

# Institute of Social and Cultural Research

## Application to Use Human Subjects

Complete Part A and Part B. On separate pages, list all questions from Part C and respond to each as applicable. Part C should be replicated on your computer. For full review protocols, return the **ORIGINAL** (with original signatures) to ISCR. If you are an individual researcher please fill in the applicable PI sections.

### PART A. COVER SHEET

New Protocol     Resubmission

1. Project Title (identical to proposal or thesis/dissertation):

2. Principal Investigator (PI):

3. Telephone:

4. Department:

5. E-mail:

6. Co-Principal Investigator:

7. Telephone:

8. Department:

9. E-mail:

10. If Co-PI is a student, is this project for a:  
Neither

Thesis     Dissertation   

(Attach thesis/dissertation prospectus, abstract, or methodology chapter.)

11. Date recruitment anticipated to begin:

(This must be a future date, please allow time for a complete review.)

12. Will this project be supported by external funds?  Yes (answer 13-15)     No (go to signatures)

13. Funding Agency (attach full proposal including budget):

14. Grant/contract number:

15. Proposal deadline:

As the PI submitting this proposed research and signing below, I agree to conduct the research involving human subjects as presented in the protocol or modifications to it and as approved by ISCR; to obtain and document informed consent and provide a copy of the consent form to each subject unless this is waived by the ISCR to present any proposed modifications in the research to the ISCR for review and approval prior to implementation; to retain records for the mandated lengths of time; and to report to the ISCR any problems or injuries to subjects.

PI Signature: \_\_\_\_\_ Date: \_\_\_\_\_

My signature below confirms that I have read this protocol and approve of this research.

**PART B. ATTACHMENTS**

Indicate those which apply to and are included for this protocol.

- \_\_\_\_\_ Telephone scripts or other recruitment scripts
- \_\_\_\_\_ Consent form(s), including parental permission and child assent for minors (model form available)
- \_\_\_\_\_ Cover letter(s), on departmental letterhead, include main elements of informed consent,
- \_\_\_\_\_ Letter(s) from counselors/specialists itemizing credentials, on letterhead
- \_\_\_\_\_ Letter(s) of agreements from organisations, on letterhead, with original signatures
- \_\_\_\_\_ Instruments/tests/photos to be used; note if purchased or provide documentation allowing use
- \_\_\_\_\_ Principal Investigator's current résumé, **if** one is not currently on file with the ISCR office
- \_\_\_\_\_ Proposal copy or methodology section (only one copy)

**OR**

- \_\_\_\_\_ Thesis/dissertation prospectus, abstract, or methodology chapter (only one copy)

**I think this qualifies for the following type of review:**

- Exempt** Category number \_\_\_\_\_  **Expedite** Category number \_\_\_\_\_  **Full**  
Submit the original application. Submit the original application & Submit the original  
application & one entire copy.
- 

**Office Use Only:**

Tracking number: \_\_\_\_\_

Type of Review:  Exempt  Expedite  Full  
Category # \_\_\_\_\_

Other:

## Part C. PROTOCOL INFORMATION

List **every question** by number, brief heading, and your response. Using a different font for your response aids the reviewer. Mark “N/A” if question does not apply to your protocol, but do not use N/A for benefit or risk questions. (Note: Focus your responses to approximately 3 pages. **DO NOT replicate the proposal here.**)

### **Objectives**

1. Objectives of proposed research and background. (Will be used in assessing the risk/benefit ratio for participants. The hypotheses to be tested may be listed.)

### **Human Participants description**

2. Source of participant population
3. Number of participants (for example, number of surveys to be distributed)
4. Characteristics of participants (such as age, gender, student, behavioural abnormalities; affiliations or memberships). Why are these appropriate for this study? If excluding a category, such as minors, explain why.
5. Recruitment procedures
6. Recruiting materials (attach advertisements, posters, letters, scripts)
7. Criteria for excluding participants involuntarily
8. Original letters of ISCR agreement/approval from organisation where participants sought (not concept support letters).
9. Other matters pertinent to the human participants

### **Procedures to be followed with participants (Methodology)**

10. Specify location of study
11. List variables to be studied (what are you measuring or examining)
12. Describe method of data collection (attach copies of surveys, instruments, etc. If using a copyrighted instrument, document authorisation of use.)
13. Describe activities involving participants, including frequency and duration of each activity (this could be an experimental stimulus, a survey, what questions would be asked in an interview, for example) Diagramming helps.
14. Describe equipment used with subjects, if any
15. Specify what factors will lead to stopping procedures causing physical or emotional stress
16. Other aspects of the procedures

