REVIEWER CHECKLIST FOR CUHSR MEMBERS

Expedited and Full Review

Reviewers: Fill out this form for studies that are considered expedited. Sign and date the form and return it to the Office of Sponsored Programs. If a primary reviewer for a Full Review, fill out this form and send it to chair prior to the full committee meeting.

**Reviewer: CUSHR #:**

**PI: SPI: Co-PI:**

**Protocol Title:**

**Primary Objective**:

Type of Review

[ ]  **Expedited – Category** [ ]  **1,** [ ]  **2,** [ ]  **3,** [ ]  **4,** [ ]  **5,** [ ]  **6,** [ ]  **7,** [ ]  **8,** [ ]  **9** (must be no more than minimal risk and fall into one of the categories - *Minimal risk* means that 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 45 CFR 46.102(j). Anything beyond minimal risk will undergo a full review. Harm or discomfort can be psychological, social, legal, economic and reputational as well as physical.

[ ]  **Full review**

**A.** [ ]  **Yes** [ ]  **No** **Does the use of human subjects have research relevance**?

The use of human subjects in this protocol is relevant and appropriate to answer the questions being asked. The study design is appropriate to answer the questions being asked.

**B.** [ ]  **Yes** [ ]  **No** **Are there any ethical issues regarding the study’s design and conduct**?

Ethical issues may include but are not limited to the Belmont report principles: respect for persons (voluntary, fully informed consent), beneficence (obligations to protect subjects from harm and secure their well-being, and justice (benefits and burdens of research are fairly distributed).

**C.** [ ]  **Yes** [ ]  **No** (MUST CHECK) **Are risks minimized by using procedures which are**

 **consistent with sound research design?**

45 CFR 46.111 (a)(1) **Risks to subject are minimized:** (i) By **using procedures which are consistent with sound research design** and which do not unnecessarily expose subject to risk, and (II) whenever appropriate, by using **procedures already being performed on the subjects for diagnostic or treatment purposes.**

[ ]  **Yes** [ ]  **No** [ ]  **NA** 1. Are the study aims/objectives clearly specified?

 [ ]  **Yes** [ ]  **No** [ ]  **NA** 2. Are there adequate preliminary data to justify the research?

 [ ]  **Yes** [ ]  **No** [ ]  **NA** 3. Are adequate references provided?

[ ]  **Yes** [ ]  **No** [ ]  **NA** 4. Is there appropriate justification for this research and thus to

involve human subjects?

[ ]  **Yes** [ ]  **No** [ ]  **NA** 5. Is the scientific design adequate to answer the questions?

[ ]  **Yes** [ ]  **No** [ ]  **NA** 6. Are the aims and objectives likely to be achievable within the

given time period?

[ ]  **Yes** [ ]  **No** [ ]  **NA** 7. Are the plans for data and statistical analysis defined and justified?

[ ]  **Yes** [ ]  **No** [ ]  **NA** 8. Is risk minimized by using standard of care practices?

[ ]  **Yes** [ ]  **No** [ ]  **NA** 9. Are the procedures structured so they do not unnecessarily

expose subjects to risk?

**D.** [ ]  **Yes** [ ]  **No** (MUST CHECK) **Are risks (physical, emotional, financial, legal) to subjects minimized?**

[ ]  **Yes** [ ]  **No** (MUST CHECK) **Are risks to subjects reasonable in relation to anticipated benefits?**

[ ]  **Yes** [ ]  **No** [ ]  **NA** (MUST CHECK) **Does the research plan provide for monitoring data to ensure safety of subjects?**

45 CFR 46.111 (a)(2**) Risks to subjects are reasonable in relation to anticipated benefits** (if any) to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should NOT consider possible long-range effects of applying knowledge gained in the research (e.g., the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

45 CFR 46.111(a) (6) When appropriate, the research **plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.**

[ ]  **Yes** [ ]  **No** [ ]  **NA** 1. Are the rationale and details of the research procedures

 accurately described and acceptable?

 [ ]  **Yes** [ ]  **No** [ ]  **NA** 2. Is the duration of participants involvement stated and reasonable?

