Office of Research and Education

Types of Supporting Materials that Require IRB Approval

Spectrum Health IRB Guidance Document

Purpose

This document provides guidance to study teams in determining when Institutional Review Board (IRB) review and approval of various types of documents is required. This document outlines the materials investigators are to include with their IRB applications for IRB review to ensure sufficient information is provided for the IRB to make specific determinations regarding the risks, potential benefits, informed consent and safeguards for human subjects.

This guidance provides common examples and should not be considered an exhaustive list.

Regulatory Citations

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

- Department of Health & Human Services (DHHS) *Policy for Protection of Human Research Subjects* 45 CFR §46
- Food & Drug Administration (FD) *Policy for Protection of Human Subjects* 21 CFR §50 and *Policy for Institutional Review Boards* §56
- Department of Health & Human Services (DHHS) *Policy for Security and Privacy* 45 CFR §164

Discussion and Guidance

The purpose of IRB review is to assure that appropriate steps are taken to protect the rights and welfare of humans participating as subjects in research. To accomplish this purpose, IRBs will review research protocols and various related materials (e.g., informed consent documents, investigator brochures, recruitment material, etc.).

The IRB reviews and approves supporting documents submit in the IRB application for the following purposes:

- Ensuring the study meets the criteria for IRB approval of research, as well as other applicable federal regulations, state laws, and local requirements;
- Verifying subject recruitment is equitable and not coercive; (i.e., patient facing materials or recruitment documents for subject comprehension);
- Measures are in place to protect subject privacy and confidentiality; and
- Documents that will be provided to subjects and will assist in making an informed decision about participation in the study.

The below tables include a list of supporting documents that are required to be included with the IRB application. All supporting documents are to be uploaded into the documents/attachment section of the xForm.

Initial New Study Application

All documents submitted in an Initial New Study Application are to be the final versions. Do not submit if consent forms, protocols, or other documents are in the 'draft' stage.

Protocol
Informed Consent Documents: (written on the current IRB Consent/HIPAA Templates) • Consent / HIPAA Authorization Form • Information Sheet (if applicable) • Assent Forms (if applicable) • HIPAA Authorization for Reimbursement (if applicable)
Recruitment Materials or Advertisements: • Letters, phone scripts, posters, flyers, online postings, brochures, to be seen by local subjects • Pamphlets and study handouts • Do not include materials provided by study-Sponsors if they will not be utilized locally • The IRB does not require the review of websites or other advertising material created by study-Sponsors if they cannot be edited or reviewed by our local PI
Data Collection and Screening Instruments • Surveys, questionnaires, assessments, or any other forms/documents to be used to collect data directly from subjects • Data collection form(s) – only for studies in which the sole activity is data collection
For Investigational Drug and/or Biologic studies: • Investigator Brochure (IB) • FDA Letter or Sponsor Communication referencing IND number when IND number is not listed on other supporting documents
For Investigational Device studies: • Instructions for use (device specifications) (IFU) • Device Labeling information • FDA Letter or sponsor communication referencing the IDE Number if not provided on other supporting documents • 510(k) documentation, if applicable • Sponsor or FDA documentation on Significant/Non-Significant Risk device determinations, if applicable
Manual of Procedures (MOP) - *only* if the MOP contains information about procedures or risks that is not found in any other supporting document (protocol, consent documents, IB, IFU, etc.).

Additional supporting that may require submission:
• Letters of support:
  ○ Vetting committee letters
  ○ Letters from Service Lines/ Departments that will participate or support the research when research is conducted outside the PIs' department
  ○ Letters from Community organizations or other non-Corewell Health collaborators that may participate or support the research
• Focus group or interview guides
• Study Memos (if applicable)
• Thank You Cards

Continuing Review Progress Report

Current approved protocol
Current approved informed consent, assent forms and / or information sheets - if the study is open to enrollment or includes subjects that may require consent at the age of 18
Protocol Deviation Log that includes deviations in the last approval period
DSMB or Study Progress Reports provided in the last approval period • Or any other materials related to multi-center trial reports, current risk-benefit assessments based on study results, etc.
Abstracts, Publications, Presentations published in the last approval period

Modification of Approve Human Research

Tracked and Clean versions of all updated documents: • Protocol • Consent Forms, assent forms, information sheets • Investigator Brochures/Instructions for use • Other documents, as applicable *All changes to documents are to occur on the most recently approved versions and have the version date(s) updated.*
Any new documents related to the proposed changes
Protocol/ Investigator Brochure summary of changes memos (if available for review)
Translated Documents Certificate of Translation

Requests to Rely on an External IRB

Protocol
Informed Consent Documents: *Written on the Lead Site's template with the Corewell Health local context information included.* • Consent / HIPAA Authorization Form • Information Sheet (if applicable) • Assent Forms (if applicable)
HIPAA Authorization for Reimbursement (if applicable)
Initial IRB Approval letter - or - the latest Continuing Review IRB Approval letter from the external IRB (IRB of Record).
IRB Authorization Agreement (IAA) (if applicable)
Local Context Form (if provided by the IRB of Record)
Recruitment Materials
Data Collection and Screening Instruments • Surveys, questionnaires, assessments, or any other forms/documents to be used to collect data directly from subjects • Data collection form(s) – only for studies in which the sole activity is data collection

The type of project (chart review, device, drug, tissue collection, etc.) and the category of research (exempt, expedited, full board) may also impact the type of documents to be submitted for IRB review. The IRB reserves the right to request copies of any study documents to complete its review.

Investigators and study team members are responsible for maintaining up to date versions of study documents and documentation of IRB review and approval in their regulatory files. The IRB submission system is not a regulatory file/binder and does not serve this purpose.

Conclusions

- The IRB reviews study documents to ensure the applicable criteria of approval is met as well as other applicable federal regulations, state laws, and local requirements.
- If a document will be provided to research subjects and will assist in making an informed decision about participation in the study, it is to be submitted to the IRB for review and approval.
- Investigators and study team members are responsible for providing the correct documents and any subsequent revisions to the IRB for review and approval according to their policies and procedures.
- The IRB reserves the right to request copies of any study documents to complete its regulatory review obligations.

Contact the IRB for more information: irbassist@spectrumhealth.org