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| C:\Users\John.Ridings\Pictures\ICSW.png  **FORM – Initial Review Application: Social and Behavioral Sciences**  Version 4.0  Date: Oct 14, 2015 | Office for the Protection of Research Subjects  (OPRS)  Institutional Review Board  FWA# 00015903  At Robert Morris Center  401 South State Street  Chicago, IL 60605  312-935-4232/312-935-4225  info@icsw.edu |

*Incomplete application packets or applications that have had questions deleted may result in review delays.*

# Checklist of Supporting Material for Investigators:

Resume or CV of principal investigator or faculty sponsor

Flyers, advertisements, oral scripts (including telephone scripts), other recruitment materials

Consent/parent permission/assent forms

Appendices

Surveys, questionnaires, interview questions, guides

Debriefing information, if applicable

Letters of collaboration, if applicable

Funding Proposals, if applicable. For federally funded research, include all sections of the proposal or grant except the budget pages.

CITI Certificate

**Dissertation or Faculty Research**

[For completing this application, use only Courier or Times New Roman font, 11+ pt.]

## Step I: Project Personnel

Project Title:

Principal Investigator: (attach resume or CV) Address:

Phone: E-mail:

# List all co-investigators and/or faculty sponsors below, including those from other institutions.

NOTE: If this is dissertation research, list dissertation chair. Name, Degree, Address, Phone and email or other contact information: 1.

2.

3.

# Contact Information

Who should be contacted for further information about this application? Name: Position on the project:

Phone: E-mail:

# Step II: Funding Sources & Performance Sites

[If this project is funded by an outside source, complete Step II]

Check all of the appropriate boxes for funding sources for this research. Include pending funding source(s).

**Federal** – If federally funded, provide name and address of individual to whom certification of IRB should be sent in the space below:

**Extramural** (non-federal funding sources) – Provide name and address of individual to whom certification of IRB should be sent:

Principal Investigator of Grant or Contract: Name of Funding Source:

Grant or Contract Number (If available): Grant, Contract or Project Title:

## Performance Sites:

List all collaborating sites:

Provide letters of cooperation or support:  Attached  Pending  Not Applicable

Provide letter of IRB approval from other site:  Attached  Pending  Not Applicable

**Step III: Specific Aims, Goals, and Objectives of the Project** (no more than 200 words)

Summarize the specific aims, goals, and objectives of the proposed research using non-technical language that can be understood by any generally informed layperson.

## Step IVa: Significance and Context of the Work, Including Any New Information to Be Obtained (no more than one page)

Using non-technical language that can be understood by any generally informed layperson, describe the significance and context of the work, including new information the Principal Investigator intends to obtain. In the case of classroom instructional activities, what types of skills or knowledge is the research intended to provide for the student?

## Step IVb: Need for and value of the Project in Relation to Prior Work in the Field (one page)

Demonstrate that the goals and objectives described are worthy of investigation and require the use of human research participants.

**Step IVc: Study Design** (one page)

Include a detailed description of the specific study design to be used demonstrating a logically derived connection between the design, the significance of the project and the need for the project. **Must include each step of the research process, research questions/hypotheses, research design, etc.** NOTE: Sample selection, protection of participants, and data collection methodology are covered below.

## Step V: Participant Population

Please indicate the total number of participants anticipated for inclusion in this project. This number should be the number of participants you will enroll in order to get the adequate data sets you will need. If multiple sites are to be used, provide an estimate of the number in each category to be recruited from each site. In addition, if you plan to study only one gender, provide detailed rationale in the inclusion/exclusion section (Step VI, C, 1 and 2) of this application.

1. Number of Participants Required: Male:

Female: Total:

1. Age range (check all that apply):

0-7 yrs. (submit parental permission form)

8-17 yrs. (submit child’s assent form and parental permission form)

18-64 yrs. (submit informed consent form)

65+ yrs. (submit informed consent form)

1. Source/Type of Participants (check all that apply): [ICSW students and faculty may not be subjects]

medical patients

volunteers from the general population

community institutions, please specify:

other, please specify:

1. Participant location during research data collection (check all that apply):

participant’s home

hospital or clinic, please specify:

community locations, please specify:

elementary or secondary schools, please specify:

other, please specify:

