California Institute for Human Science
Office of Research, Institutional Review Board
IRB APPLICATION PACKET

This packet contains all of the information and forms needed to submit an application for Institutional Review Board (IRB) research approval at California Institute for Human Science. An approved application is required for all research conducted involving human or animal participants by and as an affiliated party at California Institute for Human Science. This includes all faculty, staff, and students.

Detailed exceptions to this policy may be found in CIHS' Research Policy Handbook. The most significant exception is research done as part of a class that will not be published or reported beyond the class. This type of research does not need IRB approval.

Research approval is also not required for individuals, organizations, and groups who are using space at CIHS on a temporary and/or non-University affiliated basis, or for those renting space from CIHS and who are covered by a formal lease agreement with the University.

Following the submission of your application, the IRB committee will review your proposal. CIHS' research policy, as detailed in the Research Policy Handbook, governmental and other regulatory guidelines, and any conditions of awarded funded related to the research will be considered during the review process.

It's important to note that IRB approval is required for research involving human or animal participants, including research that will use archived data that was previously generated by the researcher or by others (e.g., records, transcripts, field notes, correspondence, and recordings).

If you are working with data sets that are already gathered, and you are seeking to collect more data to add to such a data set, approval may be granted for all of the data in the existing data set as well as for the collection of new data provided appropriate consent forms were gathered for the prior data collection.

If you are uncertain about whether an IRB is required for your research, apply for **exempt**

status to get a cursory review from the committee. In general, it's best to keep in mind that approval is most likely required before you can begin your research.

Prior to submitting an IRB application, students must have an approved proposal from a person authorized to be a Principal Investigator at CIHS (see the Research Policy Handbook), who agrees to serve as a research supervisor. Appropriate roles for this at CIHS include: faculty member, thesis supervisor, or dissertation chair. This person must sign the IRB coversheet to indicate his or her approval.

IRB approval is good for 4 years. If you do not complete your data gathering within this time frame, you must apply for an extension. Extension requests are sent to the IRB committee along with your originally approved packet, and any needed updates to your research protocol.

All documents may be submitted electronically via email.

You may seek an exception to IRB policy, or any research-related policy at California Institute for Human Science by contacting the Dean of Research.

Documents You Must Include in your IRB Application

Your IRB application must include a completed:

- ☐ Coversheet with the proper signatures
- ☐ Application that fully answers all criteria
- ☐ Appendix, as needed

Forms and detailed Instructions for these documents are below.

Coversheet Instructions

(See form on next page)

On the coversheet, you categorize your research as High or Low Risk or Request Exempt Status. It also requires your research supervisor signature, if appropriate.

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 participants; the psychologically fragile; historically marginalized; victims of trauma, physically challenged, the elderly).
  - Research participants are engaged in illegal activities that relates to 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 participant 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 are unsure if your research should have IRB Committee review. For an Exempt review, submit:
  - The coversheet
  - An abbreviated, Request for Exempt Status application

- Choose *Low Risk* for all other research.

IRB COVERSHEET TO ACCOMPANY ALL APPLICATIONS

California Institute for Human Science

Last Name_____First Name _____

_____ _____

Street Address City

_____ _____ _____

State Country Zip Code

_____ _____

Email Phone

_____ _____

Signature of researcher Date

_____

Title of Research Project

REVIEW CATEGORY REQUESTED:

_____ High Risk (4 copies required)

_____ Low Risk (3 copies required)

_____ Request for EXEMPTION (2 copies required)

==========

For students, please also complete the following:

_____ (___)_____ _____

Research Supervisor Name Telephone E-mail

_____

CIHS Program

Your signature as research supervisor indicates that you accept responsibility for the research described, and that you are fully aware of all procedures to be followed, will monitor the research, and will insure that the IRB committee is notified of any significant problems or changes.

_____ _____

Signature of Research Supervisor Date

Instructions for Request for Exempt Status Application

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

Be sure to also complete the coversheet and attach it to your abbreviated application.

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

- Single paragraph description of the research focus.
- Method(s) to be used.
- Explanation of data that will be collected.
- All possible risks to anonymity, confidentiality, and safety.
- How you will minimize these risks.

