal information in the group setting. A *Confidentiality Agreement Form* should be created by the researcher and signed by participants before a group interview begins and included in the *Appendix*.
- Indicate if participants will have the opportunity to omit particular details from the study.

Data handling

- If co-facilitators are assisting in your study, indicate who these individuals are, their relevant qualifications and backgrounds, and your protocols for maintaining confidentiality. Specify that anyone other than the researcher and supervisor with access to identified data will sign a *Confidentiality Agreement Form* and include in the *Appendix*.
- Indicate if a transcription service will be used. Indicate that the investigator will first remove personal identifiers from data and the transcriber will sign a *Transcription Services Confidentiality Agreement Form*, which participants have been provided a copy of.
- Describe how data will be collected, (e.g., notes, audio tape, video recording, participant artwork) stored, and identifiable data destroyed).

- For online research, the risk of a breach of confidentiality is always possible. To minimize risk, all electronic data collected must be stored on password protected computers. Only computers with disc-based encryption enabled via Windows 10 or MacOS must be used to collect or store participant data. Only secured websites protected with SSL (Secure Sockets Layer) and TLS 1.2 or higher must be used to collect or store participant data. Indicate compliance with these security protocols in this section.
- For use of video or audio recordings (especially for video conferencing), specify if recordings made are for note taking and transcription purposes only and will not be used for anything else.
- Personal, identifiable information must be stored separate from data. Any identifying information must be removed from data.
- Hardcopy data must be stored in a locked area accessible only by the Principle Investigator.
- Personal, identifiable information must be destroyed within seven years of completion of this research project.
- A statement must be included that either nonidentifiable data could be used or distributed to another investigator for future research studies or will not be used or distributed for future research studies.
- If you have collected participant artwork, journals, or other materials for data analysis, please indicate that you will return these materials following completion of the study.

7. Psychological and Physical Risks and Protocols to Minimize

- Describe in detail all the potential psychological risks to participants and how you intend to minimize them. No study is without risk; your sensitivity and awareness of potential risks should be demonstrated in this criterion.
- Describe in detail physical risks, if any, and how you intend to minimize them. This includes but is not limited to making sure that the physical space where the study is being conducted addresses potential physical risks to the participants.
- Describe risks to confidentiality and how you intend to minimize them for individuals sharing personal information in group settings, use of co-facilitators, and use of transcribers.
- High risk studies must offer referral to a mental health professional in case participants become stressed, anxious, or in other ways psychologically impacted in a negative manner during data gathering. In this section and in the *Informed Consent*, explain the experience of referral professionals working with the population. Provide the license numbers, addresses, and phone numbers for all referrals. Indicate that referral professionals have been directly contacted by you, are aware of the study and its risks, have agreed to accept participants should referral be needed, and can conduct remote sessions. Cost of mental health referrals should be taken into consideration.

8. Benefits

- Name any monetary or material compensation. Describe potential indirect benefits including benefits of the research to participants, the academic discipline, or to society. Indicate that there can be no guarantee of direct benefit from this study.

9. Type of Informed Consent

The type of your Informed Consent is based on the method and participants involved in your study.

Indicate the type you will be using from those noted below:

- *Written Consent* (most common): Participants sign an Informed Consent form indicating that they have been informed about the research and their part in it, and they have agreed to participate.
- *Assent*: Children of certain ages as well as certain adults need a parent, guardian, or a conservator to sign the Informed Consent form. A separate assent form or a handout with a simpler language explaining the study and its procedures is sometimes used to help with the consent process. Older children and adolescents should be included in the consent process, even though parent/guardian (written) consent is required.
- *Waiver of Signed Consent*: Federal regulations allow the HRRC to waive the requirement for the investigator to obtain a *signed* consent form if it finds either:
 - (a) that the only record linking participants and the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality; OR
 - (b) that the research presents no more than minimal risk to participants and involves no procedures for which written consent is normally required outside of the research context.

