**Criteria for IRB Approval – Supplemental Form for Major Changes**

The McLeod Health IRB has adopted this form to more efficiently and thoroughly review major changes
to ongoing human subject research. **This form must be completed and accompany your “Revisions, Addendums, and Updates Form,” whenever a major change (i.e. affecting study conduct, subject risks/benefits, etc.) is submitted to the IRB for approval.** Please type all responses. Contact the IRB Coordinator if you are unsure whether your proposed change is “major” or need help filling out this form.

Name of Principal Investigator:

Study/protocol title:

Submission type (e.g. addenda, amendment, etc.):

Amendment/addenda number(s) or name(s), if applicable:

**Criteria for IRB Approval**
*Based on the regulations at 45 CFR 46.111*

1. **Risks to subjects must be minimized.** Are new risks being added to the research? [ ]  No [ ]  Yes\*
\*If yes, please justify:
2. **Any risks to subjects must be reasonable in relation to those subjects’ anticipated benefits, and in relation to the importance of the knowledge expected to be gained from the research.**Will subject benefits (or the risk/benefit ratio) be affected in any way by this change in the research? [ ]  No [ ]  Yes, in this way:
3. **The selection of subjects must be equitable (i.e. fair and impartial).** Are the inclusion/exclusion criteria being changed in any way? [ ]  No [ ]  Yes, they are changing as follows and for this reason:
4. **Informed consent must be sought from each prospective subject (or their legal representative) unless waived by the IRB.** Will the process of obtaining informed consent change in any way?
[ ]  No [ ]  N/A (consent already waived) [ ]  Yes, in this way:
5. **Informed consent must be appropriately documented unless waived by the IRB.** Is the consent form being altered in any way? [ ]  No [ ]  N/A (form and/or signature already waived) [ ]  Yes,
in this way: Does the alteration affect HIPAA authorization\* language? [ ]  No [ ]  N/A (or separate form) [ ]  Yes
6. **The research plan contains adequate provisions for monitoring collected data to ensure the subjects’ safety.** Is the manner in which data is monitored affected by this change in the research?
[ ]  No [ ]  Yes, data monitoring is changing as follows:
7. **Adequate provisions are made to protect subject privacy and maintain data confidentiality.**Will subject privacy or data confidentiality be affected by this change in the research? [ ]  No [ ]  Yes, and the following means of protection have been added or are in place:
8. **If the study will recruit vulnerable subjects (e.g. children, persons of economic disadvantage or intellectual disability, etc.), added safeguards are present to protect their rights and welfare.**Are any vulnerable subjects currently enrolled, or might they become enrolled in the future? [ ]  No [ ]  Yes, and the safeguards in place for them are affected/altered as follows:

**Does your revised research study satisfy all of the approval criteria (1-8) listed on this form?**[ ]  Yes [ ]  No *(You must contact the IRB Coordinator to address any criteria that are not satisfied.)*

*\*Specific authorization elements are required to satisfy HIPAA. Contact the IRB office for further info.*

Additional comments, if any:

**Principal Investigator Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** **Date:** \_\_\_\_\_\_\_\_\_\_\_\_\_

Please send your completed, signed form and all other research submission materials to:

Noah Kleckner, IRB Coordinator
McLeod Health – Research Department
(843) 777-2013
nkleckner@mcleodhealth.org

**IRB USE ONLY – Primary Reviewer Feedback**

IRB Member: Using this form or a separate document, address the items below and sign. Remember to base your review not just on the information provided by the Principal Investigator above, but on all the study materials (protocol, consent form, etc.) that were submitted to the IRB.

* Identify any IRB approval criteria (cf. 45 CFR 46.111) that you feel are NOT satisfied for this study.
* Recommend an action (e.g. approve, approve with conditions, etc.) for the IRB to take regarding this study/submission, OR list questions that you have for the Principal Investigator and/or the Board.

Primary Reviewer Name:

Primary Reviewer Signature: Date: