TEA WITH THE IRB:
TIPS FOR SUCCESSFUL SUBMISSION TO THE CHLA IRB

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Learning Objectives

- Provide you with tips for successful submissions to the CHLA IRB.

- Learn about available tools and resources to make for a successful submission.

- Learn from each other through questions & answers.

Tip #1: HSPP and IRB Website

HSPP and IRB website
(https://www.chla.org/research/hspp)
- Guidance Documents
- Education and Training
- Guidance When Obtaining Electronic Consent
- Study Protocol Templates
- Consent Templates
- Consent Form Standards and Sample Language
- Translated Short Forms
- HIPAA Authorization Templates
- ESBOR

Tip #1: HSPP and IRB Website

Where do I find…?

- A study protocol template for a chart review study
- Sample language for the risk section of the consent form
- An Assent Form template
- The phone number to the IRB administrator for my study

HSPP and IRB website:

https://www.chla.org/research/hspp

Tip #2: Google

Where do I find…?

- Sample data collection forms

- A template for a focus group guide

- An interview template

Tip #3: iStar Application – Prepare Documents

- Study Protocol
- Sponsor's Template Consent(s)
- CRFs, REDCap Forms, Data Collection Forms
- Surveys & Questionnaires
- Focus Group & Interview Guides
- Investigator Brochure

Tip #3: iStar Application – Prepare Documents

- Device Information & Brochures

- Recruitment Materials

- Consent & Assent Forms

- Research Monitoring Plan

Tip #3: iStar Application – Prepare Documents

- FDA regulatory status of drug or device
  - Documentation that includes the IND#
    - Sponsor protocol imprinted with the IND#
    - Written documentation from the sponsor documenting the IND#
    - Written communication from the FDA documenting the IND# (required if the investigator holds the IND)

Tip #3: iStar Application – Prepare Documents

- FDA regulatory status of drug or device
  - Submit Investigational Drug Exemption (IDE)
    - Device Brochure
    - Premarket Approval (PMA) (https://www.fda.gov/home)
    - 510(k) (https://www.fda.gov/home)
    - Non-Significant Risk – PI Documentation

Tip #4: Required Training

- Investigators and study team members conducting human research must have current certifications.
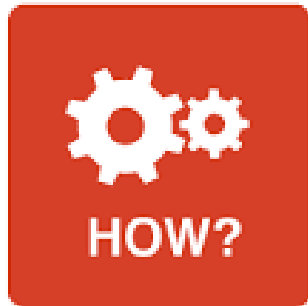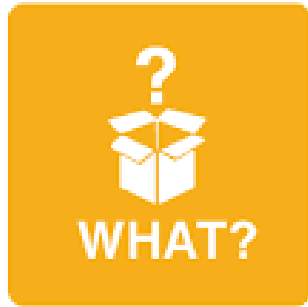
Tip #4: Required Training

- Visit CITI at: about.citiprogram.org/en/homepage/

- HIPAA certification displayed in item #2.1 is specific to USC.

Tip #5: Know Your Study Protocol

- Read the Study Protocol
- Be prepared to answer which activities will be done for research and which are done for routine clinical care

Tip #6: iStar Application – Copying/Pasting

- Avoid copying and pasting from another document.

- Reference the appropriate sections of the Study Protocol in the iStar application.

- Symbols such as less than or equal to (≤) or greater than or equal to (≥) do not always transfer correctly.

- Superscripts often used for references or footnotes do not transfer correctly.

Tip #7: iStar Application – Completeness

- Answer all the questions in the iStar application.

- Answer the questions in Section 50 of the iStar application completely and accurately.

- Skip item #22d.4 (study instructions) and item #22d.5 (instruments) if not applicable to your study.

- State "Not applicable" or "N/A" if a question does not apply to your study.

Tip #7: iStar Application – Consistency

- Check that the information provided in the iStar application is consistent throughout.

- Check that the information provided in the iStar application is consistent with the Study Protocol.

- Check that the information provided in the consent forms is consistent with the Study Protocol.

Tip #8: Instructions for Submitting Your Response

- Provide a point-by-point response of how you have addressed each item

- Click on the "Edit Study" function to enter the edit mode and make revisions to your iStar application

Current State

IRB Staff Review

Edit Study

Printer Friendly Version

View Differences
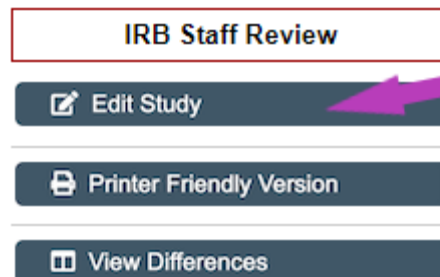
Tip #8: Instructions for Submitting Your Response

- To upload revised documents, click on the ellipsis (…) next to the documents, and then click on "Upload Revision"

Tip #8: Instructions for Submitting Your Response

- Do **not** "drag and drop" documents in iStar

- Do **not** click "+Add" to submit a revised document

- Do **not** delete any previously uploaded documents unless directed to do so

Tip #9: Contact the iStar Help Desk

- If your application is in Department or Division review for extended amounts of time

- If you have not received an "Agree to Participate" notice

- If you receive an error message

iStar Helpdesk
istar@usc.edu

323-276-2238

Tip #10: Ask for Help

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THANK YOU

- A copy of this presentation will be emailed to you.

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