HUMAN RESEARCH ETHICS BOARD
Research Proposal Checklist

Investigator’s Name: ____________________________ Date: __________________
Protocol Title: __________________________________________ Date: __________________

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  ☐ approximate 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

Revised 11/20/13
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 ☐ More frequently than annually (Specify) _______________________

M. Appropriate Signatures
☐ Page 2 of application completed (checked and signed) ☐ Other signatures as applicable

Revised 11/20/13
N. External HREB 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