

## WHAT TEACHERS COLLEGE IRB REVIEWERS TYPICALLY LOOK FOR IN A PROTOCOL

### INTRODUCTION

The following questions are for new Teachers College (TC) Institutional Review Board (IRB) protocol applications and are designed to convey what reviewers look for in a completed IRB protocol submission. These guidelines contain the U.S. Department of Health and Human Services (HHS) basic human subject protections requirements. Please use these questions to aid in developing and refining your protocol. Following these guides does not guarantee your protocol will be approved or that you will have a flawless review process. It does however, offer some suggestions on how to frame your study materials for formal IRB review.

Research is defined as a systematic investigation—including research development, testing and evaluation—designed to develop or contribute to generalizable knowledge. A project requires IRB review if it includes both research and human subjects (i.e. participants). The IRB will make the final determination of whether a study requires review.

### WRITING YOUR PROTOCOL

- 1) What are you studying?
- 2) What data are you planning to collect?
- 3) Are the aims and underlying hypotheses of the research stated clearly?
- 4) Does the research use procedures consistent with sound research design?
- 5) Does the research design allow the proposed research question to address the proposed study objectives and result in academically, scientifically, and statistically valid findings?
- 6) Does the research contribute to generalizable knowledge?
- 7) Is there an adequate justification for involving human subjects?
- 8) Is there an adequate explanation of the research issues?
- 9) Is there an adequate description of the activities involving human subjects?
- 10) Is there a detailed description of the data collection and methods of recording?
- 11) Have the questionnaires and interview tools been provided?
- 12) Is there adequate justification for the sample size?
- 13) Is the content written clearly, avoiding jargon, or unnecessarily complicated wording?
- 14) Do all research staff have updated (within the last three years) Collaborative Institutional Training Initiative (CITI) training certificates?

### PROTECTION OF PARTICIPANTS

#### RISKS & BENEFITS

- 1) Are the risks (physical, psychological, legal, economic, and social) to participants minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose participants to risk?
- 2) Are the risks minimized, whenever appropriate, by using procedures already being performed on the participants for diagnostic or treatment purposes?

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- 3) Are the risks to the participants reasonable in relation to anticipated benefits, if any, to participants and the importance of the knowledge expected to result?
- 4) Are both the risks and anticipated benefits accurately identified, evaluated, and described?

### SELECTION OF PARTICIPANTS

- 1) Is the participant selection equitable?
- 2) Are the criteria for inclusion/exclusion equitable?
- 3) Will the recruitment process alter equitable selection?
- 4) Does the nature of the research justify using the proposed participant population?
- 5) Are there adequate procedures for identifying those who might be more susceptible to the risks and who therefore ought to be excluded?
- 6) Has there been appropriate consideration of any special physiological, psychological, or social characteristics of the participant group that would pose special risks?
- 7) Are some or all of the participants likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making ability, or economically disadvantaged persons?
  - a. If yes to the previous question, have additional safeguards been included in the study to protect the rights and welfare of these participants?
  - b. If there is a special population (children, prisoners, individuals with impaired decision-making ability), has appropriate justification been provided?
- 8) Is the exclusion of study participants justified and appropriate?

## DATA MANAGEMENT, STORAGE, PROTECTION, & REPORTING

### PRIVACY & CONFIDENTIALITY

- 1) Are there adequate provisions to protect the privacy interests of participants?
- 2) Are there adequate provisions for protecting the confidentiality of the data through coding, destruction of identifying information, limiting access to the data, or other methods that may be appropriate to the study?
- 3) If the information obtained about participants might interest law enforcement or other government agencies, has a certificate of confidentiality been obtained?
- 4) Are the PI's disclosures to participants about confidentiality adequate?
- 5) If appropriate, does the Primary Investigator (PI) have a mandated reporting plan for minors at high or imminent risk or harm?

### MONITORING

- 1) Does the research plan make adequate provision for monitoring the data collected to ensure the safety and privacy of participants?
- 2) Is there documentation indicating appropriate reporting to the IRB in the event that unexpected results are discovered or there are adverse events?
- 3) If appropriate, has a data safety monitoring committee been established?
- 4) If the study is a multi-center study and TC is the institution of record, is the plan for the management of information relevant to the protection of participants adequate? (e.g. reporting of unexpected problems, protocol modifications, and interim results)

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- 5) If the PI is conducting research at an external site, is there an adequate management and communication plan among the IRBs involved?
- 6) If the PI is conducting international research is there adequate management and communication among all research staff and on-site personnel?
- 7) If the PI is conducting research at a Department of Education (DOE) site, is the PI aware that they also need to submit a separate DOE IRB protocol for review? Is the PI also using DOE IRB templates for their submission?
- 8) Is the research conducted in settings subject to high degrees of volatility?
  - a. If yes, are there additional safeguards in place, adequate to protect the privacy and confidentiality of the participants?

