

# IRB Submission Checklist

The purpose of this document is to provide guidance for researchers submitting to the UNM IRB. All documents with signature lines require a signature in the spaces provided. Please contact the Office of the IRB for assistance:

[irb.unm.edu](http://irb.unm.edu) | 505.277.2644 | [IRBMainCampus@unm.edu](mailto:IRBMainCampus@unm.edu)

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<b>IMPORTANT!</b> Submit actions separately, the OIRB will not accept combined submissions (e.g. Continuing Review + Amendment).	

## What to expect after submitting your IRB submission through IRBNet

- The IRB Staff will assess the completeness of your 'locked' (🔒 or 🔓) IRB submission package.
- If necessary, you will be contacted to provide additional information in your 'unlocked' (🔓) IRBNet package to assist with IRB review.
- Your 'locked' (🔒) IRB submission package will be reviewed by the IRB for a decision.
- The IRB Staff will upload the IRB decision letter in IRBNet on the project's 'Reviews' page.
- 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 to ensure that you are using the current version. Use of old forms and templates can delay processing and exclude your project from equivalent protections and other considerations.**
- Documents with a red underline 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.
- OIRB staff cannot upload documents on behalf of the researcher; we can only provide guidance.
- Inform the OIRB of any special circumstances that may impact the review of your submission.
- For assistance with using IRBNet, please see the following guidance documents:
  - IRBNet Submission Instructions
  - IRBNet Investigator Cheat Sheet
- Contact the OIRB if you have questions before submitting.

# New Project Submission Checklist

NOTE: Grey highlighted documents are **MANDATORY**. Submissions will be withdrawn if these documents are not included. Other documents required for a new project submission will be project-specific. All documents are located in the [IRB Library](#).

✓	Document	Document Type (in IRBNet)	Notes
*	<b>Project Information Form</b>	<b>Application Form</b>	Submit as PDF only; must be signed by PI.
*	<b>Scientific Review Form or Federal Peer Review</b>	<b>Other</b>	Submit as PDF only; must be signed by the department, dissertation or thesis committee chair.
*	<b>Protocol</b>	<b>Protocol</b>	Submit as Word doc; required for all projects; use the OIRB's template protocol.
*	<b>Project Team Form +</b> <ul style="list-style-type: none"> <li><b>CITI Completion Report(s)</b> <i>must list completed modules</i></li> <li><b>COI Decision Memo or Management Plan</b></li> </ul>	<b>Other</b> <ul style="list-style-type: none"> <li><b>Training/Certification</b></li> <li><b>Conflict of Interest – Mgmt Plan</b></li> </ul>	Must include all researchers; majority of CITI modules must be completed within 3 years; <b>researchers are required to complete the UNM COI Survey annually at: <a href="http://researchcompliance.unm.edu/coi">http://researchcompliance.unm.edu/coi</a></b>
**	<b>Consent Form (ages ≥ 12) Assent Form (ages 7-11)</b>	<b>Consent Form Child Assent</b>	Submit as Word doc; <b>Note:</b> Signed informed consent is required for all projects unless a wavier is requested and justified in the protocol.
*	<b>Data Collection Instruments</b>	<b>Data Collection Questionnaire/Survey</b>	Submit as Word doc; include surveys, questionnaires, interview questions; focus group scripts; validated assessments
**	<b>Recruitment Materials</b>	<b>Advertisement</b>	Submit in editable format (Word, Publisher, etc.); include flyers, print media, audio/video, online content, recruitment scripts/emails.
**	<b>Other Supporting Documents</b>	<b>Other</b>	Letters of Support, other IRB Approvals, Data Transfer Agreements, Certificates of Confidentiality, Translation Certification Form, Device Form, etc.
*	<b>CV/Resume of Principal Investigator</b>	<b>CV/Resume</b>	Required for Principal Investigator
**	<b>Individual Investigator Agreement</b>	<b>Investigator Agreement</b>	This form is required for external partners if their institution does not have an FWA.

