



IRB Staff - Study Document Management

The SmartForm supports an organized review and storage of study document attachments. Via the SmartForm, the IRB can help the study team to manage:

- The contextually relevant location of document attachments
- Document versions during review and following determination

During IRB Review

When a submission is created, the applicant is prompted to attach relevant documents to the SmartForm. **Documents associated with the regulatory review of a project must be attached to the appropriate section of the SmartForm** (for example: documents should not be included for review via an attachment to a comment in the submission history). These documents may be updated by members of the study team or the IRB office during the review, according to the following schedule:

SmartForm can be Edited	SmartForm Locked From Edits
Pre-Submission	Department or Faculty Sponsor Review
Clarifications Requested Faculty Sponsor Review	Pre-Review
Clarifications Requested Department Review	Pre-Review Completed
Clarifications Requested Pre-Review	Non-Committee Review
Clarifications Requested Non-Committee Review	Committee Review
Clarifications Requested Committee Review	Post Review
Modifications Required to Secure "Approved"	Approved
Modifications required to Secure "Not Human Research"	Not Human Subjects Research
Mod. Req. to Secure "Human Research, Not Engaged"	Ceded
Deferred	Human Research, Not Engaged
Disapproved	Withdrawn

Required versus Pending Documents

Some documents expected during the review of a study are not available at the time of review, but are needed for a complete record of the project. These documents still must be attached to the SmartForm once received. General practice delineating required before determination versus documents accepted post approval includes the following items. When reviewing the table, please note:

- X* Indicates "yes"; the item is required
- M* Indicates a Modification submission is required for the appropriate inclusion of updated materials
- A* Indicates that the document may be attached to the submission via alternate methods or the submission must be in an editable state (such as "modifications required...")

Anticipated Attachments	Required For Determination		Note
	Accepted	Post-Determination	
Main Study (or Modification)			
Non-Harvard Personnel Roster	X		Attach to Study Team Members page of SmartForm
CITI Training Certification		A	Can be attached to person profile rather than SmartForm
Research Protocol	X		Attach to Study Scope page of SmartForm
NHSR Request Form	X		Attach to Study Scope page of SmartForm



Anticipated Attachments	Required For Determination	Accepted Post-Determination	Note
Draft Individual Investigator Agreement (IIA)	X		Attach to Supporting Documents page of SmartForm
Draft IRB Authorization Agreement (IAA) Request	X		Attach to Supporting Documents page of SmartForm
Executed Individual Investigator Agreement (IIA)		M	Attach to Supporting Documents page of SmartForm
Executed IRB Authorization Agreement (IAA)		M	Attach to Supporting Documents page of SmartForm
Catalyst Form	X		Attach to External Sites page of SmartForm for the site
Non-Harvard IRB Approval		M	Attach to the External Sites page of SmartForm for the site
Non-Harvard Site Letter of Support		M	Attach to the External Sites page of SmartForm for the site
Non-Harvard Site Other Information		M	Attach to the External Sites page of SmartForm for the site
Device Documents	X		Attach to Devices page of SmartForm
Drug Documents	X		Attach to Drugs page of SmartForm
Consent Form	X		Attach to Consent, Assent, and HIPAA Authorization Materials page of SmartForm <i>For MINOR edits to a phone number or grammar, use the "update consent" activity post approval.</i>
Assent Form	X		Attach to Consent, Assent, and HIPAA Authorization Materials page of SmartForm <i>For MINOR edits to a phone number or grammar, use the "update consent" activity post approval.</i>
HIPAA Authorization	X		Attach to Consent, Assent, and HIPAA Authorization Materials page of SmartForm <i>For MINOR edits to a phone number or grammar, use the "update consent" activity post approval.</i>
Ancillary Approvals/Permissions		A	Attach the "Edit Ancillary Approvals" activity in the main study workspace
Draft Data use agreements or other Agreements	X		Attach to Supporting Documents page of SmartForm
Executed Data use agreements or other Agreements		M	Attach to Supporting Documents page of SmartForm
Debriefing Materials	X		Attach to Supporting Documents page of SmartForm
Federal Department Requirements Checklists	X		Attach to Pre-Review Activity form
Financial Interest Disclosure Form	X		Attach to Study Team Members page of SmartForm
Foreign Language Documents		M	Attach to Supporting Documents page of SmartForm
Funding Source Attachments	X		Attach to Supporting Documents page of SmartForm
PI's Current CV (ICH-GCP E6 Only)	X		Attach to Supporting Documents page of SmartForm
Radiation Safety Form	X		Attach to Supporting Documents page of SmartForm
Recruitment Materials/Advertisements	X		Attach to Supporting Documents page of SmartForm
Sponsor Protocol including DHHS-approved protocol	X		Attach to Supporting Documents page of SmartForm
Study Instruments/Tools	X		Attach to Supporting Documents page of SmartForm
Translation Attestation Form	X		Attach to Supporting Documents page of SmartForm
Certificate of Confidentiality		M	Attach to Supporting Documents page of SmartForm <i>If contingent approval is not issued</i>
DSMB plan/information		M	Attach to Supporting Documents page of SmartForm
Continuing Review			
Progress Report	X		Attach to box #7 of the Continuing Review Application
DSMB report		A	Attach to box #7 of the Continuing Review Application <i>Can be attached to an RNI submission which is linked to the main study</i>
Other external reports		A	Attach to box #7 of the Continuing Review Application <i>Can be attached to an RNI submission which is linked to the main study</i>



Updating the SmartForm with Pending Documents

When a submission is complete enough to issue an approval, not human subjects research, or not engaged determination while documents are pending, IRB staff should use the following guidelines to manage the missing materials:

1. Notify the study team of pending items in the determination letter. Template suggested language:
The IRB requests the following:
 - *Please email a copy of the CITI training certificate from Person's Name when it becomes available.*
 - *Please upload (via a Modification in ESTR) the fully executed Data Use Agreement when it becomes available.*
 - *Please submit (via a Modification in ESTR) translated study documents as soon as they become available as well as a signed Translation Attestation Form. Copies of locally-approved translated versions or a status update must be submitted to the IRB within 45 days of this notification letter.*
 - *Please upload (via a Modification in ESTR) local ethical review board approval notice into ESTR when it becomes available. Please note that no human research activities can occur in the field until local review has been secured.*
 - *An Administrative Modification has been opened on your behalf as a placeholder for the documentation requested above. Once these materials become available, please upload them to this Modification and submit to the IRB.*
2. The IRB Contact can immediately open an Administrative Modification on behalf of the study team and leave the modification in "pre-submission" for the study team to edit and submit once the documentation/information is available.
 - *A reminder notification is sent at a regular intervals reminding the PI, Primary Contact, Faculty Sponsor (if there is one), and email list that the Modification is open/in pre-submission.*
 - *If the study team needs to complete a more time sensitive Modification, the one opened by the IRB Contact should be used with the Modification Description revised. The IRB Contact should then open another Administrative Modification on behalf of the PI for the pending documents.*
 - *Feel free to use/edit the following text in the Modification Information box:
This Modification has been opened for you on behalf of your IRB Review Specialist. It is a placeholder for the pending documents requested in the determination letter for MOD/CR-XXXX-XX. Once these materials become available, please upload them to this Modification and submit to the IRB.*