Thus, the HRRC may approve a request for waiver of signed consent in the following situations: (a) when the identities of participants will be completely anonymous (as with some surveys) and there is minimal risk in the study; (b) when obtaining signed consent is not appropriate or feasible according to the cultural standards of the population being studied and the study involves minimal risk; (c) when there is a legal, social, or economic risk entailed in signing the consent form, (e.g., for immigrants who might be identified as illegal, or for HIV antibody-positive individuals who might be identified as such). Please note that in some cases you may still be required to provide a written consent form, even if no signature is obtained.

10. Informed Consent Form

Prepare an *Informed Consent Form* and include it in the Appendix of your HRRC application. (A sample *Informed Consent Form* can be found in the "Appendices to Submit with your HRRC Application" in this packet.)

If the Informed Consent is presented in a language other than English, the HRRC strongly recommends including a certification of the translation. Please either 1.) translate yourself and have the Informed Consent certified by a certification company/ licensed individual; 2.) have it professionally translated; or 3) have a dissertation committee member fluent in both English and the language review the document.

The following information has to be presented in the *Informed Consent Form*, or where written consent is not required, it needs to be orally presented. Please make sure that your *Informed Consent Form* is written as a stand-alone document

for participants to understand the study and is consistent with how you describe your study in the HRRC application. The following points must be clearly presented:

- **Introduce yourself** and the study in non-technical language.
 - State that participation in this study is completely voluntary. If you decide to participate, you may refuse to answer any question(s), withdraw your consent, and/or discontinue your participation at any time and for any reason without penalty or prejudice.
- **Include all the details of what participation will involve.**
 - Include each interaction with participants in data collection: how the appointment will be established, where/how it will take place, what will happen during the appointment, how long the appointment will take, and who, if anyone other than researcher and participant will be there.
 - Indicate how many participants approximately will be included in the study.
 - Ask them to find a private location for remote appointments or interviews to ensure confidentiality, privacy, and anonymity.
 - Before group meetings, indicate that all participants will agree to keep everything shared confidential, refrain from using real names, and sign a *Confidentiality Agreement Form*.
 - Indicate if any preparation or additional homework is required of participants.
- **Include data security protocols.**
 - Indicate the following: For the protection of your privacy, all information will be kept strictly confidential and your identity will be protected within the limits of the law.
 - If co-facilitators are assisting in your study, introduce these individuals, their relevant qualifications and backgrounds, and your protocols for maintaining confidentiality. Specify that anyone other than the researcher and supervisor with access to identified data will sign a *Confidentiality Agreement Form*.
 - Introduce your research supervisor and that he/she will have access to data.
 - Indicate if a transcription service will be used. Indicate that the investigator will first remove personal identifiers from data and the transcriber will sign a *Transcription Services Confidentiality Agreement Form*, which participants will be provided a copy of.
 - Describe how data will be collected, (e.g., notes, audio tape, video recording, participant artwork) stored, and identifiable data destroyed).
 - Indicate if participants will have the opportunity to omit particular details from the study.
 - Explain that for online research, the risk of a breach of confidentiality is always possible. To minimize risk, all electronic data collected must be stored on password protected computers. Only computers with disc-based encryption enabled via Windows 10 or MacOS must be used to collect or store participant data. Only secured websites protected with SSL (Secure Sockets Layer) and TLS 1.2 or higher must be used to collect or store participant data. Indicate compliance with these security protocols in this section.
 - For use of video or audio recordings (especially for video conferencing), specify if recordings made are for note taking and transcription purposes only and will not be used for anything else.