\* Required    \*\* Required if applicable

# Amendment Submission Checklist

NOTE: Grey highlighted documents are **MANDATORY**. 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. Edited documents must be uploaded creating a version trail in IRBNet. All documents are located in the [IRB Library](#).

✓	Document	Document Type (in IRBNet)	Notes
*	<b>Amendment Application</b>	<b>Application Form</b>	Submit as PDF only; must be signed by PI.
**	<b>All revised documents using track changes and new version date</b>	<b>As appropriate</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>	<b>As appropriate</b>	

\* Required    \*\* Required if applicable

## Examples of Amendments

Scenario	Include in Application	Supporting Documents/Notes
<b>1 Changes to Protocol</b> (e.g. increase enrollment number, modify recruitment strategies, revising/removing instruments, changing procedures)	<ul style="list-style-type: none"> <li>Identify the documents being changed</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 to reflect protocol changes with new version date</li> <li>✓ 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</li> </ul>
<b>2 Change the PI of record</b>	<ul style="list-style-type: none"> <li>Change the current PI Name to new PI Name; also update name in IRBNet “Project Overview”</li> <li>Identify the documents that need to be changed as a result</li> <li>Include an itemized list of all changes</li> </ul>	<ul style="list-style-type: none"> <li>✓ New PI’s CV, CITI Completion Report and COI Mgmt. Plan, if applicable</li> <li>✓ Revised documents to reflect new PI with track changes and new version dates</li> <li>✓ Updated project team form to reflect new PI and remove old PI (if applicable)</li> <li>✓ 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</li> </ul>
<b>3 Adding new data collection procedures</b>	<ul style="list-style-type: none"> <li>Identify the documents being added and/or changed</li> <li>Include an itemized list of the changes</li> </ul>	<ul style="list-style-type: none"> <li>✓ New data collection instruments</li> <li>✓ Revised protocol with track changes and new version date</li> <li>✓ 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</li> </ul>

## Continuing Review / Reactivation Submission Checklist

NOTE: Grey highlighted documents are **MANDATORY**. For a CR submission, please do not re-upload documents from previous submissions (e.g. approved protocol, etc.) and do not upload revised documents. Revised documents require an Amendment submission, which must be submitted separately from a CR submission. All documents are located in the [IRB Library](#).

✓	Document	Document Type (in IRBNet)	Notes
*	<b>Continuing Review Application</b>	<b>Application Form</b>	Submit as PDF only; must be signed by PI.  <i>NOTE: If IRB Approval expired, last section of form <b>must</b> be completed.</i>
*	<b>Project Team Form + ** CITI Completion Report(s)</b> <i>must list completed modules</i>	<b>Other</b>	Must include all researchers currently involved with the project; upload CITI completion reports for any new individuals and any whose training expired during the last approval period; current COI Mgmt. Plan(s), if applicable.
**	<b>Protocol Deviations Report</b>	<b>Protocol Deviation/ Violation 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 and/or publications</b>	<b>Abstract/Summary Publication Materials</b>	Project Findings, Interim Findings
**	<b>Other Supporting Documents</b>	<b>Other</b>	DSMB Report(s), other IRB approvals

## Deferred Projects Annual Report Submission Checklist

NOTE: For projects that have been deferred to an external IRB for review, an annual deferred projects report must be submitted to the OIRB. Grey highlighted documents are **MANDATORY**.