 [ ]  **Yes** [ ]  **No** [ ]  **NA** 3. Are procedures in place to prevent or manage adverse reactions?

 [ ]  **Yes** [ ]  **No** [ ]  **NA** 4. If applicable will counseling, referrals or other support services

be provided?

[ ]  **Yes** [ ]  **No** [ ]  **NA** 5. Has the investigator assured appropriate monitoring of subjects

during and after the research?

[ ]  **Yes** [ ]  **No** [ ]  **NA** 6. If applicable are there provision included for research related injuries?

[ ]  **Yes** [ ]  **No** [ ]  **NA** 7. Are resources available to conduct the research safely?

**E**. [ ]  **Yes** [ ]  **No** (MUST CHECK) I**s subject selection equitable?**

 [ ]  **Yes** [ ]  **No Are minorities, women and children or other vulnerable populations included in the study design?**

**If YES – what is the level of risk:**

[ ]  Not greater than minimal risk.

[ ]  Greater than minimal risk but presenting prospect of direct benefit to the individual subjects.

[ ]  Greater than minimal risk, no direct benefit to individual subjects but likely to yield generalizable knowledge about subjects’ disorder or condition

[ ]  **Yes** [ ]  **No** **Is the inclusion or exclusion or special population justified?**

 45 CFR 46. 111 (a) (3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted. The IRB should be particularly cognizant of the special problems of research that involves a category of subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons

45 CFR 46. 111 (b) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

 [ ]  **Yes** [ ]  **No** [ ]  **NA** 1. Are inclusion and exclusion criteria clearly stated and reasonable?

[ ]  **Yes** [ ]  **No** [ ]  **NA** 2. Is the principle of distributive justice adequately incorporated

into the inclusion and exclusion criteria for the research protocol?

[ ]  **Yes** [ ]  **No** [ ]  **NA** 3. For subjects who may be vulnerable to coercion or undue influence have additional safeguards included to protect the rights and welfare of these subjects?

 [ ]  **Yes** [ ]  **No** [ ]  **NA** 4. Are the methods for recruiting potential subjects adequate?

 [ ]  **Yes** [ ]  **No** [ ]  **NA** 5. Are all recruitment materials submitted and appropriate?

 [ ]  **Yes** [ ]  **No** [ ]  **NA** 6. Are there acceptable methods for screen subjects before recruitment?

[ ]  **Yes** [ ]  **No** [ ]  **NA** 7. Is the rationale for the proposed number of subjects reasonable?

[ ]  **Yes** [ ]  **No** [ ]  **NA** 8. Is the research location appropriate for the subject population?

 **Number of subjects**:

 **Age range of subjects:**

 **Recruitment materials and inducements**

[ ]  **Yes** [ ]  **No** 1. Recruitment materials included

[ ]  **Yes** [ ]  **No** 2. Materials void of over statements of benefit or incentive, void of coercion

[ ]  **Yes** [ ]  **No** 3. Required: [ ] Bradley, [ ]  research, [ ] name of PI, [ ] eligibility criteria, [ ]  contact information, [ ] incentives or compensation.

**F.** [ ]  **Yes** [ ]  **No** (MUST CHECK) **Are there procedures for protecting privacy and confidentiality?**

[ ]  **Yes** [ ]  **No Is there greater than minimal risk to the subject if there is a breach in confidentiality?** (if so it this study may need to go under full committee review depending on the probability and magnitude duration and reversibility of the risk. Provide a rationale)

45 CFR 46. 111 (a) (7) When appropriate, there are adequate provision to protect the privacy of subjects and to maintain the confidentiality of data.

 [ ]  **Yes** [ ]  **No** [ ]  **NA** 1. Are the provisions adequate to protect subject privacy?

[ ]  **Yes** [ ]  **No** [ ]  **NA** 2. Are the provisions adequate to assure confidentiality of the research subject?

[ ]  **Yes** [ ]  **No** [ ]  **NA** 3. Are the provisions adequate to protect the confidentiality of the data during and after the research?