- Personal, identifiable information must be stored separate from data. Any identifying information must be removed from data.
- Hardcopy data must be stored in a locked area accessible only by the Principle Investigator.
- Personal, identifiable information must be destroyed within seven years of completion of this research project.
- A statement must be included that either nonidentifiable data could be used or distributed to another investigator for future research studies or will not be used or distributed for future research studies.
- If you have collected participant artwork, journals, or other materials for data analysis, please indicate that you will return these materials following completion of the study.
- **Explain benefits.**
 - Indicate if no direct benefit, including any monetary recompense or treatment is offered or guaranteed.
 - Explain potential benefits for participants, the academic discipline, and society.
- **Include all risks discussed in your application.**
 - Provide protocols should participants become distressed.
 - High risk studies require a mental health referral with experience working with the population. Include relevant experience, license numbers, addresses, and phone numbers for all referrals. Indicate that referral professionals have been directly contacted by you, are aware of the study and its risks, have agreed to accept participants should referral be needed, and can conduct remote sessions.
- **Include your contact information for general questions only.**
- **Provide the following HRRC contact information for concerns:**
 - In addition, should you at any time wish to discuss issues related to your contribution to this study, including questions regarding your rights as a participant, suggestions for how to minimize potential risk, or concerns that you have been put at risk, you may share your concerns (anonymously, if you wish) with the Human Research Review Committee at the California Institute of Integral Studies 1453 Mission Street, San Francisco, CA 94103 by email: hrrcoffice@ciis.edu.
- **Include all necessary information with the signature line:**
 - Printed name;
 - *I have read, understood, and received a copy of this Informed Consent form, the Participant Bill of Rights, the Confidentiality Statement, and the Confidentiality Agreement Forms signed by anyone with access to data other than the Principle Investigator and dissertation chair.*
 - *I have had any questions about this research answered to my satisfaction;*
 - *I understand that my confidentiality will be protected within the limits of the law;*
 - *I consent to participate in this study;*
 - *I am willingly and voluntarily participating in this research.*
 - *Signature and date.*
- **Indicate that participants may receive a summary of the results** of the study by providing an email or mailing address.

11. Human Participant Bill of Rights

It is the researcher's responsibility to see that participant rights are protected. California law requires that the Experimental Subjects Bill of Rights be given to participants in research using any form of medical treatment, including *psychotherapy*, in a language in which they are fluent. Copies of these documents are included herein. Make note that you will orally inform participants of these rights and provide participants with a written copy. Include in your *Informed Consent Form*, a signature line where upon signing, the participant confirms that he or she has been given this form.

12. Funding Agency or Sponsor

- Indicate if this research is being funded and identify the agency or sponsor and their contact information.

13. Supervision by an Institution Other Than CIIS

- If other institutions are involved in your study, make note that a letter of agreement signed by the appropriate authority is in the Appendix.
- If you are using archival data collected by another institution and/or researcher, provide a copy of a letter giving you permission to use the data. If the archival data were part of the study that underwent institutional review (IRB), include a copy of the approval letter in this application as well.
- If your study will be or has been conducted under the supervision of another institution, also include copies of their HRRC/IRB review in the Appendix.

14. Samples of Interview Questions and Other Data Collection Materials.

- Include all communication and data collection materials in the Appendix. This includes but is not limited to planned email communications, interview protocols, demographic information forms, and questionnaires used in your study.
- If you are using materials in a language other than English, please make sure to provide them in the original language as well as corresponding English translations.

CIIS HRRC Application

(Please follow application instructions above)

- 1. Study, Aim, Background**
- 2. Methodology and Methods**
- 3. For High Risk Studies, Supervisor Qualifications**
- 4. Participant Inclusion-Exclusion Criteria**
- 5. Recruitment Protocols**
- 6. Data Collection Protocols**
- 7. Psychological and Physical Risk and Protocols to Minimize Them**
- 8. Benefits**
- 9. Type of Informed Consent**
- 10. Informed Consent Form**
- 11. Human Participant Bill of Rights**

(Make note where this form can be found in the Appendix.)
- 12. Funding Agency or Sponsor**
- 13. Supervision by an Institution or an Organization outside of CIIS**
- 14. Sample Interview Questions and Other Materials**

(Make note where these materials can be found in the Appendix.)

