

CIIS Human Research Review Committee

HRRC APPLICATION PACKET

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.

* "Chair" means the person overseeing your research, for example, 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.

REQUIRED SIGNATURES:

- Make sure you secure signatures (chair and program or department director) on the application where noted.

NUMBER OF COPIES TO SUBMIT:

- High Risk – 4 copies required
- Low Risk – 3 copies required
- Request for Exemption – 2 copies required

WHERE TO SUBMIT THE APPLICATION AND COPIES:

- Mail or drop-off (4th floor reception area - place in locked box for Interdepartment Delivery) to:
CIIS - HRRC Coordinator
1453 Mission Street
San Francisco, CA 94103

Dear Applicant:

Enclosed herein are the instructions and forms for completing and submitting an application for Human Research Review Committee (HRRC) approval. The committee reviews your research protocols for protecting human participants' anonymity, confidentiality, and physical and mental safety in accordance with Federal guidelines. *Approval is required before you can begin your research.*

Who should apply?

- CIIS researchers (students, faculty, or staff) whose research project involves human participants.
- In addition to qualitative methods such as narrative, case study, and ethnography, 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. Instructions are included in this application.

When can I begin my research?

- When your Proposal has been approved by your committee and Program Chair, and when your HRRC application has been approved by HRRC. (The Program Chair signs the HRRC coversheet indicating that your proposal is approved by your full committee.)

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 the HRRC Coordinator, requesting extension. Attach the original application and note any changes to protocols.

Documents Included in the HRRC Application

Your HRRC application will include a completed:

- Coversheet including proper signatures
- Application fully answering the 13 criteria
- Appendix

Forms and detailed Instructions for these documents follow.

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 or Low Risk or Request for Exempt Status?

- Choose *High Risk* if:
 - Research participants are more vulnerable than the general population (e.g., children; incarcerated subjects; the psychologically fragile; historically marginalized; victims of trauma, physically challenged, the elderly).
 - 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; prostitutes).
 - 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 you and your chair are unsure if your research should have HRRC review. For Exempt review, submit:
 - The Coversheet
 - An abbreviated, Request for Exempt Status application

- Choose *Low Risk* for all other research.

Request for Exempt Status Application

Complete the abbreviated application only if you are unsure whether you need to apply for HRRC approval.

Complete the coversheet and attach it to the abbreviated application.

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 subject data that will be collected.
- All possible risks to anonymity, confidentiality, and safety.
- How risks are minimized.

Note: All research that includes human subject participation or their previously collected information bears some risk. The researcher must demonstrate his or her sensitivity to potential issues.

Application Instructions

(Use the form that follows these instructions)

1. Study, Aim, Background

- *Concisely* (a page or less) 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

- Name the methodology and method. Here are some examples of methodology paired with methods:
 - Qualitative: Narrative
 - Qualitative: Ethnography
 - Qualitative: Case study
 - Qualitative: Art's-based research
 - Mixed method: Statistical analysis of empirical data & semi-structured interviews
 - Theoretical: Literature review with excerpts from case notes
- Make clear the relationship between the researcher and subjects that the methodology supports. Cite literature where this relationship is discussed.

3. Participants (subject population) Inclusion/Exclusion Criteria

- Describe inclusion criteria and rationale:
 - Pertinent demographics: age, gender, ethnicity, etc.
 - Geographic location.
 - Other participant characteristics required by the study.
- Describe exclusion criteria and rationale:
 - In addition to not fitting 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 criteria 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 for exclusion criteria (e.g., counselor, therapist, community member, teacher).

4. 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.
- Describe how you will screen participants (e.g., by phone, in person, via Skype).
- 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.

5. Data Gathering Protocols

- Describe the procedure for collecting data: How the appointment will be established; where it will take place (a neutral, safe place that also insures confidentiality and anonymity—researcher's or participant's homes are not acceptable unless compelling reasons can be given); what will happen during the appointment, how long the appointment will take, and who, if anyone other than researcher and participants, will be there (example: parent, guardian, support person, community).
- Some research (example, anthropological, ethnographic, case study) involve observation and participation with groups and communities and require relationships with leaders, respected community members, or members formally responsible for a group's welfare (example, school principals and instructors). Describe your relationship to the community and how it figures in your protocol for informing participants and getting their consent.
- Describe how you will put the participant at ease.

