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Standard Operating Procedure
Protocol Amendment

Purpose:
This SOP outlines the steps taken to ensure local and federal compliance when making changes to an IRB approved protocol including addition of new investigators, employees and/or research sites.

Procedure:

1) The PI decides to make changes to the IRB approved protocol.
2) No research will be conducted or new research data collected based on the amendment until the requested changes have been approved by the IRB except to eliminate an apparent, immediate hazard to subjects. If this occurs it should be documented in the regulatory binder.
3) The FDA and/or sponsor should be informed of any significant changes when applicable.
4) A member of the research team prepares the submission to the IRB, following the explicit and current instructions of the IRB of record.
5) A full copy of the IRB amendment submission sent to the IRB will be placed in the regulatory binder as well as any new advertisements, survey tools, etc. being reviewed.
6) A member of the research team will note this IRB submission on the IRB submission log, stored in the front of the regulatory binder for this study.
7) In parallel or series, other institutional approvals for the amendment such as the hospital or CTRC will be obtained.
8) Upon receipt of the approval certificate from the IRB, the coordinator will:
    a. Place a copy of the IRB approval certificate in the regulatory binder.
    b. If the protocol was amended, then the newly approved protocol will replace the last approved protocol. The last approved protocol will be stapled and moved to the “Old Protocols” section of the regulatory binder.
    c. If the amendment revised the ICF and a newly approved ICF is included in the approval packet, the last approved ICF is removed from the regulatory binder, stapled, and placed in the “Old ICFs” section of the regulatory binder.
    d. The new ICF is placed in a clear sleeve at the front of the binder for easy access by research staff.

For minor changes:

9) A member of the research team will send out via email: a copy of the revised protocol (if applicable), a memo detailing changes, and the ICF (if applicable) to all members of the study team, with a note to contact the PI with questions.
10) A member of the research team will add to the agenda for the next research team meeting, protocol review and implementation discussion, along with copies of the amended protocol and ICF (if applicable).

11) Protocol Amendment review by the study team at the regular research review meeting:
    a. New changes will be reviewed by the study team
    b. All changes to the protocol, consent form, items given to the subjects, will be IRB-approved prior to implementation
    c. PI will address questions
    d. Minutes of the meeting will be written for future reference
    e. A training log will be signed by all meeting attendees documenting that review/training on the changes (also listed on the training log) took place (include ancillary staff when appropriate)
    f. The training log is saved with the delegation of duty log, in the study-specific regulatory binder/file

For significant changes:

12) The research team needs to decide when the approved amendment will be implemented.
13) Applicable research documents such as screening tool, inclusion/exclusion form or research calendar need to be changed to reflect the approved amendment. The start date for the new documents should be identified on the revised forms.
14) The research team must be trained to the new procedure(s) and this process needs to be documented in the training log.
15) The delegation of duties log should be updated if necessary.
16) Revised documents should be added to the regulatory binder.

<u>New Materials or Changes to Materials Given to Subjects with/without ICF changes</u>

17) All materials given to study subjects will be reviewed and approved by the IRB prior to being given to study subjects.
18) A member of the research team will submit new/revised materials to the IRB, following the explicit and current instructions on the IRB of record's website.
19) The process as outlined for *Amendments* should be followed.
20) In addition, if the IRB indicates that all subjects must sign the new ICF, the research team will ensure that the new ICF is available at each subject's next study visit, so that they can be re-consented on this new ICF version.
21) The re-consenting process should be documented on the consenting log or separate re-consenting log.

<u>Adding new investigators/staff</u>

22) The PI will identify new investigators/staff.
23) The new personnel must take all University-required training (i.e. CITI and HIPS). The new investigator will consult the IRB website for most current required training.
24) The new personnel must declare any potential conflict of interest in accordance with UCD policy.

25) The study coordinator will submit the necessary documents to the IRB, following current instructions on the IRB of record's website, detailing the new team member's role.
26) The process will follow that outlined for *Amendments* above.
27) In addition:
    a. The CV for the new personnel and a copy of any applicable licenses should be added to the study binder
    b. The new personnel should review the SOPs under which the study is being operationalized
    c. The new personnel should undergo applicable protocol specific training and this process should be documented in the training log
    d. The delegation log should be updated to include the role and responsibilities for this study
    e. Applicable FDA regulated documents such as the 1572 form should be updated
    f. The new personnel should be orientated to the current status of the study

<u>Adding a new site</u>

28) Need to follow the policies and procedures of the new site to obtain the necessary approvals to conduct research at that institution.
29) If the site is to be engaged in research then the research protocol and accompanying documents must be submitted to the new institution's IRB for approval. If the site is not engaged than letters of permission may suffice.
30) An amendment must also be submitted to the IRB of record updating the research protocol to include the additional site following the process outlined above for *Amendment.*
31) All new investigators/staff who will be conducting research at the new site should be added to the amendment and the process detailed for *new investigators/staff* detailed above must be followed.
32) In addition:
    a. Site initiation orientation and training to the study should occur and be documented on the training log for all new persons added to the delegation log
    b. Processes should be developed to ensure that each site has access to the latest versions of the protocol, ICF and other IRB approved documents
    c. Adverse event reporting mechanisms should be established
    d. Additional communication mechanisms established

Forms:

Delegation of Duty Log
Training Log
Sample research team meeting agenda
IRB Submission Log

APPLICABLE REGULATIONS AND GUIDELINES

US Department of Health & Human Services	45 CFR 46
FDA	21 CFR 50 and 56
UCD Human Research Protection Program	Investigator Responsibilities for the Protection of Human Subjects