✓	Document Type	Document Type (in IRBNet)	Notes
*	<b>Deferred Projects Annual Report</b>	<b>Application form</b>	Submit as PDF only; must be signed by PI.
*	<b>Current IRB Approval letter</b>	<b>Approval letter</b>	Upload the current IRB approval letter from the IRB of oversight.
**	<b>Project Team Form</b>	<b>Other</b>	If UNM-affiliated project team members have changed since last review, upload current project team form.  <i>UNM-affiliated team members are required to complete the UNM COI Survey annually:</i> <a href="http://researchcompliance.unm.edu/coi">http://researchcompliance.unm.edu/coi</a>
**	<b>Other Supporting Documents</b>	<b>Other</b>	Ex: Related Event Reports, DSMB Reports

\* Required      \*\* Required if applicable

# Response to Modification Request Checklist

NOTE: Grey highlighted documents are **MANDATORY**. If requested by the IRB, **modifications must be submitted as a new package in the existing IRBNet project.**

- Label the Submission Type as “Response/Follow-Up”.
- See the IRBNet Submission Instructions for how to create a new package.
- Please do not submit any “new” documents in a Response package, unless requested by the IRB.

✓	Document	Document Type (in IRBNet)	Notes
*	<b>Modification Response</b>	<b>Letter</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>	<b>As appropriate</b>	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.
**	<b>New Documents</b>	<b>As appropriate</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.**

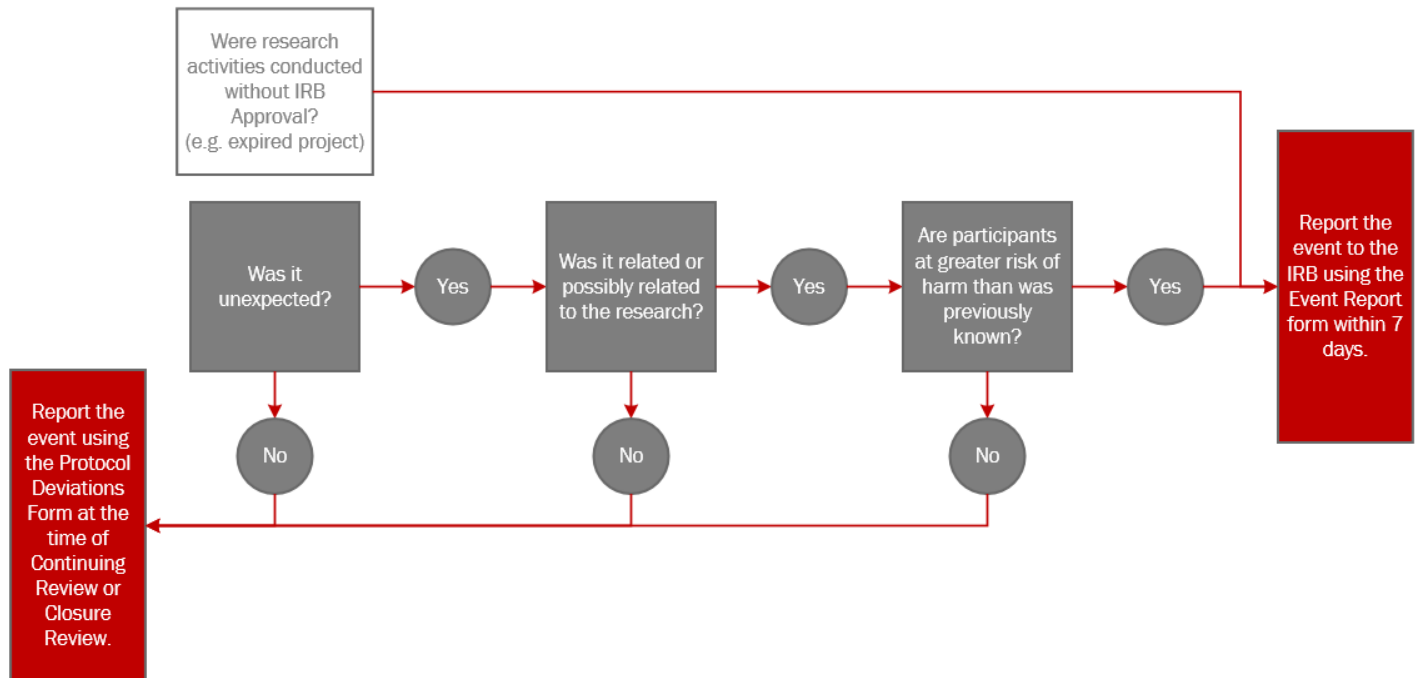
# Event Report Submission Checklist

NOTE: Grey highlighted documents are **MANDATORY**. Event Reports should be used to report Unanticipated Problems, Adverse Events, and Protocol Violations that involve harm to participants or others. **Events must be reported within 7 days of the event.** For more information, please see SOP 401: Reporting and Review of Events Involving Risk to Participants or Others. All documents are located in the [IRB Library](#).