Appendices to Be Submitted with HRRC Application

Follow this order as applicable:

- Informed Consent Form (see sample following) and/or, if applicable, an Assent Form/Protocol
- Human Participant Bill of Rights (see following)
- Confidentiality Statement (see following)
- Transcription Services Confidentiality Agreement Form to be signed by transcriber if this service is used (see sample)
- Recruitment materials (e.g., sample e-mail communications, flyers, letters, phone scripts)
- Communication to inform participant that they are included/invited to participate in the study
- Communication to inform participant they are not included
- Confidentiality Agreement Form for Group Interview
- Interview questions, questionnaires, and other materials used to collect data
- Letters of agreement with organizations who provide space, supervision, or access to their participants or other data (see sample)
- Permissions to use a space for data collection (e.g., rental agreement), as applicable)
- If applicable, letter from supervising organization other than CIIS, indicating its supervisory role and relationship to the study
- CV of research supervisor for high risk studies

Informed Consent Form – SAMPLE

(This is a sample only; this form should align with the relevant sections in the body of your application.)

Introduce yourself. Ronald Palmer, a doctoral student in clinical psychology, at the California Institute of Integral Studies (CIIS) in San Francisco, California, is conducting a study on the experience of individuals in recovery from alcoholism and addiction.

Participation in this study is completely voluntary. If you decide to participate, you may refuse to answer any question(s), withdraw your consent, and/or discontinue your participation at any time and for any reason without penalty or prejudice.

Include all the details of what participation will involve. As a person identified as having such experience, you are invited to participate in this study. It will involve completion of an online questionnaire, and the audio recording of a semi-structured group interview with roughly ten other participants who have experienced recovery from alcoholism and addiction. The questionnaire will be conducted using Survey Monkey. This may take approximately one-and-a-half hours, during which you will have the opportunity to save your work and take a break.

The group interview will be conducted using Zoom with audio only and scheduled at a time convenient to you and the group. You will need to find a private location to ensure confidentiality, privacy, and anonymity. The group interview has been designed to last approximately one hour and no longer than one-and-a-half hours. During that time, you will be invited to talk in a manner you find safe and comfortable concerning your personal understanding of recovery from alcoholism and addiction. Before participation in the group interview, all participants will agree to keep everything shared confidential, refrain from using real names, and sign a *Confidentiality Agreement Form*. No preparation on your part is required for any part of the process.

Include data security protocols. For the protection of your privacy, all information will be kept strictly confidential and your identity will be protected within the limits of the law. Sunny Dee, a counselor who has ten years of experience working with individuals in recovery from addiction will assist with the group interview as a co-facilitator. Sunny Dee has agreed to keep everything shared confidential and has signed a *Confidentiality Agreement Form*, which you are provided a copy of.

The Principle Investigator's dissertation chair, Dr. Dana Pepper, Ph.D., will have access to the data associated with this study. A transcription service will be used to convert the audio file from the Zoom interview into typed text. To ensure your privacy, the investigator will first remove personal identifiers from the recording and the transcriber will sign a *Transcription Services Confidentiality Agreement Form*, which you will be provided a copy of.

For data collected using Survey Monkey, as with all online research, the risk of a breach of confidentiality is always possible. To minimize risk, all electronic data collected will be stored on password protected computers. Only computers with disc-based encryption

enabled via Windows 10 or MacOS will be used to collect or store participant data. Only secured websites protected with SSL (Secure Sockets Layer) and TLS 1.2 or higher will be used to collect or store participant data. Personal information will be stored separate from the questionnaire and group interview data. Any identifying information will be removed from both sets of data. Hardcopy data will be stored in a locked area accessible only by the Principle Investigator. For the group interview, audio recordings from Zoom are for note taking purposes only and will be deleted following transcription. Additionally, your request to omit particular details from data that you specify to the Principle Investigator will be honored.

