

# 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](http://irb.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.
- Check your SPAM folder if you do not receive a timely response from the IRB.
- 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 <https://irb.unm.edu/library/index.html> 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.

# 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 Submissions will be withdrawn if incomplete.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"> <li>n/a</li> </ul>	Smart form in Streamlyne under Questionnaire tab.
*	Scientific Review Form or Federal Peer Review	<ul style="list-style-type: none"> <li>Other (PDF)</li> </ul>	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"> <li>Protocol</li> </ul>	Submit as Word doc; required for all projects; <a href="#">use the online template protocol</a> .
*	CV of Principal Investigator	<ul style="list-style-type: none"> <li>CV/Resume</li> </ul>	Required for Principal Investigator
*	Data Collection Instruments	<ul style="list-style-type: none"> <li>Data Collection</li> <li>Questionnaire/Survey</li> <li>Interview questions</li> </ul>	Submit as Word doc; include surveys, questionnaires, interview questions; focus group scripts; validated assessments
**	Consent Form (≥ 12 yo)	<ul style="list-style-type: none"> <li>Informed Consent Document</li> </ul>	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"> <li>Child Assent Form</li> </ul>	See above.
**	Recruitment Materials	<ul style="list-style-type: none"> <li>Advertisements</li> <li>Recruitment scripts/materials</li> </ul>	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"> <li>Other</li> </ul>	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"> <li>Conflict of Interest – Other or</li> <li>Conflict of Interest – Management Plan</li> </ul>	Only required if study personnel have been issued a COI management plan or decision memo by the COI dept.
**	Personnel List External	<ul style="list-style-type: none"> <li>Other</li> </ul>	List of non-UNM study personnel.
**	CITI Completion Report	<ul style="list-style-type: none"> <li>Training</li> </ul>	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
*	<b>IRB Amendment Questionnaire</b>	Smart form in Streamlyne that must be completed when submitting an AM.
**	<b>Revised documents with new version date revised using track changes</b>	Submit as Word doc; may include protocol, consent form, recruitment materials, data collection instruments
**	<b>New documents requiring IRB review and approval before use</b>	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
<b>1</b> <b>Changes to Protocol</b> (e.g. increase enrollment number, adding or modify recruitment strategies, revising informed consent process)	<ul style="list-style-type: none"> <li>Identify the documents being revised and list new documents being submitted</li> <li>Itemized list of all changes</li> <li>If adding procedures or increasing risk, provide justification</li> </ul>	<ul style="list-style-type: none"> <li>✓ Revised protocol with track changes and new version date</li> <li>✓ Revised consent form with track changes and new version date</li> <li>✓ Proposed recruitment flyer</li> <li>✓ Upload revised documents in Streamlyne</li> </ul>
<b>2</b> <b>Change the PI of record</b>	<ul style="list-style-type: none"> <li>State the nature of the amendment</li> <li>Include an itemized list of all documents that need to be revised as a result on the amendment questionnaire tab</li> </ul>	<ul style="list-style-type: none"> <li>✓ New PI's CV and COI Mgmt. Plan, if applicable</li> <li>✓ Revised documents to reflect new PI with track changes and new version dates</li> <li>✓ Upload revised documents in Streamlyne</li> <li>✓ Update the Personnel tab to reflect new PI and remove old PI (if applicable)</li> <li>✓ Update the Protocol tab to reflect the new PI</li> </ul>
<b>3</b> <b>Adding new or revising data collection procedures</b>	<ul style="list-style-type: none"> <li>Identify the documents being added and/or revised</li> <li>Include an itemized list of the changes on the amendment questionnaire tab</li> </ul>	<ul style="list-style-type: none"> <li>✓ New or revised data collection instruments (using track changes)</li> <li>✓ Revised protocol with track changes and new version date</li> <li>✓ Upload revised documents in Streamlyne</li> </ul>

## 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
*	<b>IRB Renewal Questionnaire</b>	Smart form in Streamlyne that must be completed when submitting a Renewal.
**	<b>Protocol Deviations Report</b>	Submit as PDF only; must be signed by PI. Only submit this form if any protocol deviations have occurred since last IRB review.
**	<b>Abstracts, Publications</b>	Project Findings, Interim Findings
**	<b>COI Decision Memo or Management Plan</b>	Only required if study personnel have been issued a COI management plan or decision memo by the COI dept.
**	<b>Other Supporting Documents</b>	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
*	<b>IRB Renewal Questionnaire</b>	Smart form in Streamlyne that must be completed when submitting a Renewal.
*	<b>IRB Amendment Questionnaire</b>	Smart form in Streamlyne that must be completed when submitting an AM.
**	<b>Revised documents with new version date updated using track changes</b>	Submit as Word doc; may include protocol, consent form, recruitment materials, data collection instruments
**	<b>New documents requiring IRB review and approval before use</b>	Submit as Word doc; may include protocol, consent form, recruitment materials, data collection instruments
**	<b>Protocol Deviations Report</b>	Submit as PDF only; must be signed by PI. Only submit this form if any protocol deviations have occurred since last IRB review.
**	<b>Abstracts, Publications</b>	Project Findings, Interim Findings
**	<b>COI Decision Memo or Management Plan</b>	Only required if study personnel have been issued a COI management plan or decision memo by the COI dept.
**	<b>Other Supporting Documents</b>	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	Notes
*	<b>Modification Response</b>	Provide a letter containing a point-by-point response to the requested changes
**	<b>Revised Documents with tracked changes and new version date</b>	Examples: Protocol, Consent Form, recruitment materials, etc.; Upload revised documents to show a version trail by clicking <i>show</i> next to the currently approved version of the document and then clicking the replace button to upload the newly revised version. Upload revised study documents with an updated version date.
**	<b>New Documents</b>	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.***

## Request for Deferral to External IRB

✓	Document	Notes
*	<b>IRB New Questionnaire</b>	Smart form in Streamlyne. First question should be answered NO, then respond YES to the 2 <sup>nd</sup> question that asks, “are you requesting deferral of this research to an external IRB.”
*	<b>Protocol</b>	Submit as Word or PDF; may submit External IRBs protocol. Make sure to include what research activities involve UNM.
*	<b>Request for External IRB Review Form</b>	Submit as Word or PDF; must be (electronically) signed by PI.
*	<b>Approval letter for external IRB</b>	If approval from the external IRB has been obtained, this should be uploaded.
**	<b>Other supporting documents</b>	Consent forms and study documents from the external IRB, if available, other supporting or relevant documents that will assist the IRB in making this determination.

## Human Subjects Research Determination

✓	Document	Notes
*	<b>IRB New Questionnaire</b>	Smart form in Streamlyne. First question that asks, “Are you requesting an IRB review not required determination” should be answered YES.
*	<b>Protocol or summary of the proposed activity</b>	Submit as Word or PDF. This document should provide information describing the proposed activity
**	<b>Other supporting documents</b>	Other supporting or relevant documents that will assist the IRB in making this determination.