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Minimum Submission Standards Implemented

May 2, 2014

As part of the Committee on Human Research (CHR) process improvement project analysis, we discovered that poorly-prepared submissions negatively impacted the review and approval times of well-prepared submissions by diverting significant time and resources to a small fraction of poorly prepared submissions. Consequently, the CHR office is implementing consistent minimum submission standards. Instituting this new procedure will enable CHR staff to focus on well-prepared applications, resulting in faster reviews and approvals overall.

Submission Standards

Initial new study applications should be complete and ?review-ready? when they are first submitted to the CHR. The CHR?s Preparation Tips are included below.

Effective May 12, 2014 the CHR will begin returning to the PI without review new study applications that are incomplete or do not meet minimum submission standards. Revised submissions will be processed in order of the date received complete and review-ready.

Descriptions of the return criteria for the ?Incomplete? or ?Submission Standards Not Met? determinations are provided below and on the CHR website [1].

?Incomplete?
Submissions will be sent back as ?Incomplete? for the following reasons:

- Missing scientific or feasibility approval (as required) [UPDATE: No longer required, as of 6/15/15 [2].)
- Missing study protocol (as required or available). All greater than minimal risk studies must have a scientific protocol.
- Missing Human Subjects Section of your federal grant if UCSF is awardee institution
- Missing Investigator?s Brochure (if required)
- Missing consent documents or consent in the wrong format

?Submission Standards Not Met?
Submissions will be sent back as ?Submission Standards Not Met? if significant issues/ambiguities are identified prior to CHR review. The most common issues include:

- Incomplete, incorrect or unreadable responses to the CHR form/application
- Major inconsistencies within or between documents (e.g., consent form does not match protocol)

- Important attachments are missing that are needed for the review (e.g. recruitment materials, non-standard instruments, etc.)

If you have any questions or concerns about the new standards, please contact Liz Tioupine at 502-3193 or elizabeth.tioupine@ucsf.edu [3].

New Study Preparation Tips

The CHR highly recommends PI?s log into iRIS to review submissions in their entirety BEFORE study staff route to them for signoff in iRIS. Once routed for signoff, the submission has to be retracted before any changes can be made.

CHR Study Application

- Provide the requested information in an easy to read summary of the study.
- As much as possible, avoid the use of jargon, define acronyms, and provide context for uncommon procedures to help the committee members quickly understand what the research involves and assess risk.
- Use care when sourcing information from the Sponsor?s Protocol ? some protocols are well written and brief while others include too much detail for the IRB review. Most content will need to be edited down.
- Proof-read the entire application, checking for clarity, completeness and consistency throughout.
- If you started with a copy of another study, pay careful attention to ensuring that any remnants of the original study have been removed and replaced with details about the new study. Leftover references to procedures and risks from other studies are a common cause for confusion and return by the committee.

Consent Documents

- Write the consent forms in UCSF?s format.
- Use simple 8th grade level language.
- Define all medical and technical terms and acronyms.
- Do not alter the Treatment and Compensation for Injury language (see the CHR?s website for explanation of restrictions on changes).
- Proof-read the consent forms carefully. The CHR will no longer ask you to fix typos.

Study Documents

- Use easy to interpret document names and categories so reviewers can quickly see what it is.
- Proof-read the attachments and make sure they are consistent with the Study Application.

Before You Submit

- Review the Initial Review Submission Checklist [4] prior to submitting to make sure the submission includes all the required components.
- Proof-read the submission to ensure there aren?t inconsistencies between sections or between the application and attachments.

Links
[1] http://irb.ucsf.edu/new-study
[2] http://irb.ucsf.edu/news/changes-scientific-and-feasibility-review-requirement
[3] mailto:elizabeth.tioupine@ucsf.edu
[4] http://irb.ucsf.edu/sites/hrpp.ucsf.edu/files/initial-submission-checklist.pdf