Important: All research that includes human participant participation, including the use of previously collected information, bears some risk. You must demonstrate sensitivity to potential issues.

Full IRB Application Instructions

(Use the form that follows these instructions)

1. Study, Aim, Background

- *Concisely*, in a page or less, summarize the purpose of the study, the inquiry question, and disciplines and bodies of literature the study relates to.

2. Methodology and Method(s)

- Outline the methodology (qualitative, quantitative, or mixed) and method(s) the study will use.

3. Participant Inclusion/Exclusion Criteria

- Detail your inclusion criteria for participants and its rationale:
  - Demographics: age, gender, ethnicity, etc.
  - Geographic location.
  - Other participant characteristics required by the study.
- Describe your exclusion criteria for participants and its rationale:
  - What specific characteristics will exclude someone from participating in the research.
  - Why are you selecting these exclusion criteria (if not obvious).
  - What protocol will you use to screne for exclusionary characteristics.
  - Include your professional and/or personal background if relevant to assessing for exclusion criteria.

4. Recruitment Protocols

- Describe how you will attract and communicate with potential participants.
- Describe how you will screen participants.
- 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.

6. Psychological and Physical Risks, and Protocols to Minimize Them

- Describe in detail all the potential psychological and physical risks to participants and how you intend to minimize them.

7. Benefits

- Describe any monetary or material compensation.

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* (includes online consent forms): 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 IRB 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 IRB Committee 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. 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 IRB application. (A sample Consent Form can be found in the "Appendices to Submit with your IRB 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 IRB application.

The following points should be clearly presented:

- Participation is voluntary.
- Participants have the right to refuse to answer any 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.
- 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").
- What the risks and/or expected benefits are to participants.
- That there will 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. For electronic forms, name and signature can be the same box.
- The researcher's name and contact information.
- The research supervisor's name and contact information, if a student.
- Participants should know that if they 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 for Human Science
  Office of Research, IRB Committee
  701 Garden View Court
  Encinitas, California 92024 USA
  760-634-1771

10. research@cihs.edu 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. 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 California Institute for Human Science

- 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.

California Institute for Human Science IRB Application

Please follow “Application Instructions” above.
Type into this document, making space under each section as necessary.

1. Study, Aim, Background

2. Methodology and Methods

3. Participants (participant 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:

- 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 California Institute for Human Science

13. Sample Interview Questions and Other Materials
(Make note where these materials can be found in the Appendix.)

Appendices that may be Appropriate to Submit with your IRB Application

- Communication to inform participants that they are included/invited to participate in the study.
- Communication to inform participants they are not included.
- Informed Consent Form and/or, if applicable, an Assent Form/Protocol.
- Human Subject Bill of Rights, if required.
- 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 CIHS, indicating its supervisory role and relationship to the study.

Consent Form – SAMPLE

CONSENT TO PARTICIPATE IN RESEARCH

Purpose:
The Laboratory for Consciousness Science at California Institute for Human Science is conducting a psychological and physiological study of Ongoing Non-Symbolic Experience (O.N.E.) and Persistent Non-Symbolic Experience (PNSE). The survey you are about to take comprises one phase of our overall study, and consists of a general information form and survey of your experiences.

Principal Investigator:
The principle investigator (PI) for this study, and his contact information are listed below:
Jeffery A. Martin, PhD
701 Garden View Court
Encinitas, California 92024 USA
E-mail: jeffery_martin@cihs.edu
Phone: 760-634-1771

Procedures:
[1] This study involves filling out forms electronically by use of the Internet. The forms include: this consent form, and a series of questions about your life experiences and ideas about them. No prior preparation is required.
[2] Please begin filling out the assessments after you have read this consent document.
[3] It could take up to a half hour to complete all of the questions.
[4] Please do not begin until you have fully read this consent information and obtained answers to any questions you have. You can stop now, email or call the Principle Investigator with your questions, and return to the survey website later to continue the process.

Possible Risks and Safeguards:
This study is designed to minimize, as much as possible, any potential psychological and social risks to you. Although very unlikely there are always risks in research, which you are entitled to know in advance of giving your consent, as well as safeguards to be taken by those who conduct the project to minimize the risks.

