** **

**Legacy Health IRB**

**RESEARCH STUDY MODIFICATION FORM -- Version 8-4-22**

**Form F Instructions**

Form F is to be used for any important proposed change in the research study, which includes minor or major modifications to the protocol or consent/assent forms, change of procedures or planned number of subjects or duration of the research, new or newly revised documents, advertisements or recruitment or other subject materials, addition of study staff, a change in the principal investigator (PI), addition of a new site, updated investigator brochures, changes in research required by the sponsor such as study halts or delays in recruitment, or new any information that affects the conduct of the study. Form F should also be used for minor or administrative changes that need to be documented.

Form F and relevant documents for review must be submitted to irbsubmissions@lhs.org. for IRB review and approval before the proposed change can be implemented.

**Submission Requirements**

Indicate new changes to the study by submitting new study documents, revised study documents **(tracked and clean copies are both required)** showing new versions and dates, documents showing addition of study staff or change in PI, and other changes in research (new sites, miscellaneous sponsor documents, study enrollment halt, etc.). New study staff changes musts be accompanied with CITI training documentation. A change in PI will require that the new PI submit CITI training documentation and an updated CV showing that they are qualified to conduct the study.

**Revisions, Modifications or Amendments**

Form F lists various categories of common amendments or changes to research. Select all that apply from the list. If there is an item that does not fit the specific categories, select “other” and describe the requested modification in detail and submit documents that support the requested change. Provide a brief summary of the requested change and the reasons for the change.

**Subject Notification of Changes in Research**

Research regulations require that subjects be notified of changes in research when the changes may relate to the subjects' willingness to continue their participation in the study (21 CFR 50.25(b)(5)). Therefore, the PI must assess whether the proposed change(s) in research will affect subjects who are actively enrolled and participating in the research regarding study procedures, risks, benefits, costs, compensation, number of visits, duration of study, standard treatment, or any other factor that might affect their willingness to continue to participate. The PI must therefore indicate on Form F a plan to notify enrolled subjects regarding the changes and propose the method that will best accomplish notification to subjects. Various methods to notify subjects may include re-consent with a revised consent form, consent via an addendum consent form, notification by letter, or other methods that provide adequate information to subjects. The PI must also indicate when notification will be done.

The IRB will determine if the PI’s plan for notification of subjects is adequate or whether additional procedures are needed.

**WHO TO CONTACT FOR FURTHER INFORMATION OR IF YOU HAVE QUESTIONS:**

**Paul Newton, JD, CIP**

Senior Research Regulatory Specialist

Research Administration

Legacy Research Institute

1225 NE 2nd Ave

Portland, OR 97232

Phone (503) 413-5355

pwnewton@lhs.org