1. Special populations to be included in the research (check all that apply):

minors under age 18 (must include Appendix A)

pregnant women (must include Appendix B)

prisoners (must include Appendix C)

economically disadvantaged

developmentally delayed (must include Appendix D)

severe and/or chronically mentally ill (must include Appendix D)

military personnel and veterans (if DoD supported, must include

Appendix E)

students (must include Appendix F)

other, please specify:

**Step VI: Recruitment Procedures** (no more than one page)

1. Describe how participants will be identified and recruited. Attach all recruitment information, e.g., advertisements, bulletin board notices, and recruitment letters for all types of media (printed, radio, electronic, TV, or Internet).
2. Initial Contact: Describe who will make initial contact and how. If participants are chosen from records, indicate who gave approval for the use of the records. If records are “private” medical or student records, provide the release forms, consent forms, letters, and HIPAA if appropriate for securing consent of the participants for the records. Written documentation for cooperation/permission from the holder or custodian of the records should be attached. (Initial contact of participants identified through a records search must be made by the official holder of the record,

i.e. primary physician, therapist, public school official.)

1. List criteria for inclusion and exclusion of participants in this study. Describe populations to be excluded from the research. Please describe procedures to assure equitable selection of participants. Researchers should not select participants on the basis of discriminatory criteria. Selection criteria that exclude one sex, racial, or ethnic group require a clear scientific rationale for the exclusion. In By whom (e.g., principal investigator, research assistant, school officials) will the inclusion/exclusion criteria be determined in the selection of the subjects?
2. Will participants receive financial or other compensation before or after the study? If yes, explain. NOTE: This information must be outlined in the consent document.

## Step VII: Informed Consent Process

Simply giving a consent form to a participant does not constitute informed consent. The following questions pertain to the process. Researchers are cautioned that consent forms should be written in simple declarative sentences. Forms should be jargon-free (see consent form templates). Foreign language versions should be prepared and included for all materials that the participants needing translations will encounter in the research.

1. Capacity to consent: Will all adult participants have the capacity to give informed consent?

Yes  No

If No: describe the likely range of impairment and explain how, and by whom, their capacity to consent will be determined. NOTE: In research involving more than minimal risk, capacity to consent should be determined by a psychiatrist, psychologist, or other qualified professional not otherwise involved in the research. Individuals who lack the capacity to consent may participate in research only if a legally authorized representative gives consent on their behalf.

1. Describe what will actually be said to the participants to explain the research. (NOTE: Do not say “see Consent Form.”) Write the explanation in lay language. If you are using telephone surveys, telephone scripts are required. If you will include participants not fluent in English, please provide an appropriate translation.
2. How will participants’ understanding be assessed? What questions will be asked to assess the participants’ understanding? If you will include participants not fluent in English, please provide an appropriate translation.

NOTE: The purpose of this question is to have you describe how you will assess participants’ understanding of the consent process. Questions requiring “yes or no” answers are not appropriate. Please ask participants to explain the purpose of the study to you along with the risks and benefits to themselves as participants. Their answers to these questions should allow you to determine whether they understand the study and their part in it. It they do not understand, informed consent has not been achieved irrespective of whether the participant signed the consent document.

1. In relation to the actual data gathering, when and where will consent be discussed and documentation obtained, for example several days before? Be specific.
2. Will the Investigator(s) be securing all of the Informed consents?  Yes  No  N/A

If no, name the specific individuals who will obtain informed consent and include their job title and a brief description of your plans to train these individuals to obtain consent and answer participants’ questions:

1. Prepare and attach the appropriate consent/assent form(s) for IRB review. If you intend to use participants that are not fluent or literate in English, have appropriate translations and back translations been developed and attached to this application?  Yes  No

## Step VIII: Risks and Benefits of the Research

1. Does the research involve (check all that apply):

use of private records (medical, mental health or educational records)

possible invasion of privacy of participant or family

the collection of personal or sensitive information in surveys or

interviews

use of a deceptive technique (If use of deception is part of the protocol,

the protocol must include Appendix E

presentation of materials that participants might consider offensive,

threatening, or degrading

other risks, specify:

NOTE: Respond to VII B-E in written form, not more than 2 pages.

