Institutional Review Board (IRB) Tip Sheet

for New Investigators

Tip1: Before you Begin

Navigating the IRB process can be daunting to anyone, especially a new investigator. Begin by reviewing the documents on our website prior to your submission. Templates and Guidance documents be found on online at https://www.choa.org/research/institutional-review-board/forms. Or call us directly at 4-785-7555.

Tip 2: The Review Process

After receiving your submission, IRB staff will check for required CITI certification. No review can proceed until all study staff have completed required training. A determination is made based on risk, and your study is reviewed via an Expedited Process by the Human Protections Analyst or scheduled for Full Board review (meet once a month).

Tip 3: Approval

You may be asked to make changes to your submission prior to review. Please respond the IRB staff member who emails you the modification requests (not irb@choa.org). Please use tracked changes for changes to the protocol, consents, or Initial Submission form. Once approved, you will be sent an approval letter and stamped documents. Please note your Continuing Renewal date and enter it into your calendar NOW. You will be sent a reminder, as a courtesy, but it is better to know it is coming. It is ultimately the PI's responsibility to submit for Continuing Renewal. Also, note expiration dates on study documents, especially consents (see Tip 6 below)

Tip 4: IRB Timeline

Children's IRB meets once a month (4th Thursday). Submission deadlines are posted at https://www.choa.org/research/institutional-review-board If you have a Full Board study, be aware of these dates. It is the PI's responsibility to submit completed documents on time to be put on the agenda. Give yourself plenty of time, in case revisions need to be made prior to the meeting.

Tip 5: Study Expiration

If your study expires, no research can be conducted until approval is complete. Any data accidently collected in an expired period may not be able to be used and the study will be reviewed for non-compliance.

Tip 6: Study Documents/Materials

Even if a study document (consent, recruitment material) does not change, you will be sent approved documents with new expiration dates at each Continuing Renewal. If documents are changed through Modifications, please note Version and Approval dates and do not store old documents with new documents, to avoid confusion. Do not print out consents/surveys/HIPAA in advance and pay special attention to

Expiration and Version Dates. The study may be found non-compliant if audits find participants signed expired consent forms.

Tip 7: Making changes

All changes to a study require approval by the IRB PRIOR to initiating the change, unless the change is made to eliminate immediate harm. This includes study staff (anyone obtaining consent or accessing identifiable data), any changes to the protocol, consent or study documents. Modification forms are listed with other submission forms (link above).

Tip 8: Getting organized

Have a plan for your study files before you start the study. Contact our Compliance Manager (Emily.smotherman@choa.org) for a pre-study start up meeting for guidance on how to best organize your study and stay in compliance. Compliance reviews to assure your study meets Federal regulatory requirements can be done with or without notice.

Tip 9: Reporting

There are specific requirements for reporting Adverse Events, Unanticipated Problems, Non Compliance or Protocol Deviations. Please review our policies regarding Event Reporting or call our office.

Tip 10: CALL US!

Children's IRB is here to help you. Please feel free to call any of our staff with questions. We are here to support you and your research.

IRB Contacts

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