**TCSPP Institutional Review Board (IRB)**

**Questions and Answers (Q&A) Form**
**Application for approval of a research project involving human participants**

**IMPORTANT INFORMATION: All application must be submitted via the electronic submission system. Paper versions of this form submitted via email will not be accepted.**

When providing information, please type your responses directly below each item. The prompts in this document are locked and cannot be deleted. Use your cursor to navigate through each section. Each item will move depending on the length of your previous response. For example, the longer the response to Item 1 the further down Item 2 will move.

This document allows you to format your responses as needed (e.g., indent, italicize, etc.). However, formatting may get lost if copying and pasting responses from this document onto the form in the online submission system.

## General Information

### Research Personnel

**1. TCSPP Research Personnel**

**If applicable, provide the name of TCSPP research assistants and describe their role in the conduct of this study and their qualifications. Submit a copy of each person's CITI certification**

*[Delete this sentence and place your response here.]*

**2. Non-TCSPP Research Personnel**

**If applicable, provide the name of non-TCSPP research assistants and describe their role in the conduct of this study and their qualifications. Submit a copy of each person's CITI certification.**

[*Delete this sentence and place your response here.]*

### Other Research Sites

**1.* Provide the name and contact information of each site outside of TCSPP where research procedures will be performed. Describe the sites' role in the research (i.e., recruitment, interactions with participants, access to private identifiable data, etc.).**

[*Delete this sentence and place your response here.]*

a. **If you are conducting research outside the U.S.A., in addition to providing the information that is requested above, please also address the following:**
   - **Describe the site's experience conducting research with human participants.**
   - **Describe the site's experience working with the population you intend to research.**
   - **Specify the local regulations that govern research in the country.**

[*Delete this sentence and place your response here.]*

2. **Submit a letter of support from each site that describes their involvement in the research. If the sites have an IRB please attach the IRB Approval. If a letter of support or IRB Approval is not necessary please explain why. If the letter of support or IRB Approval is not available at this time, explain why and indicate "letter to follow".**

[Delete this sentence and place your response here.]

## Purpose and Subjects

### Purpose of the Study

1. ***Please provide 3-4 paragraphs that will summarize the purpose of this study using nontechnical language. Include the following in your summary:**
   - **The importance of the study and knowledge to be gained (e.g., gaps to the literature, importance to society and/or the field).**
   - **The research hypothesis or hypotheses and expected results.**

   ***Please do not copy information directly from your dissertation proposal.***

[*Delete this sentence and place your response here.]*

### Subject Population

2. **Human subject is defined by federal regulation (45 CFR 46) as a living individual about whom an investigator (whether professional or student) conducting research obtains: (1) data through intervention or interaction with the individual, or identifiable private information (i.e., archival data, documents, or records, etc.).**

a) ***Number of Subjects/Participants:*** **Specify the number of participants to be enrolled in the study.**

[*Delete this sentence and place your response here.]*

b) ***Age ranges:*** **For research that involves interacting with people, specify the age range of participants to be enrolled.**

[*Delete this sentence and place your response here.]*

c) ***Inclusion Criteria:*** **Describe the relevant characteristics of the individuals eligible to participate in this study.**

[*Delete this sentence and place your response here.]*

d) ***Exclusion Criteria:*** **Please describe the relevant characteristics of individuals ineligible to participate in this study.**

[*Delete this sentence and place your response here.]*

## Recruitment & Screening

### Recruitment

1. ***Will The Chicago School Directory Information be used to recruit participants for study participation? If yes, please contact the IRB Office and the Office of Institutional Research (OIR) after IRB Approval of your study has been granted to assist you with the recruitment message.**

[*Delete this sentence and place your response here.]*

2. ***Describe how the participants will be recruited for study participation (e.g., flyers/brochures, internet, newspaper, recruitment letters, social media, direct contact, etc.). Attach the recruitment materials use will use for the research. If flyers will be used please specify the location(s) where they will be posted. If recruitment is occurring on-line specify the website where your study flyer or ad will be posted.**

[*Delete this sentence and place your response here.]*

3. **List and submit all documents that will be used for recruitment.**

[*Delete this sentence and place your response here.]*

### Screening

1. ***Describe how the participants will be selected for participation in this study. For example will participants be asked to complete any screening procedures (i.e., questionnaire, survey, etc.) prior to the research intervention to determine study eligibility?**