✓	Document	Document Type (in IRBNet)	Notes
*	<b>Event Report.pdf</b>	<b>Application Form</b>	Submit as PDF only; must be signed by PI.
**	<b>Other Supporting Documents</b>	<b>Other</b>	Sponsor reporting documentation

\* Required \*\* Required if applicable

## When do I need to report an event to the IRB?



# Closure Submission Checklist

NOTE: Grey highlighted documents are MANDATORY. Other documents required for a closure are project-specific. All documents are located in the [IRB Library](#).

✓	Document	Document Type (in IRBNet)	Notes
*	<b>Closure Application</b>	<b>Application Form</b>	Submit as PDF only; must be signed by PI.
**	<b>Protocol Deviations Report</b>	<b>Protocol Deviation/ Violation 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 and/or publications</b>	<b>Abstract/Summary Publication Materials</b>	Any Project Findings, Interim Findings

\* Required    \*\* Required if applicable

## Human Subjects Research Determination or Request for External IRB Review

NOTE: Grey highlighted documents are **MANDATORY**. Researchers are encouraged to consult with the OIRB prior to requesting reliance on an external IRB. All documents are located in the [IRB Library](#).

✓	Document	Document Type (in IRBNet)	Notes
*	<b>Project Information Form</b>	<b>Application Form</b>	Submit as PDF only; must be signed by PI.
*	<b>Protocol</b>	<b>Protocol</b>	This document should explain the project procedures. If requesting external IRB review, explain what research activities involve UNM faculty or will be conducted at UNM; also include a justification for deferring IRB oversight (e.g. all study procedures are done at the external institution).
**	<b>Request for External IRB Review Form</b>	<b>Other</b>	Required when requesting deferral to an external IRB.
**	<b>Project Team Form</b>	<b>Other</b>	Required when requesting deferral to an external IRB; must include all UNM-affiliated researchers. All are required to complete the UNM COI Survey annually: <a href="http://researchcompliance.unm.edu/coi">http://researchcompliance.unm.edu/coi</a>
**	<b>Other Supporting Documents</b>	<b>Other</b>	IRB Approval letter from external IRB; other supporting or relevant document that will assist the IRB in making this determination.

\* Required    \*\* Required if applicable



## Grant Funded Research NOAs/JITs without full IRB Applications

NOTE: Grey highlighted documents are **MANDATORY**. For federally funded projects that receive a Notice of Award (NOA) or Just in Time (JIT) notice where the funding agency requests IRB certification before the human subject research components of the project are fully developed, an abbreviated submission can be reviewed to meet funding requirements. Note that no human research activities can be conducted under this determination until a complete new project submission has been reviewed and approved by the IRB. All documents are located in the [IRB Library](#).

	Document Type	Document Type (in IRBNet)	Notes
✓			
*	<b>Project Information</b>	<b>Application Form</b>	Submit as PDF only; must be signed by PI.
*	<b>Grant Proposal</b>	<b>Proposal</b>	The proposal submitted to the funding agency. <b>Do not include budget information.</b>
**	<b>Other Supporting Documents</b>	<b>Other</b>	Any other supporting or relevant document that will assist the IRB in making this determination.

\* Required    \*\* Required if applicable

The IRB will need specific information about the project in order to make this determination. Please make sure that the grant proposal includes the following information or submit supporting documents that details the information:

- The HSR activities that are being conducted that engage UNM.
- The scope of the research involving human subjects.
- The timeline for when HSR components of the research will begin.