All electronic and hardcopy data with personally identifying information will be destroyed within seven years of completion of this research project. Nonidentifiable participant data will be retained for future research studies or distributed to another investigator for future research studies. No information that could personally identify any of the participants will be used in the published dissertation or for any other purpose.

Explain benefits. For your participation, no direct benefit, including any monetary recompense or treatment is offered or guaranteed. If you choose to take part, your contribution will help increase understanding about the nature of long-term recovery from alcoholism or addiction, an area of knowledge that has rarely been discussed in the professional literature. In addition, participation in the study may benefit others seeking to enter recovery, those already in recovery, or you directly. That is, based on the experiences of participants in similar research studies, I expect you may find the interview affords an opportunity for reflection and self-expression.

Include all risks discussed in your application, (not this sample discussion of risks). Before you agree to participate, it is important to understand that, while this study is designed to minimize potential risks, this inquiry may touch sensitive areas. In other words, depending on your unique history with the topic, it is possible to experience discomfort when discussing situations that were challenging for you.

Provide protocols should participants become distressed. High risk needs referral information. If you have any concerns or questions before, during, or after your interview, the Principal Investigator will make every effort to discuss them and inform you of options for resolving your concerns.

The following crisis numbers are available to you:

- San Francisco Suicide Prevention Drug Line: 1-800-000-000
- San Francisco Suicide Prevention Relapse Line: 415-000-0000

Please see information on San Francisco 12-Step meeting times and locations:

Sun	7:00 AM	Marina	2118 Greenwich St at Fillmore St The Dry Dock	Daily, Big Book
Sun	7:00 AM	Mission	2900 24th St at Florida St Mission Fellowship	Daily, Wheelchair Access
Sun	8:00 AM	Bernal Heights	515 Cortland Ave at Andover St Neighborhood Center	Book Study, Steps & Traditions

The following Licensed Clinical Psychologists have experience working with individuals in recovery from alcoholism and addiction, are aware of this study, are willing to accept referrals, and can conduct remote sessions:

- Yerba Mate (license number # 1234); Address: 0000 Mission Street, San Francisco, CA 94103; Phone: 415-000-0000.
- Ginger Allen (license number # 5678); Address: 0000 Mission Street, San Francisco, CA 94103; Phone: 415-000-0000.

If you have any questions about the study, please feel free to contact the Principle Investigator, Ronald Palmer by email, tLemon@gmail.com or phone, 415-000-000.

Provide HRRC contact information. In addition, should you at any time wish to discuss issues related to your contribution to this study, including questions regarding your rights as a participant, suggestions for how to minimize potential risk, or concerns that you have been put at risk, you may share your concerns (anonymously, if you wish) with the Human Research Review Committee at the California Institute of Integral Studies 1453 Mission Street, San Francisco, CA 94103 by email: hrrcoffice@ciis.edu.

Include all necessary information with the signature line.

I, _____ (your printed name), attest that:

- *I have read, understood, and received a copy of this Informed Consent Form, the Participant Bill of Rights, the Confidentiality Statement, and the Confidentiality Agreement Forms signed by anyone with access to data other than the Principle Investigator and dissertation chair.*
- *I have had any questions about this research answered to my satisfaction;*
- *I understand that my confidentiality will be protected within the limits of the law;*
- *I consent to participate in this study;*
- *I am willingly and voluntarily participating in this research.*

Participant's Signature

Date

If you would like to receive a summary of the results of the study, please provide an email or mailing address below where it can be sent to you.

Human Participant Bill of Rights

You have the right to...

