TANEY COUNTY HEALTH DEPARTMENT

IRB CHECKLIST – CONTINUING REVEIW

HRPP # _____

Date:	Name of Reviewer:
Reviewer Type: ☐ Primary ☐ Secondary ☐ Expedited	
Type of Project:	Name of Agencies Lead Investigator:
Name of Principal Investigator (if different from above):	Name of Lead IRB:

REVIEWER RECOMMENDATIONS SUMMARY

Level of Risk (please check one): ☐ Remains…. ☐ Has changed to…. ☐ Minimal Risk (the probability and magnitude of harm or discomfort are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests) ☐ Greater than minimal risk	Device Category (please check one): ☐ Not Applicable ☐ Significant Risk ☐ Non-significant Risk
Child Category (see also Attachment 1): ☐ Not Applicable ☐ Cat. 1 (45 CFR 46.404) – minimal risk w/prospect of direct benefit ☐ Cat. 2 (45 CFR 46.405) – greater than minimal risk w/prospect of direct benefit	Recommended IRB Action (check one): ☐ Approve as submitted ☐ Modifications required to secure approval ☐ Defer for the reasons described below ☐ Table for the reasons described below ☐ Disapprove for the reasons described below ☐ Suspend for the reasons described below ☐ Terminate for the reasons described below
Maximum Total Subject Enrollment Number (upper limit):	Independent Verification of No Material Changes Since Previous IRB Review (check one): ☐ Not Recommended ☐ Recommended (please comment):
Continuing Review Frequency (check one): ☐ 12 months ☐ 6 months ☐ Other: _____	Type of Review (check one): ☐ Expedited reviewer acting on behalf of the IRB Category No.: _____ ☐ Recommendations to convened IRB by expedited reviewer ☐ Recommendations by convened IRB
Signature of Reviewer:	Date:

PART A – BACKGROUND INFORMATION

1. Please verify that the investigator has provided adequate information for the continuation of the proposed research.

	Yes	No	N/A
a. Investigator has been using the current, approved informed consent document	☐	☐	☐
b. The proposed informed consent document for the next approval period reflects all proposed changes and revisions	☐	☐	☐
c. The number of subjects enrolled corresponds to the number approved for enrollment	☐	☐	☐
d. The research project and progress to date are described adequately	☐	☐	☐
e. Serious, unanticipated adverse events for the whole study are summarized adequately	☐	☐	☐
f. The following information since the last IRB review is described adequately	☐	☐	☐
1) Serious adverse events and unanticipated problems involving risks to subjects or others	☐	☐	☐
2) Withdrawal of subjects	☐	☐	☐
3) Complaints	☐	☐	☐
4) New information provided in study reports and recent literature	☐	☐	☐
g. Host country continuing approval obtained and received (If necessary)	☐	☐	☐
h. Continuing IRB approval from collaborating institutions obtained	☐	☐	☐

Comments or Concerns:

PART B – REGULATORY CRITERIA FOR APPROVALS

Regulatory Criteria: The IRB is required to conduct **substantive and meaningful continuing review** of research at intervals appropriate to the degree of risk, but not less than once per year. In order to approve continuation of the research, the IRB must have sufficient information to determine that the eight required criteria below have been satisfied.

2. Please verify that the investigator has submitted sufficient information to determine that the following criteria have been satisfied:

	Yes	No	N/A
a. Risks are minimized through sound research design	☐	☐	☐
b. Risks are reasonable in relation to anticipated benefits	☐	☐	☐
c. Selection of subjects is equitable	☐	☐	☐
d. The informed consent process is adequate (or has previously been waived by the IRB)	☐	☐	☐
e. Documentation of informed consent is adequate (or has previously been waived by the IRB)	☐	☐	☐
f. Safety monitoring is adequate and appropriate	☐	☐	☐
g. Provisions for the protection of privacy of subjects and the confidentiality of data/records are adequate and appropriate	☐	☐	☐
h. Safeguards for vulnerable subjects are adequate	☐	☐	☐

Comments or Concerns:

3. Please verify that safeguards for vulnerable subjects are adequate:

☐ **Military personnel** *(complete **Question 7-A**)*
☐ **Adults with Impaired Capacity for Decision-Making** *(complete **Question 7-B**)*
☐ **Other vulnerable adults** *(e.g., socially or economically disadvantaged, complete **Question 7-C**)*
☐ **Children** *(complete **Attachment 1,** see 45 CFR Part 46 Subpart D)*
☐ **Prisoners** *(complete **Attachment 2,** see 45 CFR Part 46 Subpart C)*
☐ **Pregnant Women and Fetuses** *(complete **Attachment 3**, see 45 CFR Part 46 Subpart B)*
☐ **Neonates** *(complete **Attachment 3**, see 45 CFR Part 46 Subpart B)*
☐ **N/A – no vulnerable subjects** *(skip to Question 13 below)*

A. Military Personnel	Yes	No	N/A
1. Deployment of military personnel has been considered and contingency planning is appropriate	☐	☐	☐
2. Approval from appropriate supervisors has been obtained	☐	☐	☐
3. For research involving more than minimal risk, procedures to prevent influence by unit officers and noncommissioned officers (NCOs) on the decisions of their subordinates to participate or not participate. (e.g., unit officers and NCOs are not present during recruitment and consent process)	☐	☐	☐
4. When a percentage of the unit is being recruited to participate as a group, an ombudsman (independent from research and unit) will be present to monitor the recruitment briefings	☐	☐	☐
Comments or Concerns:			

B. Adults with Impaired Capacity for Decision-Making	Yes	No	N/A
1. Procedures to assess subjects' decisional capacity and understanding of the research are adequate	☐	☐	☐
2. Procedures for obtaining consent from legally authorized representative are adequate	☐	☐	☐
3. Protections for subjects' with impaired decision making are adequate	☐	☐	☐
Comments and Concerns:			

C. Other Vulnerable Subjects	Yes	No	N/A
Procedures to address subjects' vulnerabilities are included, appropriate, and adequate (e.g., provisions for coercion and operational commitments)	☐	☐	☐
Comments or Concerns:			

PART C – DOCUMENTATION REVIEWED

4. Please check if you have reviewed the following additional documentation:

I have personally reviewed:	Yes	No	N/A
a. Investigator assurance	☐	☐	☐
b. Research protocol, clinical investigator's brochure, grant application (as applicable)	☐	☐	☐
c. Current informed consent, parental permission, and/or child assent documents	☐	☐	☐
d. Proposed informed consent, parental permission, and/or child assent documents (if applicable)	☐	☐	☐
e. Forms for non-English speakers	☐	☐	☐
f. Previous initial review packet	☐	☐	☐
g. Previous continuing review packet	☐	☐	☐
h. Host country government approvals (if necessary)	☐	☐	☐
i. Host country ethical approvals (if necessary)	☐	☐	☐
j. Collaborating institutions' IRB approvals	☐	☐	☐

Comments or Concerns:

Revised 9/15