- As appropriate, indicate that you will present Informed Consent and Bill of Rights (see #8 – #10 below) for participants’ review prior to their appointment with you and that you will secure a signed Informed Consent before the interview commences, first answering any questions they may have.
- Describe how data will be collected (e.g., notes, audio tape, video recording).

6. Psychological and Physical Risks and Protocols to Minimize Them

- Describe in detail all the potential psychological risks to participants and how you intend to minimize them.
- Referral to a mental health professional is one protocol used in studies where participants may become stressed, anxious or in other ways psychologically impacted in a negative manner during data gathering. If you are using this protocol, provide the referral’s license numbers, addresses, and phone numbers for all referrals. Indicate that referral professionals have been directly contacted by you and are aware of the study and its risks and have agreed to accept participants should referral be needed.
- 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.

7. Benefits

- Name any monetary or material compensation.
Note: Do not promise benefits that cannot be guaranteed

8. 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 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 will usually 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.

9. Informed Consent Form

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

The following information has to be presented in the written consent form, or where written consent is not required, it needs to be orally presented. You must describe the project and the

procedures in non- technical language appropriate to the (aural or reading) level of the participants. Please make sure that your Informed Consent Form is written as a stand-alone document and is consistent with how you describe your study in the rest of your HRRC application. The following points must be clearly presented:

- Participation is voluntary.
- Participants have the right to refuse to answer particular question(s), as well as to discontinue participation at any time without penalty.
- If audiotape, videotape, or other types of recordings will be made, participants must be informed of this, along with where and how securely these recordings will be stored and how long they will be kept before they are disposed.
- Where applicable, who will transcribe recordings and how will confidentiality be assured. Indicate if a transcription service is used. If yes, provide a copy of Transcription Services Confidentiality form to the participants and include it with your HRRC application.
- How confidentiality and individual privacy will be maintained in published and written data resulting from the study; if the data are sensitive you must be specific about confidentiality procedures (e.g., "Questionnaires with all identifying information removed will be kept in the investigator's home in a locked file cabinet to which only she has the key, and the master list of names will be kept in a separate locked file cabinet").
- Where data will be published and in what form.
- What the risks and/or expected benefits are to participants.
- There can be no guarantee of direct benefit from this study.
- Participants have received a copy of the consent form and the researcher retains a copy signed by the participant noting that they have received a copy of the consent form. (e.g., "By signing below I acknowledge that I have received a copy of this consent form").
- The consent form must have a space for a name, signature and date line for all participants.
- The researcher's name, signature line, and contact information.
- The dissertation chair's name and contact information.
- If participants have any concerns or are dissatisfied at any time with any part of the study, they may report their concerns (anonymously, if they wish) to:

California Institute of Integral Studies (CIIS)
Coordinator of the Human Research Review Committee
1453 Mission Street
San Francisco, CA 94103
415-575-6292
hrrcoffice@ciis.edu.

10. Human Subject 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.

11. Funding Agency or Sponsor

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

12. 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 into 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.

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

- Make sure that sample questions are included in the Appendix. This includes but is not limited to 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 translations.

CIIS HRRC Application

(Please follow “Application Instructions” above)

1. Study, Aim, Background

2. Methodology and Methods

3. Participants (subject population) and Inclusion-Exclusion Criteria

- Inclusion Criteria and rationale:

- Exclusion Criteria and rationale:

4. Recruitment Protocols

- Initial contact for prospective participants:

- Screening:

- Contacting included participants:

- Contacting excluded participants:

5. Data Collection Protocols

- Process:

- Putting participant at ease:

- Presenting Informed Consent form and other documents:

- Means of capturing data (e.g., audio recording, internet, etc.)

6. Psychological and Physical Risk and Protocols to Minimize Them

7. Benefits

(No direct benefits can be guaranteed)

8. Type of Informed Consent

(e.g., written, assent, waived name & signature)

9. Informed Consent Form

(Make note where this form can be found in the Appendix.)

10. Human Subject Bill of Rights

(Make note where this form can be found in the Appendix.)

11. Funding Agency or Sponsor

12. Supervision by an Institution or an Organization outside of CIIS

13. Sample Interview Questions and Other Materials

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

Appendices to Be Submitted with HRRC Application

- 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.
- Informed Consent Form (see samples following) and/or, if applicable, an Assent Form/Protocol
- Human Subject Bill of Rights, if required (see following).
- 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.
- 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.
- Confidentiality agreement form to be signed by transcriber if transcription service is used (see following).