- be treated with dignity and respect;
- be given a clear description of the purpose of the study and what is expected of you as a participant;
- be told of any benefits or risks to you that can be expected from participating in the study;
- know the researchers' training and experience;
- ask any questions you may have about the study;
- decide to participate or not without any pressure from the researcher or his or her assistants;
- have your privacy protected within the limits of the law;
- refuse to answer any research question, refuse to participate in any part of the study, or withdraw from the study at any time without any negative effects to you;
- be given a description of the overall results of the study upon request;
- discuss any concerns or file a complaint about the study (anonymously, if you wish) with the Human Research Review Committee, California Institute of Integral Studies, 1453 Mission Street, San Francisco, CA 94103, via email: hrrcoffice@ciis.edu

SAMPLE Confidentiality Statement

Your privacy with respect to the information you disclose during participation in this study will be protected within the limits of the law. However, there are circumstances where a researcher is required by law to reveal information, usually for the protection of a patient, research participant, or others. A report to the police department or to the appropriate protective agency is required in the following cases:

1. if, in the judgment of the researcher, a patient or research participant becomes dangerous to himself or herself or others (or their property), and revealing the information is necessary to prevent the danger;
2. if there is suspected child abuse, in other words if a child under 16 has been a victim of a crime or neglect;
3. if there is suspected elder abuse, in other words if a woman or man age 60 or older has been victim of a crime or neglect.

**SAMPLE Transcription and/or Translation Services
Confidentiality Agreement**

I, _____, transcriptionist and/or translator, individually and on behalf of [name of business or entity if applicable] , do hereby agree to maintain full confidentiality in regards to any and all audiotapes, videotapes, and oral or written documentation received from _____[researcher's name] related to his/her research study titled _____.

Furthermore, I agree:

1. To hold in strictest confidence the identification of any individual that may be inadvertently revealed during the transcription of audio-taped or live oral interviews, or in any associated documents;
2. To not disclose any information received for profit, gain, or otherwise;
3. To not make copies of any audiotapes, videotapes, or computerized files of the transcribed interview texts, unless specifically requested to do so by [researcher's name];
4. To store all study-related audiotapes, videotapes and materials in a safe, secure location as long as they are in my possession;
5. To return all audiotapes, videotapes and study-related documents to _____[researcher's name] in a complete and timely manner.
6. To delete all electronic files containing study-related documents from my computer hard drive and any backup devices.

Please provide the following contact information for the researcher and the transcriber and/or translator:

For Transcriber/Translator:

Address: _____

Phone number: _____

For Researcher:

Address: _____

Phone number: _____

I am aware that I can be held legally liable for any breach of this confidentiality agreement, and for any harm incurred by individuals if I disclose identifiable information contained in the audiotapes, videotapes and/or paper files to which I will have access. I am further aware that if any breach of confidentiality occurs, I will be fully subject to the laws of the State of California.

Transcriber/ Translator's name:

Transcriber/Translator's signature:

Transcriber/Translator's Name of Business and Title (if applicable):

Date: _____

Information Letter

If using an Information Letter, only include introductory information about the study such as what participation will involve.

Do not include protocols for confidentiality, data storage and destruction, or risks.

Including information intended for the Informed Consent can be redundant and confusing.

SAMPLE Letter of Authorization to Conduct Research at Facility

Correspondence must be on the facility's letterhead

[cut and paste all below to your document]

Human Research Review Committee (HRRC)
California Institute of Integral Studies
1453 Mission Street
San Francisco, CA 94103
hrrcoffice@ciis.edu

Subject: Letter of Authorization to Conduct Research at

Dear HRRC:

This letter will serve as authorization for the California Institute of Integral Studies (CIIS) researcher/research team, [name must be included] to conduct the research project entitled at [facility name and location].

The [Facility] acknowledges that it has reviewed the protocols presented by the researcher, as well as the associated risks to the Facility. The Facility accepts the protocols and the associated risks to the Facility and authorizes the research project to proceed. The research project may be implemented at the Facility upon approval from the CIIS HRRC.

If we require additional information, we will contact the researcher. If we have concerns, we will contact the CIIS HRRC via email: hrrcoffice@ciis.edu.

Sincerely,

(Signature of Facility's Authorized Signatory)

Date

Printed Name and Title of Authorized Signatory