[*Delete this sentence and place your response here.]*

2. **If your research involves screening procedures, list and submit all documents that will be used for recruitment.**

[*Delete this sentence and place your response here.]*

## Study Design

### Archival Data

1. *** Will archival data be used, such as case files, etc. for this study? *Archival data is defined as data that is in existence at the time the study proposal is submitted to the IRB for review*.**

☐ Yes - Answer items a - d

☐ No - Skip to Vulnerable Populations

a. **To ensure that only archival data will be used, please provide the dates in which the data was originally collected.**

[*Delete this sentence and place your response here.]*

b. **Please provide the name of the database or dataset from which the data will be collected. Describe the information that will be culled from the database or dataset.**

[*Delete this sentence and place your response here.]*

c. **When the data was originally collected was it labeled in a manner that the participant could be identified?**

☐ Yes- If yes, indicate whether or not you will have access to the identifiers or codes that link the subject to the data collected.

☐ No

[*Delete this sentence and place your response here.]*

d. **If appropriate, please submit a letter from the original researcher, data collector, or their representative, giving you permission to use the data. *Where relevant, the writer of the letter should indicate whether or not informed consent was obtained and describe all efforts that were made to guard the confidentiality of participants.***

[*Delete this sentence and place your response here.]*

**Vulnerable Populations**

**Please select any vulnerable populations to be targeted for participation in the research (please check all that apply) as they require special consideration by the IRB.**

- ☐ Pregnant Women - Submit Supplemental Form P
- ☐ Minors under 18 - Submit Supplemental Form C
- ☐ Prisoners- Submit Supplemental Form J
- ☐ Vulnerable populations will not be targeted

**Special Populations**

**Please select any special populations to be targeted for participation in the research Describe your rationale for enrolling these subjects.**

- ☐ Non-English Speaking

Translated documents must be submitted as appropriate. Specify the name of the document(s). Provide the name of the person who translated the documents and his/her qualifications for translating.

[*Delete this sentence and place your response here.]*

- ☑ Illiterate - provide a rationale for enrolling these participants.

[*Delete this sentence and place your response here.]*

- ☐ Decisionally Impaired Adults - Provide a rationale for enrolling these participants.

[*Delete this sentence and place your response here.]*

- ☐ Special populations will not be targeted.

## Informed Consent

Informed consent is a not just a document but a conversation or process that informs the research participants about the purpose of the study, the risks, potential benefits, and alternatives. It allows the potential participant to make an informed decision about whether or not to participate based on their goals or ideas.

Find regulations regarding this here: http://answers.hhs.gov/ohrp/categories/1566.
Please select the method of consent appropriate to your study.

☐ **Waiver or Alteration of Consent**

The IRB may approve a consent procedure that does not include or alters some or all of the elements of informed consent or the IRB may waive the requirement to obtain consent provided that the following criteria are met. This method could be appropriate for studies using archival data collection or studies that may involve deception.

To request approval for a waiver or alteration of consent indicate in the text box below how your study fulfills each criteria.

- The research involves no more than minimal risk to the participants.
- The waiver or alteration will not adversely affect the rights and welfare of the participants.
- The research could not practicably be carried out without the waiver or alteration.
- Whenever appropriate, the participants will be provided with additional pertinent information after participation.

[*Delete this sentence and place your response here.]*

☐ **Waiver of Consent Documentation**

When consent for research is obtained through means other than in writing, such as verbally, online or through audio or video recording, a *waiver of consent documentation* may be requested. The IRB may grant a waiver of consent documentation if criterion 1 or 2 is met.

To request approval for a waiver of consent documentation describe the consent process. Indicate the criterion that applies to your study and how your study fulfills the criterion.

*Criterion 1* – The principal risks are those associated with a breach of confidentiality concerning the participant's participation in the research, and the consent document is the only record linking the participant with the research.

*Criterion 2* - Study participation presents minimal risk of harm to the participant and the research involves no procedures requiring consent outside the context of participation in a research study.

[*Delete this sentence and place your response here.]*

Submit a copy of the document that will be used to obtain consent such as a script, online consent form, etc. Specify the document name(s) below.

