Submitting Modifications to Exempt Research

Spectrum Health IRB Guidance Document

Purpose

The purpose of this document is to serve as a guide for determining if a Modification of Approved Human Research xForm needs to be submitted to the IRB for a research study determined to be exempt by the IRB. This guidance should only be used for those studies determined by the IRB to be "exempt" per DHHS regulations (45 CFR part 46). Researchers can make *minor changes* to the study without notifying the IRB if they do not impact the exempt determination of the study or any determinations related to HIPAA.

Regulatory Citations

The following regulations form the foundation for the discussion and guidance in this document.

Exemption Criteria Department of Health and Human Services 46.104
https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-a-46104/index.html

Exempt Research Frequently Asked Questions (DHHS)
https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/exempt-research-determination/index.html

HIPAA Regulations
https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-C/part-160?toc=1

Discussion and Guidance

An Investigator should first check to see if their research study has been determined to be exempt research on their IRB determination letter or in IRB Manager. If the status is exempt research, they may follow this guidance on submitting modifications to the IRB. If another status (such as expedited or full board review was determined, please follow the guidance for submitting modifications to the IRB referenced in the Investigator Manual).

Changes that need to be submitted to the IRB for exempt research are those that potentially change the overall determination of exemption, changes to the HIPAA waiver or authorization, personnel updates, or changes related to the collection of sensitive data points. Below are examples of changes that are to be submitted to the IRB. If there is a question regarding whether something should be submitted to the IRB, please contact the IRB for further guidance.

Examples of changes that SHOULD be submitted to the IRB:

- Adding new study procedures
- Adding new collaborators or outside sites (each site must obtain their own Exempt Determination or IRB Approval)

- Addition of data collection about sensitive aspects of the subjects' behavior – such as illegal conduct, substance use, HIV, sexual behavior, mental health information, collection of payment or cost data – to a survey, interview or data collection tool
- Change in Principal Investigator or other study personnel (All individuals involved in research need to complete CITI and COI requirements)
- Changes to payment (adding, revising, or removing)
- Addition of patient facing recruitment material
- Increasing or decreasing the number of subjects
- Adding new vulnerable populations (children, prisoners, cognitively impaired adults)
- The addition of any physical interventions
- Changes that increase risk (including additional or new risks related to privacy or confidentiality)
- Changes to the plans for secure storage and/or destruction of Identifiable Protected Health Information (PHI).

Examples of changes to exempt studies that <u>do not need</u> to be submitted to the IRB:

- Editorial or administrative revisions to consent documents or other study documents such as a survey tool where the changes clarify but do not alter the over meaning of the document
- Minor changes to data collection tools that do not include changes to sensitive data points
- Changes to behavioral interventions where the resulting intervention is very similar to the previous one in nature and duration, and potential for harm or discomfort remains the same
- Adding non-sensitive questions to a survey or interview or revising current questions
- Changing or adding funding information (although you may need to inform our Office of Sponsored Programs staff)

Conclusions

If you are unsure if your modification requires submission to the IRB contact the SH IRB for more information at irbassist@spectrumhealth.org