## STUDY REVIEW, FEASIBILITY, & IMPLEMENTATION

### RESOURCES

- 1) Will the PI have access to a population that will allow recruitment of the required number of participants?
- 2) Does the PI have adequate experience and training to conduct this study?
- 3) Will the PI have sufficient time to conduct and complete the research?
- 4) Is the study activity period reasonable for participants?
- 5) Will the PI have adequate numbers of qualified staff?
- 6) Will the PI have adequate facilities?
- 7) Does the PI have an adequate process to ensure that all persons assisting with the research are adequately informed about the protocol and their research related duties and functions?
- 8) Will the PI have adequate medical or psychological services available that participants might require as a consequence of the research, when applicable?

### INCENTIVES FOR PARTICIPATION

- 1) Are the incentives offered reasonable, based upon the complexities and inconveniences of the study and the particular participant population?
- 2) Is the compensation or reimbursement appropriately prorated?

### CONFLICT OF INTERESTS

- 1) PIs should be alert to the potential for undue influence in research with those in employer-employee status, teacher-student, supervisor-subordinate relationships, or deployed active duty personnel. Is there a conflict of interest that requires management?
- 2) Is the PI in a leadership role within the study site?
- 3) Will the PI (or research staff) individually profit from this research?

## CONTINUING REVIEW

- 1) Does the research require more than annual continuing review? If yes, how often?
- 2) Should continuing review be conducted under the expedited review process? (e.g. the study meets the definition of minimal risk?)

## INFORMED CONSENT PROCESS & CONTENT

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- 1) Do the proposed explanations of the research provide an accurate assessment of its risks and anticipated benefits?
- 2) Is the possibility (or improbability) of direct benefit to the participants fairly and clearly described?
- 3) Is the language and presentation of the information to be conveyed appropriate to the participant population?
- 4) Are the timing of and setting for the explanation of the research and obtaining informed consent conducive to good decision making?
- 5) Is it clear who is authorized to obtain informed consent for the study?
- 6) Have the informed consent issues for secondary study participants been addressed?
- 7) Will the PI obtain legally effective informed consent of the participant or the participant's legally authorized representative?
- 8) Will the circumstances of the consent process provide the prospective participant or the representative sufficient opportunity to consider whether to participate?
- 9) Will the circumstances of the consent process minimize the possibility of coercion or undue influence?
- 10) Will the individuals communicating information to the participant or the representative during the consent process provide the information in language understandable to the participant or the representative (individuals talking to the participants and answering questions will be able to communicate in a manner that is understandable to the participant)?
- 11) Will the information being communicated to the participant or the representative during the consent process not include exculpatory language through which the participant or the representative is made to waive or appear to waive any of the participant's legal rights?
- 12) Did the PI report that they plan to enroll non-English speaking participants?
  - a) If yes, does the PI have a translated copy of the informed consent for non-English speaking participants?
- 13) Are participants informed to take as much time necessary to read the consent form?
- 14) Are participants informed that they will receive a copy of the consent form?
- 15) Does the consent form contain contact information for a person independent of the research team for the following situations?
  - a) To obtain answers to questions about the research.
  - b) In the event the research staff cannot be reached.
  - c) In the event they wished to talk to someone other than the research staff.

### BASIC ELEMENTS OF INFORMED CONSENT FOR ALL PROTOCOLS

Does the informed consent contain:

- 1) A statement that the study involves research.
- 2) An explanation of the purposes of the research.
- 3) The expected duration of the participant's participation.
- 4) A description of the procedures to be followed.
- 5) Identification of any procedures which are experimental.
- 6) A description of any reasonably foreseeable risks or discomforts to the participant.
- 7) A description of any benefits to the participant or to others which may reasonably be expected from the research.

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- 8) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant.
- 9) A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained.
- 10) An explanation of whom to contact for answers to questions about the research.
- 11) An explanation of whom to contact for answers to questions about injury.
- 12) An explanation of whom to contact concerning rights as a research participant.
- 13) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits and the participant may withdraw without penalty.
- 14) For research involving more than minimal risk, an explanation as to whether any compensation or medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.