Consent Form – SAMPLE 1

John Smith, a doctoral candidate in clinical psychology, at the California Institute of Integral Studies in San Francisco, California, is conducting a study on the experience of individuals in recovery from alcoholism and addiction.

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 interview at a location and time convenient to you and the interviewer. The 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. No preparation on your part is required for any part of the process.

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. The research procedure has been designed to not collect unnecessary identifiers, and personal information will be kept separate from the questionnaire and interview data. The interviewer will also ask you to refrain from giving names and when necessary to use pseudonyms when referring to any other persons in the questionnaire and interview. All audio recordings will be erased following transcription. Additionally, any identifying information will be removed from both sets of data. Your request to omit from the dissertation particular details that you specify to the Principle Investigator will be honored.

Only the Principal Investigator, John Smith, M.A., and his dissertation Chair, Dr. Alex Adviser, Ph.D., will have access to the data associated with this study. Electronic data will be password protected and hardcopy data will be stored in a locked area accessible only by the Principal Investigator and destroyed within five years of completion of this research project. To further ensure your privacy, the investigator will use numeric identifiers of all data used by any third-party transcribers. In the publication or presentation of the findings, no information that could personally identify any of the participants will be used.

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 enjoyable opportunity for reflection and self-expression.

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. 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, including providing crisis numbers, referral to a therapist, and information on local 12-Step meeting times and locations.

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 phone (415) 575-6100 or e-mail hrrcoffice@ciis.edu.

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. You may also request a summary of the research findings by providing a mailing address along with your signature below.

I, _____(your name), attest that:

- *I have read, understood, and received a copy of this consent form, the Bill of Rights, and the Confidentiality Statement;*
- *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 on the experience of individuals in recovery from alcoholism and addiction; and*
- *I am willingly and voluntarily participating in this research.*

Participant's Signature

Date

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

Consent Form – SAMPLE 2

"Project Kindness" is a survey conducted by Mary Johnson as part of the requirements for a Doctorate of Clinical Psychology at the California Institute of Integral Studies. The purpose of this research project is to explore and better understand the experiences of adolescents at the Kindness Outreach Center (KOC). You are invited to participate in this research project because you have been identified as someone who has participated in KOC's Teen Program and are between the ages of 18-24 years old.

Participant Rights:

Your participation in this research study is completely voluntary. You may choose not to participate. If you decide to participate in this research survey, you have the right to refuse to answer particular question(s), as well as to discontinue participation at any time. If you decide not to participate in this study or, if you withdraw from participating at any time, you will not be penalized in any way.

This study involves filling out a survey that will take approximately 20-30 minutes. The survey questions will be about your personal experiences as they relate to meditation, spirituality, your participation in KOC's Teen Program, and what these experiences mean to you personally. There are no right or wrong answers, rather the researcher is solely interested in your honest opinions and beliefs.

All responses are treated as confidential. This means that your individual answers to survey questions will only be reviewed by this researcher and his dissertation chair, Dr. My Adviser. All data from this survey will be stored in a locked file cabinet accessible only by Mary and, when appropriate, stored in a password protected electronic format. The results of this survey will be presented as group information whenever possible and used for scholarly purposes only, unless you provide a written permission that states otherwise.

There are no reasonably foreseeable risks or negative consequences of participating in this research other than talking about personal experiences and the time/energy commitment to complete the survey. There are also no direct benefits to individual participants except for the potential of finding it enjoyable and meaningful to share their experiences and gain insight through their own process. Participants may also have the opportunity to learn from the results of the study once it is completed. To compensate for the time/energy commitment, you will be entered to win a \$25.00 gift card for completing the survey, and another \$25 gift card if you chose the complete the option interview.

All participants who complete this survey will be eligible to participate in an optional interview, which will ask open-ended questions to further explore your experiences with kindness in the Teen Program. This will last no longer than 60 minutes, and will be audio-recorded. These recordings will be stored in a locked file cabinet and will be password protected on the recording device itself to protect your confidentiality. These recordings will be disposed upon completion of the research project.

