Continuing Review Checklist for Reviewers

PI Name:	Reviewer:
Title of Protocol:	

Section 1 – Regulatory Criteria for Approval

Regulatory Criteria (Section 111 Criteria): The following information is designed to assist the reviewer in determining that the Federally required criteria for IRB approval codified at 38 CFR Part 16.111, FDA regulations, and the Common Rule continue to be met.

Regulatory criteria for approval *(please note and comment below as to whether the following elements continue to be met)***:**

	Yes	No	NA
a. **Risks to subjects are minimized: (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.**	☐	☐	
b. **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 (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.**	☐	☐	
c. **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 and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.**	☐	☐	
d. **Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by §46.116.** (or has previously been waived by the IRB)	☐	☐	

e. **Informed consent will be appropriately documented, in accordance with, and to the extent required by §46.117.** (or has previously been waived by the IRB)	☐	☐	

	Yes	No	NA
f. **When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.**	☐	☐	☐
g. **When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.**	☐	☐	☐
h. **When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.**	☐	☐	☐

Section 2 – Continuing Review Issues

Please verify the following continuing review information for the research.

	Yes	No	NA
a. Preliminary results and interim findings are summarized adequately	☐	☐	☐
b. Publications relative to the research are summarized adequately	☐	☐	☐
c. Problems and/or changes to the research since the last IRB review are summarized adequately.	☐	☐	☐
d. The number of subjects enrolled corresponds to the number approved for enrollment	☐	☐	☐
e. Subject accrual is summarized adequately	☐	☐	☐
f. A summary of any withdrawal of subjects from the research since the last IRB review is described adequately	☐	☐	☐
g. A summary of any relevant information regarding this research, especially information about risks associated with the research is described adequately	☐	☐	☐
h. Study-wide or multi-center trial reports received since the last IRB review are included with the continuing review	☐	☐	☐
i. Data Safety Monitoring Reports received since the last IRB review are included with the continuing review	☐	☐	☐
j. A summary of any unanticipated problems and available information regarding adverse events since the last IRB review is described adequately	☐	☐	☐

k. A summary of any unanticipated problems and available information regarding adverse events (in many cases, such a summary could be a simple brief statement that there have been no unanticipated problems and that adverse events have occurred at the expected frequency and level of severity as documented in the research protocol, the informed consent document, and any investigator brochure) is described adequately	☐	☐	☐
l. A summary of any complaints about the research since the last IRB review is described adequately	☐	☐	☐
m. Any benefits experienced by the subjects are summarized adequately	☐	☐	☐
n. The investigator has been using the current, IRB stamped approved informed consent document	☐	☐	☐
o. The currently approved consent document is still accurate and complete	☐	☐	☐
p. The research project and progress to date are described adequately	☐	☐	
q. Overall, continuing review information is adequate	☐	☐	

Comments or Concerns:

Section 3 – Additional Documentation

a. **Are there any new significant findings that may relate to the subject's willingness to continue participation in this research project?** ***If no proceed to item 10.***	☐	☐	
b. **Are the new significant findings stated in the informed consent form:**	☐	☐	
c. Should the PI notify currently enrolled subjects of this information?	☐	☐	

Comments or Concerns:

Section 4 – Reviewer Recommendations

1. 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**

2. Device Category *(please check one)*:

- ☐ **Not applicable**
- ☐ **Significant risk**
- ☐ **Non-significant risk**

3. Independent Verification of No Material Changes Since Previous IRB Review *(check one)*:

☐ **Not Recommended** ☐ **Recommended** *(please comment)*:

4. Recommended IRB Action *(check one)*:

- ☐ **Approve as submitted**
- ☐ **Board modifications (pending non-substantive changes described below)**
- ☐ **Defer for the reasons described below**
- ☐ **Disapprove for the reasons described below**

Comments or Concerns:

5. Continuing Review Frequency *(check one)*:

☐ **12 months** ☐ **6 months** ☐ **Other:**

6. Type of Review *(check one)*:

- ☐ **Recommendations to Convened IRB**
- ☐ **Determination by Expedited Reviewer Acting on Behalf of the IRB, Complete Expedited Review Determinations on the last page of this form**

As a reviewer, are you an investigator, consultant, collaborator, or study personnel on the proposed study; do you have a financial interest in the study; or do you have any other conflict of interest with this study? ☐ **Yes**** ☐ **No**

****If yes, please do <u>not</u> perform the review and contact the Office of Research Integrity and Compliance at (304) 293-7073.**

EXPEDITED REVIEW DETERMINATIONS

Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the allowable categories, may be reviewed by the IRB through the expedited review procedure. The activities listed should not be deemed to be of minimal risk simply because they are included on the list. Inclusion on the list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

EXPEDITED REVIEW CRITERIA

1. **The research is no more than minimal risk.**
   ☐ Yes
   ☐ No. If the research is more than minimal risk, it is not eligible for expedited review.

2. **The research is not classified.**
   ☐ Yes
   ☐ No. If the research is classified, it is not eligible for expedited review.

3. **Would identification of the subjects and/or their responses reasonably place them at risk of criminal or civil liability or be damaging to the subjects= financial standing, employability, insurability, reputation, or be stigmatizing.**
   ☐ Yes.
   If yes, have reasonable and appropriate protections implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal?
   ☐ Yes ☐ No (If No, the research is not eligible for expedited review).
   ☐ No

ELIGIBLE CATEGORIES

Clinical studies of medical devices only when following condition is met. **(a)** Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.	☐ **Yes** ☐ **No**
Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows: **(a)** from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or **(b)** from other adults and children[2], considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.	☐ **Yes** ☐ **No**

Prospective collection of biological specimens for research purposes by noninvasive means.	☐ **Yes** ☐ **No**
Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, **excluding procedures involving x-rays or microwaves.**	☐ **Yes** ☐ **No**
Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for **non-research purposes** (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)	☐ **Yes** ☐ **No**
Collection of data from voice, video, digital, or image recordings made for research purposes.	☐ **Yes** ☐ **No**
Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. **(NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)**	☐ **Yes** ☐ **No**
Continuing review of research previously approved by the convened IRB as follows: (a) where : (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or, (b) where no subjects have been enrolled and no additional risks have been identified; or, (c) Where the remaining research activities are limited to data analysis.	☐ **Yes** ☐ **No**
Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.	☐ **Yes** ☐ **No**

DETERMINATION

Based on the information in the protocol, I have made the following determination:

- ☐ The activity is not eligible for expedited review and must be reviewed by the full IRB
- ☐ The activity is eligible for expedite review but should be reviewed by the full IRB I recommend:
  - ☐ Approval
  - ☐ Modifications (see below)
  - ☐ Disapproval
- ☐ The activity is eligible for expedited review and is:
  - ☐ Approved
  - ☐ Modifications required (see below)

Please list any changes, modifications, or clarifications required to the research protocol, informed consent form, or IRB application. If the research is to be deferred or disapproved, please also provide a brief explanation.