### **Risks to participants**

17. Describe potential risks and assess the likelihood, severity, duration, and effects of each. (Use “no known risks” if none are anticipated.) **N/A is not an acceptable response for this question.** Common risks include:
- |                             |                         |
|-----------------------------|-------------------------|
| a. physical injury          | c. legal risk           |
| b.. loss of confidentiality | d. social/economic harm |
18. Describe methods for minimizing risks. For example, document how potential psychological distress will be addressed, by whom, and with what credentials (provide letter of agreement to serve as a counselor)
19. Describe other methods, if any, that were considered alternatively and why they will not be used
20. Other matters relative to risk to participants

### **Benefits to participants**

- 21 Describe the direct benefits to these participants because of their participation. **N/A is not an acceptable response for this question.**
23. Describe the benefits accruing to the class of participants these individuals represent
24. Describe the benefits accruing to society-at-large or other
25. Other aspects of benefits to participants

### **Consent procedures**

26. Describe how potential participants will be informed about the project activities
27. Attach the consent form (*use reading level and terminology understandable to participants*) or cover letter, script, or other substitution for a consent form. Check Section A for criteria for waiver of documentation of consent, and Section B for waiver of consent entirely. If you employ these, provide complete justification of how this project meets the criteria.
28. Other aspects of the consent process

### **Confidentiality**

29. Describe the method(s) used to protect the identity of individual participants. If a linked list is used, when will it be destroyed? Provide a sample of the code.
30. Describe plans for maintaining data after study is complete. Faculty should keep a copy for 3 years following the conclusion of the project, so the data are auditable. Who retains copies, stored where/how, how is confidentiality maintained, for how long.
31. If audio- or video-taping, specify tape storage, use, and when and how disposition of the tapes will take place
32. Other aspects of confidentiality

## Exemption Criteria (Section A)

In order to qualify for exemption, *all* of the project activity must qualify as one or more categories from the left column. To qualify for a category, a project must meet the conditions to the right of the category.

Category	Conditions
(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:	(a) research on regular and special education instructional strategies, <b>OR</b> (b) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, if:  <b>NOTE: all three conditions must apply.</b>	(a) Information obtained is recorded in such a manner that human subjects cannot be identified, directly or through identifiers linked to the subjects; <b>AND</b> (b) any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, or reputation; <b>AND</b> (c) subjects are not under the age of 18 or members of a vulnerable class, including prisoners, pregnant women, individuals who are mentally disabled or educationally disadvantaged.
(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (2) above if:	(a) The human subjects are elected or appointed public officials or candidates for public office; <b>OR</b> (b) without exception, the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
(4) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:	(a) Public benefit or service programs; <b>OR</b> (b) procedures for obtaining benefits or services under those programs; <b>OR</b> (c) possible changes in or alternatives to those programs or procedures; <b>OR</b> (d) possible changes in methods or levels of payment for benefits or services under those programs.

## Expedite Criteria (Section B)

### Applicability

(A) Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories, may be reviewed through the expedited review procedure authorized by. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

(B) The categories in this list apply regardless of the age of subjects, except as noted.

(C) The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing,

employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

(D) The expedited review procedure may not be used for classified research involving human subjects.

(E) Researchers are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review--expedited or convene--utilised by the researcher.

## Research Categories

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
  - (a) Research on drugs for which an investigational new drug application is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
  - (b) Research on medical devices for which (i) an investigational device exemption application is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
  - (a) From healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may no occur more frequently than 2 times per week; or
  - (b) From other adults and children<sup>1</sup> considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.
3. Prospective collection of biological specimens for research purposes by noninvasive means.

Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.
4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography; electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.
5. Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for non research purposes (such as medical treatment or diagnosis).

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<sup>1</sup> Children are defined as "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted."

6. Collection of data from voice, video, digital, or image recordings made for research purposes.
  7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. This listing refers only to research that is not exempt.
  8. Continuing review of research previously approved by the convened researcher as follows: (a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or (b) where no subjects have been enrolled and no additional risks have been identified; or (c) where the remaining research activities are limited to data analysis.
  9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the researcher has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.
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**Dated: July 2005**

## COMMON PROCEDURES AND THEIR ASSOCIATED RISKS

Procedure: Questionnaires Involving Drug/Alcohol Use and Intimate Issues

Risks: break in confidentiality could reveal responses; emotional distress

Procedure: Focus Group Risks: breach of confidentiality (even if participants all warned about confidentiality of information)

## DEFINITIONS

**Human participant:** “a living individual about whom an investigator . . . obtains data through intervention or interaction with the individual or identifiable private information.”

