TANEY COUNTY HEALTH DEPARTMENT

IRB CHECKLIST – INITIAL 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): ☐ 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
Recommended Total Enrollment Number (upper limit):	Comments or Concerns:
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 background information for the proposed research.

	Yes	No	N/A
a. Agency personnel have completed human subject protection training	☐	☐	☐
b. Lead researcher is appropriate to serve as Principal Investigator	☐	☐	☐
c. Sponsorship of the research is clear and appropriate	☐	☐	☐
d. Purpose of the research is clear and appropriate	☐	☐	☐
e. Collaborative relationships are clear and appropriate	☐	☐	☐
f. Specimen banking procedures are clear and adequately discussed in protocol and consent document	☐	☐	☐
g. DNA testing procedures are clear and adequately discussed in protocol and consent document	☐	☐	☐
h. Procedures for use of FDA-regulated products are clear and IND/IDE information is adequate	☐	☐	☐
i. Host country approval obtained and documentation received (If necessary)	☐	☐	☐
j. IRB approval from collaborating institutions obtained	☐	☐	☐

Comments or Concerns:

PART B – REGULATORY CRITERIA FOR APPROVALS

Regulatory Criteria: In order to approve research, the IRB must have sufficient information to determine that the eight criteria below have been satisfied. These criteria include: (1) risks are minimized through sound research design; (2) risks are reasonable relative to anticipated benefits; (3) selection of subjects is equitable; (4) informed consent will be obtained; (5) informed consent will be documented; (6) privacy and confidentiality provisions are adequate; (7) data safety monitoring is adequate; (8) appropriate safeguards are included for vulnerable subjects.

1. Risks Are Minimized & Reasonable in Relation to Benefits *(please note and comment below as to whether the following elements are adequately addressed)***:**

Risks include physical, psychological, emotional and social harms (e.g., stigmatization, loss of service, loss of employment, etc.) Examine the research plan, including research design and methodology, to determine that there are no flaws that would place subjects at unnecessary risk. **Risk/benefit analysis** evaluates the most current information about the risk and benefits of the interventions involved in the research, in addition to information about the reliability of this information. Consider only those risks that result from the research rather than the long-range effects (e.g., public policy implications) of applying the knowledge gained in the research.

	Yes	No	N/A
a. All risks to subjects are clearly and accurately identified and considered	☐	☐	☐
b. Risks to others (e.g., relatives, friends) are accurately identified and considered	☐	☐	☐
c. Risks are minimized through sound research design	☐	☐	☐
d. Research personnel are qualified	☐	☐	☐
e. Anticipated benefits to subject and importance of knowledge to be gained are clearly and accurately identified	☐	☐	☐
f. Risks are reasonable in relation to anticipated benefits	☐	☐	☐

Comments or Concerns:

2. Recruitment and Selection of Subjects Are Equitable *(please note and comment below as to whether the following elements are adequately addressed)*:

	Yes	No
a. Active duty military representation is appropriate *(if involved, please complete Question 7)*	☐	☐
b. Minority/ethnic representation is appropriate	☐	☐
c. Gender representation is appropriate	☐	☐
d. Recruitment methods and advertising materials are non-coercive and appropriate	☐	☐
e. Selection of subjects is equitable	☐	☐
f. Children; pregnant women, fetuses, or, neonates; or prisoners are involved *(If Yes, please complete Question 7)*	☐	☐

Comments for Concerns:

3. Informed Consent Is Obtained and Documented *(please note and comment below as to whether the following elements are adequately addressed)*:

	Yes	No	N/A
a. Informed consent **process** is described adequately *(if informed consent is waived, complete Part C, Waiver of Informed Consent)*	☐	☐	☐
b. Circumstances of consent (e.g., timing, place, person obtaining consent) minimize coercion or undue influence *(if vulnerable subjects are involved, complete Question 7)*	☐	☐	☐
c. For greater than minimal risk research, the signature on the informed consent document will be performed in the presence of a witness	☐	☐	☐
d. Informed consent will be **documented** by obtaining a written consent form that is **signed and dated** *(if documentation is waived, complete Part C, Waiver of Informed Consent)*	☐	☐	☐
e. The informed consent document does not include exculpatory language (i.e., waiving or appearing to waive any of the subject's legal rights, or releasing or appearing to release the investigator, the sponsor, the institution or its agents form liability for negligence.	☐	☐	☐
f. The informed consent document does not include complex language (e.g., technical terms or un-defined medical terms)	☐	☐	☐
g. The informed consent document does not include coercive language (e.g., use of first person)	☐	☐	☐
h. Appropriate translated and back-translated consent forms are available for anticipated non-English speaking subjects	☐	☐	☐
i. The following **8 required elements** below are included:			
1) Statement that study involves research and includes including the purpose, duration, procedures, identification of experimental procedures	☐	☐	☐
2) Disclosure of reasonably foreseeable risks or discomforts	☐	☐	☐
3) Description of any benefits to subjects or others	☐	☐	☐
4) Disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to subjects	☐	☐	☐
5) Description of the extent to which confidentiality of records will be maintained (including that records may be inspected by monitors, the Study Sponsor, or Federal funding agency).	☐	☐	☐
6) If research is more than minimal risk, whether any compensation or medical treatments are available for injury with description.	☐	☐	☐
7) Three contacts: study information (PI's name & phone number), research related injury, subjects' rights (IRB)	☐	☐	☐
8) Voluntary participation, including "refusing to participate or withdrawing from the research involve no penalty or loss of benefits to which the subject is otherwise entitled"	☐	☐	☐

j. The following **additional elements as appropriate** (i.e., greater than minimal risk studies) are include:			
	Yes	No	N/A
1) Unforeseeable risks	☐	☐	☐
2) Investigator-Initiated Termination of Participation	☐	☐	☐
3) Additional Costs	☐	☐	☐
4) Early Withdrawal/Procedures for Termination	☐	☐	☐
5) Significant New Findings	☐	☐	☐
6) Approximate Number of Subjects	☐	☐	☐
Comments or Concerns:			