[ ]  **Yes** [ ]  **No** [ ]  **NA** 4. Are the demographics handled in such a way to avoid re-identification of the subject?

[ ]  **Yes** [ ]  **No** [ ]  **NA** 5. Is the data linkage to identifier adequate to protect privacy and assure confidentiality?

 [ ]  **Yes** [ ]  **No** [ ]  **NA** 6. Are the steps adequate to secure the data?

**G. Informed consent**

[ ]  **Yes** [ ]  **No** (MUST CHECK) **Informed consent is sought from each subject or LAR? If no then**

[ ]  **Yes** [ ]  **No** Investigator is seeking a waiver or alteration of consent.

45 CFR 46. 111 (a) (4) Informed consent will be sought from each prospective subject or the subjects legally authorized representative in accordance with and to the extent required by 46.116

[ ]  **Yes** [ ]  **No** [ ]  **NA** 1. The circumstances of consent provide sufficient opportunity for the subject or LAR to participate or not.

[ ]  **Yes** [ ]  **No** [ ]  **NA** 2. The circumstance of the consent minimizes the possibility of coercion or undue influence.

[ ]  **Yes** [ ]  **No** [ ]  **NA** 3. The consent language is understandable to the subject or LAR. (consider professional jargon, abbreviations, complex wording)

[ ]  **Yes** [ ]  **No** [ ]  **NA** 4. The consent provides information that a reasonable person would want to make an informed decision and has opportunity to discuss

 [ ]  **Yes** [ ]  **No** [ ]  **NA** 5. The consent (complex studies) must begin with key information.

[ ]  **Yes** [ ]  **No** [ ]  **NA** 6. The consent has sufficient detail and is organizes to facilitate understanding the reasons to participate or not.

 [ ]  **Yes** [ ]  **No** [ ]  **NA** 7. The consent has no exculpatory language.

 [ ]  **Yes** [ ]  **No** [ ]  **NA** 8. For minors, assent procedures in place

 [ ]  **Yes** [ ]  **No** [ ]  **NA** 9. The procedures in the application agree with the consent

 **REQUIRED ELEMENTS OF DISCLOSURE** (\*Can omit if there are none)

 [ ]  **Yes** [ ]  **No** 1. The study involves research

 [ ]  **Yes** [ ]  **No** 2. The purpose of the research

 [ ]  **Yes** [ ]  **No** 3. The expected duration of the subject’s participation

 \*[ ]  **Yes** [ ]  **No** 4. A description of procedures that are experimental

 [ ]  **Yes** [ ]  **No**  5. The procedures to be followed

 [ ]  **Yes** [ ]  **No**  6. Foreseeable risks or discomforts

 [ ]  **Yes** [ ]  **No** 7. Any benefits to the subject from the research

 \*[ ]  **Yes** [ ]  **No** 8. A disclosure of alternate procedures that may benefit the subject

 [ ]  **Yes** [ ]  **No** 9. The extent of to which the confidentiality of records will be maintained

 \*[ ]  **Yes** [ ]  **No** 10. If more that minimal risk, an explanation of any compensation if injury occurs

 [ ]  **Yes** [ ]  **No** 11. Contact information of the research team or PI, who to contact if injury occurs

 [ ]  **Yes** [ ]  **No** 12. Contact information of CUHSR for regarding rights of a research subject

 [ ]  **Yes** [ ]  **No** 13. Participation is voluntary

[ ]  **Yes** [ ]  **No** 14. Statement that refusal to participate will not result in penalty or benefit subject has a right to otherwise.

 [ ]  **Yes** [ ]  **No** 15. Statement that withdrawal will not result in penalty or loss or benefit

[ ]  **Yes** [ ]  **No** 16. Statement about what will happen to the data after the research

 **ADDITIONAL ELEMENTS OF DISCLOSURE AS APPROPRIATE**

 [ ]  **Yes** [ ]  **No** [ ]  **NA** 1. Treatment or procedure may involve unforeseeable risks

 [ ]  **Yes** [ ]  **No** [ ]  **NA** 2**.** Disclosure if randomization occurs

 [ ]  **Yes** [ ]  **No** [ ]  **NA** 3. Circumstance when participation can be terminated without subject’s consent

