**Appendix 1: Investigator’s Checklist**

Please use this checklist to ensure that your protocol meets IRB requirements.

 **NAME \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

 **ADDRESS \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

 **TELEPHONE \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

 **ADVISOR \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

\_\_\_\_\_ **Submit application for full board review before the deadline indicated on the IRB website**

 **COVERSHEET**

\_\_\_\_\_ Completed

\_\_\_\_\_ Typed

\_\_\_\_\_ Signed (investigators, and if appropriate, faculty advisor)

\_\_\_\_\_ CITI Training Certificate of Completion attached

 **PROTOCOL** (5 pages maximum)

\_\_\_\_\_ Pages numbered

\_\_\_\_\_ Introduction and brief background

\_\_\_\_\_ Specific aims

\_\_\_\_\_ Materials and methods

 a. project description, including testing, instrumentation, interventions, etc.

\_\_\_\_\_ b. how subjects are chosen

\_\_\_\_\_ c. why specific subject population chosen

\_\_\_\_\_ d. source of subjects

\_\_\_\_\_ e. method of obtaining informed consent

\_\_\_\_\_ f. costs and payments

\_\_\_\_\_ g. flow chart (if applicable)

\_\_\_\_\_ h. significance of the research

 **PROTECTION OF HUMAN SUBJECTS:** (Risk/Benefit Ratio)

\_\_\_\_\_ Procedure used to protect confidentiality

\_\_\_\_\_ Manner of recording information

\_\_\_\_\_ Use of audio and visual tapes and their disposition

\_\_\_\_\_ How long identifying information will be kept

\_\_\_\_\_ Deception or assent (if applicable)

 **QUALIFICATIONS OF INVESTIGATOR(S)**

\_\_\_\_\_ Faculty: Short biographical sketch

 **CONSENT FORMS**

 Procedural Details:

\_\_\_\_\_ a. Page 1 is on appropriate institution letterhead with 1” or greater margin at top

\_\_\_\_\_ b. Title (consent form title and project title are the same)

\_\_\_\_\_ c. Pages numbered (protocol and consent form numbered separately).

\_\_\_\_\_ d. list all investigators, email addresses, and business telephone numbers

\_\_\_\_\_ e. Blank for subjects‘ initials in lower right corner of each page of consent form.

\_\_\_\_\_ f. Signature line for subject, witness, parent, corroborator.

 Separate Consent Forms for:

\_\_\_\_\_ a. adults in treatment group

\_\_\_\_\_ b. control group

\_\_\_\_\_ c. children

\_\_\_\_\_ d. parent or guardian

\_\_\_\_\_ e. other

 **CONTENT**

\_\_\_\_\_ Description of study written in non-technical language

\_\_\_\_\_ Risks/benefits

\_\_\_\_\_ Alternative treatments, if applicable

\_\_\_\_\_ Costs and payments, if applicable

\_\_\_\_\_ Confidentiality and use of protected health information

\_\_\_\_\_ Dean's phone number

\_\_\_\_\_ Right to refuse or end participation

\_\_\_\_\_ No compensation for injury, if applicable

\_\_\_\_\_ Voluntary consent

\_\_\_\_\_ Acknowledgment of parent, if applicable

\_\_\_\_\_ Investigator's certification

 **ADVISOR'S STATEMENT** (if applicable):

***Faculty Advisor’s Statement*** (student projects only): I, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ am the advisor for \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. My signature below indicates that I have read the attached protocol and have checked the contents with the IRB Guidelines. I thereby recommend this protocol as:

Exempt Review\_\_\_\_\_\_ Expedited Review \_\_\_\_ Full Board Review \_\_\_\_

Signature:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Email: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_