**Minimal risk:** “the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.”

**Research:** “systematic investigation, including research development, testing and evaluation, designed to develop or contribute to general knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.”

## Elements of informed consent

**(a) Basic elements of informed consent.** In seeking informed consent, the following information shall be provided to each subject:

(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.

(2) A description of any reasonably foreseeable risks or discomforts to the subject.

*(NOTE: This includes any information about procedures that might make a subject hesitant to participate.)*

(3) A description of any benefits to the subject or to others which may reasonably be expected from the research.

(4) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained and that notes the possibility that ISCR may inspect the records.

(5) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.

(6) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject.

(7) A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

**(b) Additional elements of informed consent.** When appropriate, one or more of the following elements of information shall also be provided to each subject:

(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.

(3) Any additional costs to the subject that may result from participation in the research.

(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.

(5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject.

(6) The approximate number of subjects involved in the study.

[MODEL]  
National Institute of Culture and History/ISCR  
INFORMED CONSENT TO PARTICIPATE IN A RESEARCH PROJECT

*[You are encouraged to model your consent form after this consent form. If you chose not to use this format, your consent form must at a minimum include the same elements as this mode and the required texts. Before using this model, remove all text in brackets. **Provide a camera-ready copy for review.**]*

TITLE OF PROJECT:

NAME OF PRINCIPAL INVESTIGATOR:

NAME OF CO-INVESTIGATOR:

CONTACT NAME AND PHONE NUMBER FOR QUESTIONS/PROBLEMS:

SPONSOR OF PROJECT: *[Funding Agency or company]*

PURPOSE OF THE RESEARCH:

*[Explain that the study involves research and describe its purpose.]*

PROCEDURES/METHODS TO BE USED:

*[Use **LAY LANGUAGE at 6<sup>th</sup>- 8<sup>th</sup> grade reading level** so participants clearly understand how the study will be conducted and what will be expected of them. Explain the techniques and procedures the participants will experience. Using "you" to refer to the participant, describe the expected duration of participation (such as "20 minutes a day, one day a week, for six weeks") and identify and describe any experimental or non-standard procedures. Tell the participants if they will receive remuneration for participation and under what conditions. Tell them if they will be videotaped or audiotaped. State how the tapes will be disposed of at the end of the study.]*

RISKS INHERENT IN THE PROCEDURES:

*[Describe any reasonably foreseeable risks or discomforts to the participants; state "There are no known risks" if there are none. Also include the following statement.]*

BENEFITS:

*[Describe benefits to the participants or to others which may reasonably be expected from the research Compensation/remuneration for time and effort is not considered a benefit –label these as Compensation. If there are no known benefits to the participant then please state so.]*

CONFIDENTIALITY:

*[Describe how confidentiality of records identifying the participants will be maintained. Do not maintain that only the PI will see data, as the ISCR and other human protection bodies may inspect the records.]*

LIABILITY:

*[Include this statement.]*

Page 1 of 2 Participant's initials \_\_\_\_\_ Date \_\_\_\_\_

*[Insert the page number and space for participant initials and date on every page.]*

**PARTICIPATION:**

*[Include these paragraphs with minimal modification. Do not have signatures appear on a page without this text.]*

Your participation in this research is voluntary. If you decide to participate in the study, you may withdraw your consent and stop participating at any time without penalty or loss of benefits to which you are otherwise entitled.

Your signature acknowledges that you have read the information stated and willingly sign this consent form. Your signature also acknowledges that you have received, on the date signed, a copy of this document containing 2 pages.

\_\_\_\_\_  
Participant name (printed)

\_\_\_\_\_  
Participant signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Witness to signature (project staff)

\_\_\_\_\_  
Date

*[Use the following block only if parental/guardian consent is required. You may wish to preface it with a sentence such as "Obtain your parent's permission ONLY if you are under 18 years of age." Include the text explaining to what the parents are agreeing. If the child is about 7-13, strongly consider preparing a separate, simplified child's assent and make the consent form only for the parent. In that case, you may need to re-work the phrasing on the consent form to distinguish who is the research participant ("we are asking if your child may...")]*

**PARENTAL SIGNATURE FOR MINOR**

As parent or guardian you authorise \_\_\_\_\_ (print name) to become a participant for the described research. The nature and general purpose of the project have been satisfactorily explained to you by \_\_\_\_\_ and you are satisfied that proper precautions will be observed.

\_\_\_\_\_  
Minor's date of birth

\_\_\_\_\_  
Parent/Guardian name (printed)

\_\_\_\_\_  
Parent/Guardian signature

\_\_\_\_\_  
Date