

Office Use Only	
<input type="checkbox"/> Chair Approved	
<input type="checkbox"/> Reviewer approved / _____ date	
<input type="checkbox"/> Required revisions / _____ date	

Appendix K
 INSTITUTIONAL REVIEW BOARD
 Research Proposal Checklist

Investigator's Name: _____ Date: _____
 Protocol Title: _____

- A. Descriptions of Proposed Research
 Purpose is clear Hypothesis or specific aims are clear Relationship of this to work of others
- B. Descriptions of Subjects/Participants
 Source of participant population maximum number Characteristics of participants as individuals and as a pool Cultural consultant contact information for non-English speaking or foreign subjects criteria for inclusion/exclusion
 Rationale for use of vulnerable subjects (if applicable) Recruitment procedure and related documents
 Other
Decision: Selection of subjects is equitable. Yes No Dependent on revision(s) Revisions approved (if applicable) date:
- C. Procedures
 Specify location List variables studied Description data collection, record-keeping, data analysis
 Copies of surveys, interview guides, questionnaires, instruments, stimuli are attached Documentation of authorization to use/permission to modify instruments, or public domain attached Describe activities involving participants, include frequency and duration, total time commitment
 Describe equipment used Specify factors leading to cessation of procedures causing physical or emotional stress Describe biological samples taken, method for their handling and qualifications of individuals Debriefing method, rationale for deception and debriefing protocol Other
Decision: Research uses procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk. Yes No
 Dependent on revision(s) Revisions approved (if applicable) date:
Decision: Research uses procedures already being performed on the subject's for diagnostic or treatment purposes
 Yes No Not applicable
- D. Risk Statements
 Description of risks Description of precautions to minimize risks Statement of any alternative procedures
 Other
Decision: Risks are minimized. Yes No Dependent on revision(s) Revisions approved (if applicable) date:
Decision: When appropriate, research plan makes adequate provision for monitoring the data collected to ensure safety of subjects. Yes No Dependent on revision(s) Revisions approved (if applicable) date:
Decision: Safeguards are included for vulnerable subjects. Yes No Dependent on revision(s)
 Revisions approved (if applicable) date:
Decision: Level of risk is minimal risk or below greater than minimal risk
- E. Benefit Statements
 Description of anticipated benefits to subjects (if none so state) Description of anticipated benefit to others
 Description of anticipated benefits to society at large Other

Decision: Risks are reasonable relative to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. Yes No Dependent on revision(s) Revisions approved (if applicable) date:

F. Consent Procedures

Description of potential participants and how they are informed Attached consent form and assent form/script Translations and certifications of equivalence Discussion of any other aspects Other

G. Confidentiality Statements: Description of confidentiality insurance procedures

Methods used to protect identity Plans for maintaining data Storage Description of how requirement for consent forms will be retained following project Other

Decision: Privacy and confidentiality provisions are adequate. Yes No Dependent on revision(s) Revisions approved (if applicable) date:

H. Justification for Exempt or Expedited Status

Justification included Category requested: _____

I. Justification for Waiver of Elements of Informed Consent Process

Decision: The research involves no more than minimal risk to the subjects. Yes No

Dependent on revision(s) Revisions approved (if applicable) date:

Decision: The waiver or alteration will not adversely affect the rights and welfare of the subjects Yes

No Dependent on revision(s) Revisions approved (if applicable) date:

Decision: The research could not practicably be carried out without the waiver or alteration Yes No

Dependent on revision(s) Revisions approved (if applicable) date: , AND

Decision: Whenever appropriate, the subjects will be provided with additional pertinent information after participation Yes No Dependent on revision(s) Revisions approved (if applicable) date:

Not applicable

J. Justification for Waiver of Informed Consent Signed Documentation

Decision: That the only record linking the subject and the research would be the consent document and the principal risk would be potential resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research and the subject's wishes will govern; Yes No Dependent on revision(s) Revisions approved (if applicable) date: , OR

Decision: That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context. Yes No Dependent on revision(s) Revisions approved (if applicable) date: Not applicable

Decision: Written statement regarding the research is required. Yes No

K. Special Considerations Required: State Category _____

L. Period of Review

Decision: Annually More frequently than annually (Specify) _____

M. Appropriate Signatures

Page 2 of application completed (checked and signed) Other signatures as applicable

N. External IRB Approval

Present if applicable

Decision: Exempt _____ Category No. _____
Expedited _____ Category No. _____
Needs Full Review _____
Modifications _____

Decision: Additional CITI Modules needed Yes
 International Res. Vul. Subj. – Women & Fetuses
 HIPAA Vul. Subj. – Group/Community Harms
 Res. using Internet Records Based Research
 Genetics Research VA Research

With revisions listed on the Research Proposal Checklist and the Informed Consent Checklist this would qualify for:

Exempt, Category No. _____ Expedited, Category No. _____ Needs Full Review

Signature of Reviewer: _____ Date: _____

KEY: X = adequate O = missing or not acceptable NA = not applicable