4. Privacy & Confidentiality Protections Are Adequate *(please note and comment below as to whether the following elements are adequately addressed)***:**

Considerations: Consider the nature, probability, and magnitude of harms that would be likely to result from a disclosure of collected information outside the research. Evaluate the effectiveness of proposed anonymizing techniques, coding systems, encryption methods, storage facilities, access limitations, and other relevant factors in determining the adequacy of confidentiality protections. **Sensitive information** includes, but is not limited to, child abuse, violence, some infectious diseases, conditions affecting insurability, compensation or litigation, etc. Research records are not medical records and can be subpoenaed.

	Yes	No	N/A
a. Methods for obtaining, recording, and coding of data and/or samples (e.g., saliva, blood, tissue) are described and satisfactory	☐	☐	☐
b. Storage of data and/or samples is described and satisfactory	☐	☐	☐
c. Procedures for sharing (including electronic transmission) of data and/or samples are described and satisfactory	☐	☐	☐
d. Provisions protecting the privacy of subjects and the confidentiality of data/records are adequate and appropriate	☐	☐	☐
e. Plans for de-identification of data at completion of study or rationale for not de-identifying data are adequate and appropriate	☐	☐	☐
f. Plans for storage and retention or records are described and satisfactory	☐	☐	☐
g. Plans for future use and disallowance are adequate and satisfactory	☐	☐	☐
Comments or Concerns:			

5. Safety Monitoring Is Adequate *(please note and comment below as to whether the following elements are adequately addressed)*:

The IRB must determine that, where appropriate, the research plan makes adequate provision for monitoring the data to protect the safety of subjects. For research in which risks are substantial, a detailed description of the data and safety monitoring plan should be submitted as part of the proposal. This plan should contain reporting adverse events procedures.

	Yes	No	N/A
a. Independent medical monitor has been identified by name	☐	☐	☐
b. Independent medical monitor responsibilities are clearly described and appropriate (e.g., assess subject recruitment, subject enrollment, data collection, or data storage and analysis.)	☐	☐	☐
c. Internal and/or external data safety monitoring will occur	☐	☐	☐
d. A Data Safety Monitoring Board or Data Monitoring Committee has been established	☐	☐	☐
e. Overall safety monitoring is adequate and appropriate (e.g., stopping criteria for FDA-regulated research)	☐	☐	☐

Comments or Concerns:

6. 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 – WAIVER OF CONSENT OR DOCUMENTATION OF CONSENT

Note: These criteria also apply to waiver of parental permission or waiver of child assent. Waiver of informed consent, waiver of parental permission, and waiver of documentation are **NOT permitted under FDA regulations** or for the involvement in research of nonviable neonates.

Pursuant to 10 USC 980, waiver of informed consent is **NOT permitted for "research involving experimental subjects."**

7. Criteria for Waiver of Consent (or Permission or Assent) *(please verify that the criteria have been satisfied.)*

	Yes	No	N/A
a. The research involves no more than minimal risk; **AND**	☐	☐	☐
b. Waiver/alteration will not adversely affect rights and welfare of subjects; **AND**	☐	☐	☐
c. The research could not practicably be conducted without waiver/alteration; **AND**	☐	☐	☐
d. Whenever appropriate, subjects will be provided additional pertinent information after participation.	☐	☐	☐

Comments or Concerns:

8. Criteria for Waiver of Documentation Only *(please verify that the criteria have been satisfied.)*

	Yes	No	N/A
a. The only record linking the subject to the research would be the consent form, and the principal risk to the subject would be potential harm resulting from breach of confidentiality; **OR**	☐	☐	☐
b. The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is not normally required outside of the research context	☐	☐	☐

Comments or Concerns:

PART D – DOCUMENTATION REVIEWED

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

I have personally reviewed:	Yes	No	N/A
a. Investigator assurance (signed by all investigators)	☐	☐	☐
b. Privacy Act Statement (applicable if volunteers are U.S. citizens or legally admitted foreign nations)	☐	☐	☐
c. Investigator *curriculum vitae*	☐	☐	☐
d. Medical monitor *curriculum vitae*	☐	☐	☐
e. Protocol (approved by IRB)	☐	☐	☐
f. Clinical investigator's brochure, package insert, PDR monograph or other labeling materials	☐	☐	☐
g. Informed consent, parental permission, and/or child assent	☐	☐	☐
h. Forms for non-English speakers	☐	☐	☐
i. Comprehension assessment instruments, i.e., quizzes	☐	☐	☐
j. Foreign language translations and back translations	☐	☐	☐
k. Advertisements, announcements, letters, or other recruiting materials	☐	☐	☐
l. Scales, survey instruments, questionnaires, interview scripts, etc.	☐	☐	☐
m. Case report forms	☐	☐	☐
n. Federal grant application	☐	☐	☐
o. Conflict of interest declarations for all researchers	☐	☐	☐
p. Host country approvals (if necessary)	☐	☐	☐
q. Collaborating institutions' IRB approvals	☐	☐	☐

Comments or Concerns:

Revised 9/15