1. Identify the risks (current and potential) and describe the expected frequency, degree of severity, and potential reversibility. Include any potential late effects. (NOTE: Risks can be psychological, physical, social, economic, or legal.)
2. Describe the precautions taken to minimize risk.
3. Why are the risks mentioned above reasonable? What is the expected scholarly yield from the project? Justify the risks in relation to the anticipated benefits to the participants and in relation to the importance of the knowledge that may reasonably be expected to result from the research.
4. Benefits of participation: List any anticipated direct benefits of participation in this research project. If none, state that fact here and in the consent form. The knowledge gained from the study could produce a benefit to society. Payment or course credit is not considered to be a benefit of participation. Any benefits of the specific research procedures should be listed as potential benefits.

## Step IX: Data Collection Methodology

Describe the tasks, tests or other procedures, including the interview process, participants will be asked to complete. (Suggestion: explain step by step what the participants will be asked to do and distinguish those which are experimental from those which comprise routine tasks encountered in everyday life). Specify exactly how these tasks, tests, or procedures will generate the data that will permit achievement of the goals and objectives of this research.

## Step X: Confidentiality of Data

1. Indicate the identifiable identifiers that will be collected and or included in the research records for this study. (check all that apply)

Names  Social Security Numbers

Phone numbers  Medical record numbers

Street address  Health plan numbers

City or state  Account numbers

Zip code  Fax numbers

E-mail address  License/Certificate numbers

Financial account information

All elements of dates (except year) for dates directly related to an individual

Any other unique identifier: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

None of the identifiers listed above

1. Describe provisions made to maintain confidentiality of data.
   1. Who will have access to raw data?
   2. Will raw data be made available to anyone other than the Principal Investigator and immediate study personnel (e.g., school officials, medical personnel)?  Yes  No

If yes, who, how, and why?

* 1. If applicable, describe the procedure for sharing data.
  2. If applicable, describe how the participant will be informed that the data may be shared.
  3. If data are collected, stored, or analyzed on computers, describe the actual security measures used to ensure confidentiality.

1. Where will the data be kept? (Data must be secured for 5 years after graduation.) How will data stored on audio and videotapes be disposed of? (Disposition of audio and video tapes should be included in consent form.). If data will be stored in a database, Appendix E must be completed.
2. Will data identifying the participants be made available to anyone other than the principal investigator, that is, study sponsor, Institutional Review Board?  Yes  No

If yes: Who:

1. Will the research data and information be part of any permanent record? (Explanation must be in the consent form.)  Yes  No
2. If participants are students, will school officials receive the data with identifiers attached? (Explain here and in the consent form using appropriate language.)  Yes  No

# Investigator’s Assurance

I certify that the information provided in this application is complete and correct.

I understand that as Principal Investigator, I have ultimate responsibility for the protection of the rights and welfare of human participants, conduct of the study and the ethical performance of the project. I agree to comply with all IRB policies and procedures, as well as with all applicable federal, state and local laws regarding the protection of human participants in research, including, but not limited to, the following:

* The project will be performed by qualified personnel according to the ICSW IRB certified protocol,
* No changes will be made in the protocol or consent form until approved by the ICSW IRB,
* Legally effective informed consent will be obtained from human participants if applicable, and
* Adverse events will be reported to the ICSW IRB in a timely manner.

I further certify that the proposed research is not currently underway (except for those protocols of research previously approved and currently seeking renewal) and will not begin until approval has been obtained.

Principal Investigator’s Signature: Date:

# Dissertation Chair or Faculty Assurance for Student or Guest Investigators

By my signature as Chair or Sponsor on this research application, I certify that the student or guest investigator is knowledgeable about the regulations and policies governing research with human participants and has sufficient training and experience to conduct this particular study in accord with the approved protocol. In addition,

* I agree to meet with the investigator on a regular basis to monitor study progress,
* Should problems arise during the course of the study, I agree to be available, personally, to supervise the investigator in solving them,
* I insure that the investigator will promptly report significant or untoward adverse effects to the ICSW IRB in a timely manner,

If I will be unavailable, as when on sabbatical leave or vacation, I will arrange for an alternate faculty sponsor to assume responsibility during my absence and I will advise the ICSW IRB by letter of such arrangements. I further certify that the proposed research is not currently underway and will not begin until approval is obtained.

Faculty Sponsor’s Signature: Date:

NOTE**:** The faculty sponsor must be a member of the ICSW faculty. The faculty member is the responsible party for legal and ethical performance of the project.

*Submit this application to the office in either hard copy or as attachment to an email.*

**Send questions to:** John Ridings, Chair, ICSW IRB: irbchair@icsw.edu

Revised 1 Feb 2014