If you have any questions about this study or would like to obtain additional information, please contact Mary Jonson at mjjsn@gmail.com. This research has been reviewed and

approved by the Human Research and Review Committee (HRRC) at the California Institute of Integral Studies for research involving human subjects. If you have any concerns or are dissatisfied at any time with any part of the study, you may report your concerns (anonymously, if you wish) to the Coordinator of the Human Research Review Committee, California Institute of Integral Studies, 1453 Mission Street, San Francisco, CA 94103, or by telephone at 415-575-6100 or via email to hrrcoffice@ciis.edu.

Signing your name below indicates that:

- you have read and understood the above information
- you voluntarily agree to participate
- you are at least 18 years of age
- you have participated in at least one KOC Teen Program event and/or activity

Participant's Signature

Date

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

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 research psychologist's 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 with the Human Research Review Committee, California Institute of Integral Studies, 1453 Mission Street, San Francisco, CA 94103.

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 psychologist 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 psychologist, 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.

If a report is required, the psychologist should discuss its contents and possible consequences with the patient or research participant.

SAMPLE Confidentiality Agreement Transcription and/or Translation Services

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: _____

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

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").

The Facility acknowledges that it has reviewed the protocol presented by the researcher, as well as the associated risks to the Facility. The Facility accepts the protocol 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 have any concerns or require additional information, we will contact the researcher and/or CIIS HRRC.

Sincerely,

(Signature of Facility's Authorized Signatory)

Date

Printed Name and Title of Authorized Signatory

Check List used by HRRC to Guide Application Evaluation

This Check List is intended to help you produce an accurate and complete proposal. Use this list as a final check that your application is complete.

1. Study:

- _____ Describe more completely the aim of the study
- _____ Describe more completely the study design

2. Subject population:

- _____ Describe more completely the inclusion/exclusion criteria
- _____ Describe more completely the use of special subject groups, and the population's country if other than USA.
- _____ Describe more completely the methods of accessing potential participants

3. Research methods or procedures:

- _____ Provide sample interview questions
- _____ Provide sample survey questions
- _____ Describe participant observational methods and procedures
- _____ Describe other interventions or procedures more completely

4. Risks:

- _____ Describe all potential risks more completely
- _____ Describe more completely all potential discomforts to subjects
- _____ Describe more completely the methods of minimizing risks
- _____ Describe more completely potential risks involved with procedures/ interventions used in study
- _____ Describe more completely the student researcher's formal clinical skills
- _____ Indicate a specific licensed therapist referral name in case needed as a result of this study, other than the student researcher, and describe referral process

5. Benefits:

- _____ Describe more completely the potential direct benefits to subjects
- _____ Describe more completely the potential general benefits to subject groups
- _____ Describe more completely the potential benefits to academic discipline
- _____ Describe more completely the potential benefits to society
- _____ Modify language to indicate that any potential benefits from this study are not guaranteed

6. Consent process and documentation:

- _____ Include a sample detailed consent form that participants will sign or describe rationale for not using a written consent form
- _____ Include the name and credentials of the accredited referral person noted in your application as a prime referral
- _____ Include a "translated" sample detailed consent form that participants will sign or describe rationale for not using a written consent form
- _____ Indicate that participation is voluntary, that participants can refuse to participate in particular aspects of the study, and can discontinue participation at any time
- _____ Indicate how audio or video recordings will be made, maintained, used, stored, and eventually disposed within the study and list this information directly within the consent form
- _____ Indicate, by providing specific clerical, procedural, and security details, how confidential information will be maintained during all phases of the study

- _____ Indicate how participant's data will be maintained or disposed following completion of this study within the study description and consent form
- _____ Indicate how participants can anonymously report their concerns to the CIIS HRRC Coordinator
- _____ Please provide a copy of the agreement contract between researcher and facility which has given research permission
- _____ Please create a confidentiality form for the transcriber/translator that is signed in advance to insure confidentiality
- _____ Indicate how "Human Subjects Bill of Rights" will be presented to participants
- _____ Indicate how limits of confidentiality (Appendix D) information will be provided to participants where the high-risk consent form is required other than child abuse
- _____ Describe rationale for not using a written consent form more fully
- _____ Describe in detail any alternatives to having the participants sign a written consent form (as with minors, individuals in institutions, individuals in preliterate cultures, etc.)
- _____ If not using a written consent form, explain how you will determine that participants understand all of what would be included in a written consent form
- _____ Include the HRRC application cover sheet, with proper signatures, and contact information