 [ ]  **Yes** [ ]  **No** [ ]  **NA** 4. Any additional costs

 [ ]  **Yes** [ ]  **No** [ ]  **NA** 5. Any payments or proration explained

 [ ]  **Yes** [ ]  **No** [ ]  **NA** 6. Consequence of subject’s decision to withdraw

 [ ]  **Yes** [ ]  **No** [ ]  **NA** 7. New findings that may alter the subject’s willingness to continue will be provided

 [ ]  **Yes** [ ]  **No** [ ]  **NA** 8. Whether research results will be disclosed to the subject

[ ]  **Yes** [ ]  **No** [ ]  **NA** 9. Biospecimens may be used for commercial profits, might undergo genome sequencing

 [ ]  **Yes** [ ]  **No** [ ]  **NA** 10. Translations provided, or provisions made, for non-English speakers

**H. Alteration or waiver of Informed Consent**

[ ]  **Yes** [ ]  **No** Waiver or Alteration requested? IF YES state the reques.

 To grant the request all the following must be checked YES:

 [ ]  **Yes** [ ]  **No** 1. The research involves no more that minimal risk

[ ]  **Yes** [ ]  **No** 2.The research could not be practicably carried out without the requested waiver or alteration

[ ]  **Yes** [ ]  **No** [ ]  **NA** 3. If the research involves identifiable private information or biospecimens the research could not be practicably carried out withoutusing such information in an identifiable format.

[ ]  **Yes** [ ]  **No** 4. The waiver or alteration will not adversely affect the rights or welfare of the subjects
[ ]  **Yes** [ ]  **No** 5.Whenever appropriate the subjects or LAR will be provided with pertinent information after participation.

**I. Documentation of Consent (if NO to the following, a waiver of documentation should be requested by the investigator)**

[ ]  **Yes** [ ]  **No** 1.Approved consent form will be signed (including electronic signature) by the subject or LAR

[ ]  **Yes** [ ]  **No** 2.A copy will be given to the person signing the form.

 [ ]  **Yes** [ ]  **No** [ ]  **NA** 3. For minors, appropriate parent/guardian signatures

 [ ]  **Yes** [ ]  **No** 4.The subject or LAR has an opportunity to read the consent before sign

OR [ ]  **Yes** [ ]  **No** A short form of the element of consent are presented orally, an approved written summary provided, with witness signature.

 [ ]  **Yes** [ ]  **No** Waiver or Alteration of documentation requested? IF YES state the request:

 To grant the request ONE of the following must be checked YES:

[ ]  **Yes** [ ]  **No** The only record linking the subject and the research would be the informed consent form and the principle risk would be potential harm resulting in a breach of confidentiality.

[ ]  **Yes** [ ]  **No** That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required.

[ ]  **Yes** [ ]  **No** Subjects or LAR are members of a distinct cultural group or community in which signing forms is not the norm and the research presents no more than minimal risk

J. See documentation and regulations regarding procedures for special populations

K. [ ]  **Yes** [ ]  **No** [ ]  **NA** Questionnaires, surveys, interview guides, measures, or data collections sheets included.

[ ]  **Yes** [ ]  **No** [ ]  **NA** Letters that give permission to have access to any special populations or locations

**Risks:** [ ]  **Greater than minimal** [ ]  **minimal**

**Benefits:** [ ]  **direct** [ ]  **indirect** [ ]  **both:**

**Reviewer Decision – Expedited** [ ]  **Approve without modifications**

[ ]  **Approve with modifications**

[ ]  **Consultation needed prior to decision**

[ ]  **Move to Full Committee – Provide typed rationale- Contact committee chair**

**Reviewer Recommendation:** [ ]  **Approve without modifications**

**(for Full Committee review)** [ ]  **Approve with modifications**

[ ]  **Recommend to full committee to table**

[ ]  **Recommend to full committee to Disapprove**

[ ] **Approval for 1 year** [ ] **Approval for less than 1 year - explain and provide interval**

**Additional Comments:**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Signed (Primary Reviewer) Date