[*Delete this sentence and place your response here.]*

☐ **Written Consent**

Written consent refers to obtaining the participant's or the participant's legal representative's signature on a consent form. The consent form should be used as a tool to discuss the research study with the participant. The subject should be given adequate time to read the consent form and to have his/her questions about research answered by the researcher before signing the consent form. The signed consent form provides a record that the consent process took place.

Describe the consent process for the research. Indicate when and where the consent process will take place and who will conduct the consent process.

Use the consent form template, containing the required elements of consent, on the IRB website to develop the consent form that will be used to obtain written consent. Consent forms should be written at a 10th grade reading level using simple sentences and written as if speaking with the participant. Upload a copy of the consent form. If applicable, upload foreign language versions of the consent form.

[*Delete this sentence and place your response here.]*

Submit a copy of the consent form(s). Specify the document name(s) below.

[*Delete this sentence and place your response here.]*

## Study Participation

### Description of Study

1. ***Using non-technical language, please provide a step-by-step study plan/protocol. Include: what the participant will be asked to do during their study participation; frequency of the study visits if applicable; description of how data will be collected; provide a copy of data collection tool/sheet.**

[*Delete this sentence and place your response here.]*

**Submit a copy of the questionnaires that will be used in the research. Specify the document name(s) below.**

[*Delete this sentence and place your response here.]*

2. ***Please indicate whether or not the subjects will be exposed to deception, contrived social situations, manipulation of the participants' attitudes, opinions, or self- esteem, psychotherapeutic procedures, or other psychological influences. If so, describe procedures for follow-up and/or debriefing.**

[*Delete this sentence and place your response here.]*

### Risks of the Research

1. ***List the potential risk or discomforts to the research participants to be enrolled in your study. Please consider all types of risks, such as physical, emotional, social, invasion of privacy, breach of confidentiality, and other unforeseeable risks.**

[*Delete this sentence and place your response here.]*

2. ***Describe the measures taken to minimize the risks described above.**

[*Delete this sentence and place your response here.]*

## Benefits of Participation

***Please outline the potential direct benefits of this project to the participant. If there are no direct benefits to participants, please state so and describe the potential benefits to the field of study and/or society. *Please note remuneration/compensation should not be described as a benefit to participants.***

[*Delete this sentence and place your response here.]*

## Compensation for Participation

**If applicable, please describe any compensation to be received by the study participants, the source of this compensation, and when the participants will receive this compensation.**

[*Delete this sentence and place your response here.]*

## Confidentiality

1. **Please indicate the personal identifying information about the study participant that will be accessed or collected during their study participation.**

- ☐ Name
- ☐ Address
- ☐ Telephone Number
- ☐ E-mail Address
- ☐ Social Security Number
- ☐ Other
- ☐ Medical Information
- ☐ Academic Information (e.g., grades, etc.)

2. *** Please describe the steps taken to guard anonymity of the participants and/or the confidentiality of their responses.**

[*Delete this sentence and place your response here.]*

3. **Describe procedures for storage and ultimate disposal of information. *Please note, per APA guidelines data must be kept for a minimum of 5 years.***

[*Delete this sentence and place your response here.]*

## Certification of Application Readiness

For student researcher's thesis/dissertation chair or primary advisor.

All Dissertation and Thesis Chairs are asked to complete this section to ensure that only complete, ready-to-review applications are submitted.

**By typing your name below, you are verifying that you are the Chair/primary advisor of the student's dissertation/thesis/research project and have reviewed the present application and approved it for IRB review.** You understand that typing your name will serve as an electronic signature and initiate the review of this application. This electronic signature gives the Institutional Review Board of The Chicago School of Professional Psychology permission to review this application. As chair/primary advisor of the student's dissertation/thesis/research project, I have reviewed the present application and approve it for IRB review.

**Name:**

**Date:**

## Principle Investigator's Certification

By checking this box and typing your below, you are verifying that you are the author of this application. You understand that typing your name will serve as an electronic signature and initiate the review of this application. This electronic signature gives the Institutional Review Board of The Chicago School of Professional Psychology permission to review this application.

☐ I am the author of this application.

**Name:**

**Date:**