

IRB Submission Checklist

The purpose of this document is to provide guidance for researchers submitting to the UNM IRB. Please contact the Office of the IRB for assistance:

irb.unm.edu | 505.277.2644 | IRBMainCampus@unm.edu

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What to expect after submitting your IRB protocol in Streamlyne:

- The IRB Staff will assess the completeness of your IRB submission package.
- If necessary, the protocol will be returned to your queue to provide additional information and/or revise documents. You will receive an email notification as well as an FYI in Streamlyne.
- Your final IRB submission package will be reviewed by the IRB for a decision.
- A decision letter will be published in Streamlyne.
- If necessary, you may need to provide revised or additional information in a 'Response' package.

Tips for a complete IRB submission

- Use this checklist to ensure a complete submission package.
 - **Check the version date of forms and templates at irb.unm.edu to ensure that you are using the current version.** Documents with a red hyperlink are linked to the corresponding document in the IRB Library.
 - Follow the naming conventions on this checklist for your documents and include version dates in the file name before saving the document.
 - Submit all documents as Word documents if possible; use pdfs only if required (e.g. signature pages); and keep all documents unprotected/unlocked.
 - Combined PDFs are not accepted; attach documents separately.
 - Inform the OIRB of any special circumstances that may impact the review of your submission.
 - For assistance with using Streamlyne, visit <https://irb.unm.edu/streamlyne/index.html>
 - Contact the OIRB if you have questions before submitting.
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New Project Submission Checklist

NOTE: You must complete the IRB New Questionnaire in Streamlyne. Submissions will be withdrawn if incomplete. Documents required for a new project submission are project-specific. All template documents are located in the [IRB Library](#).

✓	Document	Attachment Type (in Streamlyne)	Notes
*	IRB New Questionnaire	<ul style="list-style-type: none"> n/a 	Smart form in Streamlyne under Questionnaire tab.
*	Scientific Review Form or Federal Peer Review	<ul style="list-style-type: none"> Other (PDF) 	Scientific reviews must be signed by the department, dissertation or thesis committee chair. Federal Peer Reviews can be email PDF from Sponsor.
*	Protocol	<ul style="list-style-type: none"> Protocol 	Submit as Word doc; required for all projects; use the online template protocol .
*	CV of Principal Investigator	<ul style="list-style-type: none"> CV/Resume 	Required for Principal Investigator
*	Data Collection Instruments	<ul style="list-style-type: none"> Data Collection Questionnaire/Survey Interview questions 	Submit as Word doc; include surveys, questionnaires, interview questions; focus group scripts; validated assessments
**	Consent Form (≥ 12 yo)	<ul style="list-style-type: none"> Informed Consent Document 	Submit as Word doc only. If requesting waiver of documentation (signature), remove signature lines prior to uploading.
**	Assent Form (7-11 yo)	<ul style="list-style-type: none"> Child Assent Form 	See above.
**	Recruitment Materials	<ul style="list-style-type: none"> Advertisements Recruitment scripts/materials 	Submit in editable format (Word, Publisher, etc.); include flyers, print media, audio/video, online content, recruitment scripts/emails.
**	Other Supporting Documents	<ul style="list-style-type: none"> Other 	Letters of Support, other IRB Approvals, Data Transfer Agreements, Certificates of Confidentiality, Translation Certification Form, Device Form, etc.
**	COI Decision Memo or Management Plan	<ul style="list-style-type: none"> Conflict of Interest – Other or Conflict of Interest – Management Plan 	Only required if study personnel have been issued a COI management plan or decision memo.
**	Personnel List External	<ul style="list-style-type: none"> Other 	List of non-UNM study personnel.
**	CITI Completion Report	<ul style="list-style-type: none"> Training 	Only required for non-UNM study personnel.

* Required

** Required if applicable

Amendment Submission Checklist

You must complete the IRB Amendment Questionnaire in Streamlyne. Other documents required for an amendment submission depend on what is being changed; see examples below. Please submit the track changes version of any revised documents, do not submit “clean” copies. All template documents are located in the [IRB Library](#).

