Tips from CPHS for Successful Submissions

Initial Submissions

1. When submitting a new study for review, please make sure your protocol, application, and consent forms contain identical information.
2. Please READ the form questions.
3. Attach study documents. Please do not copy and paste your protocol into the "Study Summary" section.
4. Do not upload every CRF as a separate document
5. When developing a recruitment plan, try to make a plan where subjects contact you (the study team) to enroll. No cold calling.
6. Please do not list compensation amounts in recruitment materials.
7. Be careful how you answer the questions in the "Study Procedures, Clinical Services" section.
8. Please route the initial submission to the PI and all Co-PIs for sign off on the conflict of interest statement
9. After submissions have been routed and signed, please do not retract them. You will lose all your signatures.
10. After you submit a new study for review, please be responsive when we send questions. Do not wait until the morning of the meeting to respond; your study will most likely be deferred.

Change Requests

1. You can submit more than one change in a change request form.
2. Please answer question 1.10 in the change request form and give a rationale and justification for the changes requested.
3. Please revise and submit ALL documents impacted by the requested change.

Continuing Reviews

1. Question 1.7 of the continuing review form: if the study ever had contact with human subjects (i.e., provided consent in some manner), the study "involves contact with subjects."
2. In the continuing review form, when updating key study personnel, if you see that there is a person who is no longer on the study still listed or someone you've already added who isn't there, select "refresh constant fields" at the top of the form to see if those personnel disappear/appear. These forms do not automatically update—you have to force them to update.
3. Submit DSMB Reports (using the Data and Safety Monitoring Report (DSMB) form), AE's logs, and protocol deviation logs during continuing review.
4. If you know your study qualifies for waiver of continuing review, you still need to submit the continuing review for CPHS to issue that determination letter.

Stipulations

1. Do not answer a stipulation with "this will be done," only re-submit when it has been done.
2. Do not create an entirely new submission in response to a stipulation. Please answer the stipulation issued and correct the application or provide the missing documents within the same submission.
3. Attach revised documents to submissions.
4. Only re-submit when ALL the stipulations have been appropriately addressed.

Consent Forms

1. Please use the templates provided on the CPHS website.
2. When you need to revise your consent forms…DO NOT DOWNLOAD THE PDF AND TRY TO CONVERT IT TO A WORD DOCUMENT. Select "create a new version," download the Word document provided and edit that document.
    a. Consent form style guide:
        i. Use narrow margins
        ii. Remove large gaps of space/section breaks
        iii. Top margin 0.5" / Bottom margin 0.8" **Please leave the bottom right corner vacant for IRB stamp**
3. Please use the check-out/check-in function of iRIS.
4. Please do not print a lot of copies of your consent forms/study documents. These items can change and then you have wasted a bunch of paper.
5. The HIPAA language (now found in the "Privacy and Confidentiality" section) and the injury language are sections in the ICF that we cannot alter.
6. Do not submit documents that already contain an IRB Stamp; we will send those back.
7. Please submit Word versions of documents because we cannot edit PDFs.

Adverse Events

1. Adverse events (AEs) should be reported at the time of continuing review (in the adverse events log).
2. Serious adverse events (SAEs) should be reported within 7 calendar days of the first knowledge of the event.

Personnel Change Requests

1. Several people can be added or removed on the same form.
2. Please include the full name (first and last name) of the person you are adding to the study.
3. Please specify the role of the personnel you are adding
4. When changing a PI and/or adding a new Co-PI, please route to that person for COI sign off.
5. When changing to a new PI, please attach ALL revised study documents with the new PI's name.
6. Personnel changes may be included on an IRB - Change Requests and Amendments form IF and ONLY IF you are submitting other study changes in the same submission.

Education

1. Human subjects education = CITI Group 1: Biomedical Researcher and Key Personnel OR Group 2: Social and Behavioral Researchers and Key Personnel. Those are the only human subjects education courses we accept.
2. GCP training is required for clinical trials.
3. Do not indicate on a submission form that your CITI training certificate was included on another study submission.
4. Additional education is available for iRIS by attending the iRIS training class with Barbara Legate. It's free and extremely helpful
5. IRB Office hours are also a wonderful way to ask questions and learn answers.

Potpourri

1. Please allow at least 5 business days for all non-initial submissions.
2. Please include as much detail as possible with your submissions.
3. If your study will involve Memorial Hermann, (data or facilities) include the Memorial Hermann Hospital System Research Application.

4. If your study involves the Medical School and will be reviewed by the Full Board, include the Medical School Departmental Review form.
5. Include the Diagnostic and Interventional Imaging (DII) form if your study will use radiology for research purposes only.
6. Include the Pathology Review form if your study will involve banked or left over biological samples.
7. Please include the current IBC approval number (or exemption) if you study involves biological specimens.
8. You worked really hard for those letters behind your name, please include your credentials on your iRIS profile information (MD, PhD, etc.)
9. Attach your CV to your iRIS profile
10. Please do not submit the same document twice.
11. If you upload new documents into iRIS we do not know about it until you submit a change request form.
12. Current Commercial IRB options: Advarra IRB (includes Quorum) and WIRB
13. After reciprocity approval, ONLY submit personnel changes, site changes, SAEs/UPs/Protocol deviations if they are significant and result in harm, and study closure report.
14. Submit to Harris Health as well as to CPHS.
15. Please visit the CPHS website for information.
16. Please call us at 713.500.7943 or 713.500.7960 for questions about your study or help with iRIS, etc.

Study Miscellaneous Form

1. Please do not submit new or revised documents for approval using a Study Miscellaneous form. The Study Miscellaneous form should only be used for communications from the sponsor (i.e., annual updates), updated CITI training, etc.

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