University of Vermont
Research Protections Office
Institutional Review Boards

Guidance: Materials Required for IRB Review and Approval

This document outlines the materials investigators should assemble and include with their applications for IRB review or Determination of Exemption to provide sufficient information for the IRB/RPO to make specific determinations regarding the risks, potential benefits, informed consent, and safeguards for human participants.

Initial Review

The following materials are required for initial review of all types of research:

- Completed human subjects protocol or Exempt form

Required if Applicable to the Study

Social-Behavioral Research Components

- Investigator-authored or standardized Psychological or Educational Measures
- Investigator-authored or standardized Surveys, Questionnaires

Biomedical Research Components

- Investigator's Drug Brochure or Package Insert
- Device Brochure and/or other device information

Other

- Recruitment and Screening materials
- Informed Consent Document(s)
- Data Management and Security Plan
- Study surveys/questionnaires
- Letters of support
- Privacy Policies for Apps and Databases
- Participant Study Brochures
- Wallet Cards
- Any other participant-facing material or documentation the Investigator deems pertinent

Continuing Review

The following materials are required for continuing review:

- Copy of the last signed consent form of each type that was used on this protocol over the last review period. Subject's name/signature (only) should be blanked out leaving the date of consent for auditing purposes.
- All monitoring reports occurring in the last 12 months conducted by study sponsor or grant agency or lead institutional site.
- A list of non-risk deviations

- Any additional pertinent documentation

Modifications to Approved Research

The following materials are required for amendments to approved/exempted research:

- Relevant modified study documents such as, Recruitment Materials, Screening Materials, and Consent Documents, as applicable
- Any supporting post approval reports from the Sponsor to indicate the change in protocol documents
- DSMB Report recommendations
- Updated Investigator Drug/Device Brochures
- Any additional pertinent documentation

Reportable New Information

- Corrective action plan,
- Redacted consent deviation,
- SAFE or MedWatch report,
- Unfavorable audit report

Quality Assurance Responses

The following materials are required when submitting an RNI response to a QA:

- Original QA report
- Point by point response to questions in the QA report
- Corrective action plan,
- protocol changes (submitted as a separate modification)
- Relevant modified study documents (submitted as a separate modification)

Responses to IRB Clarifications for Initial Protocol Review

The following materials are required for investigator responses to IRB clarifications:

- A point-by-point memo to address the required clarifications/changes. Below each clarification, please do not simply state “done” or “revised”, but provide a written summary of each change or answer to a question, including but not limited to what sections of documents were edited and how, specific procedural changes, responses from Sponsors, etc.
- Revised consent documents, screening and recruitment materials, as applicable
- All other modified study documents
- Any additional pertinent documentation

Non-English Language Translations

Informed Consent: Federal regulations require that informed consent information be presented in language understandable to participants, thus participants who do not speak English should be presented with a consent document written in a language understandable to them. Documentation of qualifications of the translator and the date of translation must also be provided when submitting translated consent forms.

Other Study Materials: UVM investigators must translate all participant facing materials that will be distributed to non-English-speaking subjects and these translated documents must be approved by the IRB. Study instruments may be in English and translated orally. If an investigator prefers to have any study instruments translated, the translations must be completed by a certified translator and approved by the IRB.

Study Closure

- Closure memo from Sponsor (if applicable)

Materials Required for Administrative Local Context Review of Studies Relying on an External IRB

Initial Submission – Before Submission of Site Materials to External IRB

- Protocol approved by the External IRB
- Study Consent/HIPAA template(s), edited to include required UVM language
- Data Management and Security Plan
- Request to Rely Form
- Reliance Agreement (if not already completed)
- Local Context Forms (if required by External IRB)
- Initial Study Level/Lead Site Approval Memo from External IRB
- HIPAA Authorization Form (if applicable)

Initial Submission – Following External IRB Site Approval

- Local Site Approval Memo from External IRB
- Final, stamped Consent/HIPAA form(s) approved by External IRB
- Final, External IRB-approved protocol (if different from version first submitted to UVM)

Modifications to Research Approved by External IRB

- Only required for amendments affecting UVM local context
- Amended protocol, approved by External IRB
- Amended Consent/HIPAA template(s), edited to include required UVM language
- External IRB modification approval memo

Reportable New Information and Quality Assurance Reports

- See above

Study Closure

- Study-wide or UVM site closure approval memo from External IRB