Emory IRB Continuing Review Checklist

1. Do you have a conflict of interest with this project?
2. Do you think there is a need for a consultant to assist in the review?
3. Can this CR be reviewed using the expedited procedure? Expedited review is permitted all of the following are true:
    a. The remaining research procedures present no more than minimal risk to participants. (Not applicable to category (ii) below)
    b. The identification of the participants or their responses will not reasonably place them at risk of criminal or civil liability or be damaging to their financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal. (Not applicable to category (ii) below)
    c. The research is not classified.
    d. The research falls into one or more of the following categories:
        i. The research is permanently closed to enrollment of new subjects and the research remains active only for long-term follow-up such as medical records review and telephone follow-up. NOTE: If one of the research follow-up procedures is an intervention such as blood draw or an X-ray, the renewal is not eligible for expedited review.
        ii. No subjects have ever been enrolled locally and no additional risks have been identified since the last Full-Board review.
        iii. Studies initially reviewed using expedited review and the study procedures continue to qualify for expedited review.
4. Should verification be obtained from sources other than the PI that no material changes have taken place since prior IRB review?
5. Should review take place more often than annually?

If you answered "Yes" to any of the above, please report this to the IRB office as soon as possible so we may assist with the review of this project.

Criterion for Continuing Review Approval
The risks to subjects remain minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk.
The risks to subjects remain minimized whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
The risks to subjects remain reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.
The number of participants initially requested and approved has not been exceeded.
Subject selection remains equitable.
When some or all participants are likely to be vulnerable to coercion or undue influence, additional safeguards are included.
Specific additional protections are included for research involving pregnant women, fetuses,

neonates, prisoners, or children as specified in the regulations.
Unless waived or altered, 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 the regulations. • The investigator will obtain the legally effective informed consent of the participant or the participant's legally authorized representative. • The circumstances of consent provide the prospective participant or the representative sufficient opportunity to consider whether or not to participate. • The circumstances of consent minimize the possibility of coercion or undue influence. • The information that will be given to the participant or the representative will be in language understandable to the participant or the representative. • No information will be provided to the participant or the representative that waives or appears to waive any of the participant's legal rights, or that releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence. • All required and appropriate additional disclosures will be provided to the participant or the participant's representative. *(See Elements of Informed Consent Disclosure)*
Unless waived, informed consent will be appropriately documented, in accordance with, and to the extent required by regulations
The consent document remains accurate and complete based on your review of the progress of the research and reported events.
For research involving more than minimal risk to participants, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
Procedures for protecting the subject's privacy interests remain adequate.
Procedures for maintaining the confidentiality of data remain adequate.

Please make sure you have reviewed the following:

1. The initial IRB Application updated with any changes
2. The Continuing Review Application
3. The current consent document
4. Any newly proposed consent document or amendment
5. The complete protocol including any protocol modifications previously approved by the IRB
6. Any reported events and a summary of reported events for internal and external sites, if applicable.
7. A summary of withdrawals and reasons for them