✓	Document	Notes
*	IRB Amendment Questionnaire	Smart form in Streamlyne that must be completed when submitting an AM.
**	All documents with new version date revised using track changes	Submit as Word doc; may include protocol, consent form, recruitment materials, data collection instruments
**	New documents requiring IRB review and approval before use	Submit as Word doc; may include protocol, consent form, recruitment materials, data collection instruments

* Required

** Required if applicable

Examples of Amendments

	Scenario	Include in IRB Amendment Questionnaire	Supporting Documents/Notes
1	Changes to Protocol (e.g. increase enrollment number, adding or modify recruitment strategies, revising informed consent process)	<ul style="list-style-type: none"> Identify the documents being changed Itemized list of all changes If adding procedures or increasing risk, provide justification 	<ul style="list-style-type: none"> ✓ Revised protocol with track changes and new version date ✓ Revised consent form with track changes and new version date ✓ Proposed recruitment flyer ✓ Upload revised documents in Streamlyne
2	Change the PI of record	<ul style="list-style-type: none"> Update the Personnel tab to reflect new PI and remove old PI (if applicable) Identify the documents that need to be changed as a result Include an itemized list of all changes 	<ul style="list-style-type: none"> ✓ New PI's CV and COI Mgmt. Plan, if applicable ✓ Revised documents to reflect new PI with track changes and new version dates ✓ Upload revised documents in Streamlyne
3	Adding new or revising data collection procedures	<ul style="list-style-type: none"> Identify the documents being added and/or changed Include an itemized list of the changes 	<ul style="list-style-type: none"> ✓ New or revised data collection instruments (using track changes) ✓ Revised protocol with track changes and new version date ✓ Upload revised documents in Streamlyne

Renewal (Continuing Review) Submission Checklist

NOTE: When submitting a renewal, you must complete the IRB Renewal Questionnaire in Streamlyne. Please do not re-upload documents from previous submissions (e.g. approved protocol, etc.).

✓	Document	Notes
*	IRB Renewal Questionnaire	Smart form in Streamlyne that must be completed when submitting a Renewal.
**	Protocol Deviations Report	Submit as PDF only; must be signed by PI. Only submit this form if any protocol deviations have occurred since last IRB review.
**	Abstracts, Publications	Project Findings, Interim Findings
**	COI Decision Memo or Management Plan	Only required if study personnel have been issued a COI management plan or decision memo.
**	Other Supporting Documents	DSMB Report(s), other IRB approvals

Renewal with Amendment Submission Checklist

NOTE: When submitting a renewal with amendment, you must complete both the IRB Renewal Questionnaire and the IRB Amendment Questionnaire in Streamlyne.

✓	Document	Notes
*	IRB Renewal Questionnaire	Smart form in Streamlyne that must be completed when submitting a Renewal.
*	IRB Amendment Questionnaire	Smart form in Streamlyne that must be completed when submitting an AM.
**	Revised documents with new version date updated using track changes	Submit as Word doc; may include protocol, consent form, recruitment materials, data collection instruments
**	New documents requiring IRB review and approval before use	Submit as Word doc; may include protocol, consent form, recruitment materials, data collection instruments
**	Protocol Deviations Report	Submit as PDF only; must be signed by PI. Only submit this form if any protocol deviations have occurred since last IRB review.
**	Abstracts, Publications	Project Findings, Interim Findings
**	COI Decision Memo or Management Plan	Only required if study personnel have been issued a COI management plan or decision memo.
**	Other Supporting Documents	DSMB Report(s), other IRB approvals

Response to Modification Request Checklist

If requested by the IRB, modifications must be submitted within 30 days. Please do not submit any “new” documents in a Response package, unless requested by the IRB.

✓	Document	Document Type (in IRBNet)	Notes
*	Modification Response	Letter	Provide a letter containing a point-by-point response to the requested changes
**	Revised Documents with tracked changes and new version date	As appropriate	Examples: Protocol, Consent Form, recruitment materials, etc.; Upload revised documents in IRBNet to show a version trail by clicking on the pencil icon next to the currently approved version of the document to upload the edited document.
**	New Documents	As appropriate	Only submit if requested by the IRB.

* Required

** Required if applicable

Note: You will receive a Modifications Requested Letter. This is not an approval letter - you cannot start project activities until after the IRB has approved your response.