By providing your consent to participate, you state that you understand that:
[1] My participation will not have any bearing on my relationship with the Principle Investigator.
[2] Only the Principle Investigator will know my identity in relationship to the forms filled out on this site. He will hold it in strictest confidence. My identity will not be kept separate from my responses on the assessments. All of my answers will be linked to me in the research database.
[3] My response to the questions will be pooled with others and will not be able to be associated to me in any publicly available report written on this research unless authorized by me. If quotes of my responses are used, in any and all publications of these quotations my identity shall remain anonymous, unless authorized by me in writing, and at most make use of a fictitious name or symbolic representation of me such as a numerical or alphanumerical code.
[4] After the data collection phase is completed all data will be downloaded by the Principle Investigator, as well as remain on this server. The Principle Investigator will conduct the analysis of the raw data on his computer. I am aware that any data I enter that contains personally identifiable information will be available during analysis regardless of if it is explicitly linked to my identity.
[5] Except as stated here, all the information I give will be kept confidential to the extent permitted by law.
[6] I should not expect there to be individual feedback regarding my individual responses or interpretations of my responses.

[7] I have the right to refuse at any time to engage in any procedure requested of me or to refuse to answer questions put to me.
[8] I have the right to withdraw from participation at any time for any reason without stating my reason.
[9] I have the right to participate without prejudice on the part of the Principle Investigator.
[10] The Principle Investigator or a qualified research team member is available to talk about any concerns I have while the study is ongoing.

Possible Benefits:
I understand no direct benefit, either monetary or resulting from the experience itself, is offered or guaranteed, and that by participating in this research:
[1] I may obtain a greater awareness, knowledge, and understanding of aspects of myself.
[2] I may find the process interesting and thought-provoking.
[3] Through future communications and possible applications of the findings of the research, indirectly my participation may bring future benefits to others.

Consent:
It is recommended that you print a copy of this page for your records.

If you have any questions of the Principle Investigator at this point, please take this opportunity to submit them in person, via Phone, or via E-mail before granting your consent. If you are ready to provide your consent, read the statement below then type your name and the current date into the input boxes provided above.

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:

California Institute for Human Science
Office of Research, IRB Committee
701 Garden View Court
Encinitas, California 92024 USA
760-634-1771
research@cihs.edu

I have read the above information, have had an opportunity to ask questions about any and all aspects of this study, and give my voluntary consent to participate.

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;
-
- 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;
-
-

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.
4. 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 participant 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]

Office of Research, IRB Committee
California Institute for Human
Science
XXXX
Encinitas, CA XXXXX

Subject: Letter of Authorization to Conduct Research at .

Dear IRB Committee:

This letter will serve as authorization for California Institute for Human Science ("CIHS") 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 California Institute for Human Science IRB Committee.

If we have any concerns or require additional information, we will contact the researcher and/or the California Institute for Human Science IRB Committee.

Sincerely,

_____ _____
(Signature of Facility's Authorized Signatory) Date

_____
Printed Name and Title of Authorized Signatory

Check List used by IRB Committee 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. General

_____Include the IRB Committee application cover sheet, with proper signatures, and contact information

2. Study:

_____Describe more completely the aim of the study
_____Describe more completely the study design

3. Subject population:

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

4. Research methods or procedures:

_____Describe more completely the research methods and procedures, as noted below:

_____

_____

_____

5. Risks:

_____Describe all potential risks more completely
_____Describe more completely all potential discomforts to participants
_____Describe more completely the methods of minimizing risks
_____Describe more completely potential risks involved with procedures/ interventions used in study
_____Describe more completely the 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

6. Benefits:

_____Describe more completely the potential direct benefits to participants
_____Describe more completely the potential general benefits to participant groups
_____Describe more completely the potential benefits to related academic discipline
_____Describe more completely the potential benefits to society
_____Modify language to indicate that any potential benefits from this study are not guaranteed

7. 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 California Institute for Human Science IRB Committee

_____Provide a copy of the agreement contract between researcher and facility which has given research permission

_____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 information will be provided to participants where the high-risk consent form is required for research 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