### ADDITIONAL ELEMENTS OF INFORMED CONSENT

The following elements may be applicable for specific categories of research or special populations:

- 1) A statement that the particular treatment or procedure may involve risks to the participant or to the embryo or fetus, if the participant is or may become pregnant which are currently unforeseeable.
- 2) Anticipated circumstances under which the participant's participation may be terminated by the investigator without regard to the participant's consent.
- 3) Any additional cost to the participant that may result from participation in the research.
- 4) The consequences of a participant's decision to withdraw from the research and procedures for orderly termination of participation by the participant.
- 5) A statement that significant new findings developed during the course of research which may relate to the participant's willingness to continue participation will be provided to the participant.
- 6) The approximate number of participants involved in the study.
- 7) The storage and use of research specimens disclosed.
- 8) Agreement and spaces for signatures/dates for the participant, and/or representative (if applicable) and person obtaining consent.
- 9) If a witness signature is required.
- 10) If FDA regulated, a statement that the FDA may inspect records (include if the research is participants to FDA regulations).

### WAIVER OF INFORMED CONSENT DOCUMENTATION

- 1) Have the criteria for waiver of informed consent documentation been met?
  - a) The consent form would be the only record linking the participant to the research, and a potential leak would be a breach of confidentiality. In such case, it is up to the participant when asked if they want documentation. This is not applicable for FDA regulated research.
  - b) The study is no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context.
- 2) If informed consent documentation is waived, should the PI be required to provide participants with a written statement regarding the research?

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- 3) If children are included, have the criteria for waiver of parental/guardian consent been met?
  - a) The IRB will determine if a waiver of parent/guardian consent is a reasonable approach for research participants.
  - b) Appropriate mechanisms must be implemented to protect children as participants.
  - c) Provisions for waivers of parental permission are not applicable for FDA regulated research.

## SPECIAL POPULATION GUIDELINES

### WORKING WITH CHILDREN - ASSENT

1. Is assent required?
2. Will assent be documented?
3. Is the process of obtaining/documenting assent adequate?

### WORKING WITH CHILDREN – CONSENT FOR CHILDREN UNDER THE JURISDICTION OF THE DEPENDENCY COURT

- 1) Has a court order been obtained to allow the child to participate in the research without parental consent?
- 2) Is the research either related to the children’s status as wards; or conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of the children involved as participants are not wards?
- 3) Has an advocate been appointed for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or in loco parentis?

### PARENTAL PERMISSION

- 1) Is consent of one parent appropriate?
- 2) Is consent of both parents required? (Consent from both parents is required when the research is greater than minimal risk without potential for benefit.)

### WORKING WITH INDIVIDUALS WITH IMPAIRED DECISION-MAKING ABILITY

- 1) Does the research involve greater than minimal risk?
- 2) If the research involves greater than minimal risk does it present the prospect of direct benefit to the individual participants?
- 3) Are the risks to the participants reasonable in relation to anticipated benefits, if any, and to the importance of the knowledge that may reasonably be expected to result?
- 4) Is the relation of the anticipated benefit to the risk at least as favorable to the participants as that presented by available alternative approaches?
- 5) Are there adequate provisions for soliciting the assent of the participants and permission of their legally authorized representative?
- 6) Is the proposed plan for the assessment of the participant’s capacity to consent adequate?

### WORKING WITH YOUR OWN STUDENTS

- 1) Are you working with your own students for this study?

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- 2) Have you reviewed the “*Working With Your Own Students*” form (located in Mentor/Documentation)?
- 3) Are safeguards in place to decrease the presence of coercion inherent in research where teachers study their own students?

## INTERNATIONAL RESEARCH

If the research involves human participants who are not U.S. citizens or Department of Defense personnel, and is conducted outside the United States, its territories, and possessions, the following should be considered.

- 1) Are there adequate provisions to protect the privacy interests of participants?
- 2) Are there adequate provisions for protecting the confidentiality of the data through coding, destruction of identifying information, limiting access to the data, or whatever methods that may be appropriate to the study?
- 3) If the information obtained about participants might interest law enforcement or other government agencies, has a certificate of confidentiality been obtained?
- 4) Are the PI’s disclosures to participants about confidentiality adequate?

For all protocols, PIs should strive first and foremost to protect the rights and privacy of participants and uphold ethical standards of research. All writing should be clear, concise, and easily understood by the intended audience, whether the IRB or research participants. For more information and resources, please visit MyTC/Research/Mentor IRB/Documentation or tc.edu/IRB.