OFFICE OF THE INSTITUTIONAL REVIEW BOARD

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 | 505.277.2644 | IRBMainCampus@unm.edu

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' ( ) IRB submission 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 "stellar" 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: Documents required for a new project submission will depend on nature of the project. The minimum required CITI training is Main Campus Researchers course; if you have questions, please contact the OIRB.

✔	Document Type	Document Description (Name)	Notes
	These are documents that the researcher and IRB will see.		
	Application Form	*** Project Information.pdf**	This form must be signed by the PI.
	Other	*** Scientific Review.pdf**	This form must be signed by the Department Chair/ Committee Chair.
	Other **Training/Certification** **Conflict of Interest – Management Plan**	*** Project Team Records:** • **Project Team Form.doc** • **CITI Completion Report(s).pdf** *must list completed modules* • **COI Decision Memos.pdf**	Must include all researchers; All researchers listed are required to complete the UNM FCOI Survey: http://researchcompliance.unm.edu/coi Any researcher COI decision memos/management plans must be uploaded.
	Protocol	*** Protocol.doc**	This document is required for all projects; use the OIRB's template protocol.
	Other	**** Other Supporting Documents.doc/.pdf**	Letters of Support, Other IRB Approvals, Data Transfer Agreements, Certificates of Confidentiality, Translation Certification, Device Form, etc.
	Proposal	**** Grant Proposal.doc**	The proposal is required for federally funded research only.
	Investigator Agreement	**** Ind. Investigator Agreement.pdf**	This form is required for external partners if the institution does not have an FWA.
	These are documents that the participant will see/hear.		
	Consent Form **Child Assent** **HIPAA Authorization**	*** Consent Document.doc** **** Assent Document.doc** **** HIPAA Authorization.doc**	Note: Signed informed consent is required for all projects unless a wavier is requested and justified in the protocol.
	Advertisement	**** Recruitment Materials.doc**	Flyers, Posters, Print Media, Audio/Video, Online Content, Scripts
	Data Collection Questionnaire/Survey	**** Project Instruments.doc/.pdf** ****Questionnaires/Surveys.doc/.pdf**	Surveys, Questionnaires, Data Collection Tools, Interview Scripts/Questions
	Other	**** Other Participant Documents.doc/.pdf**	Appointment/Post Cards, Flair/Swag, Translations of any document
	These documents can be attached in the Designer Page of a single project or your individual User Profile (requires IRBNet account and linking the training & Credentials record to a project).		
	Training/Certification	*** CITI Completion Report.pdf**	Required for all researchers and must have been taken within the past 3 years.
	CV/Resume	*** Curriculum Vitae.doc/.pdf**	Required for Principal Investigator.

* Required ** Required if applicable

Amendment Submission Checklist

NOTE: Documents required for an amendment submission depend on what is being changed. Please submit the tracked-changes version only, do not submit "clean" copies. Edited documents must be uploaded creating a version trail in IRBNet.

✔	Document Type	Document Description (Name)	Notes
	Application Form	*** Amendment Application.pdf**	Must be signed by Principal Investigator of Record
	See New Project Submission Checklist for appropriate document type	**** Revised Documents with tracked changes and new version date.doc**	Examples: Protocol, Consent/Assent Document/Script, HIPAA Authorization, Recruitment Materials, Data Collection Tools, Other Participant Documents
	See New Project Submission Checklist for appropriate document type	**** New documents requiring IRB review and approval before implementation.doc**	Examples: Consent Document/Script, HIPAA Authorization, Recruitment Materials, Project Instruments, others…

* Required ** Required if applicable

Examples of Amendments

	Scenario	Include in Application	Supporting Documents
1	**Changes to Protocol** (e.g. increase enrollment number, modify recruitment strategies, revising/removing instruments, changing project procedures…)	• Identify the documents being changed • Include an itemized list of the changes • If adding procedures or increasing risk, provide justification	✓ Revised protocol to reflect changes (use tracked-changes) with new version date ✓ Revised consent form to reflect protocol changes (use tracked-changes) with new version date ✓ Copies of other revised documents with version trails
2	**Change the PI of record**	• Changing the old PI Name to new PI Name • Identify the documents that need to be changed as a result • Include an itemized list of the changes	✓ New PI's CV & CITI ✓ Revised project documents to reflect new PI (use tracked-changes) with new version dates
3	**Adding new data collection procedures**	• Identify the documents being added and changed • Include an itemized list of the changes	✓ Revised protocol to reflect changes (use tracked-changes) with new version date ✓ Upload new data collection documents

Continuing Review / Reactivation Submission Checklist

NOTE: For a CR submission, please do not re-upload documents from previous submissions (e.g. already approved protocol, etc.). Also, do not upload edited documents. Edited documents require an AM submission, which must be submitted separately from a CR submission.

✔	Document Type	Document Description (Name)	Notes
	Application Form	*** Continuing Review Application.pdf** NOTE: If IRB Approval expired, last section of form **must** be completed.	Must be signed by Principal Investigator of Record
	Other	*** Project Team Form.pdf**	A project team form that reflects active researchers involved with the project (remove no longer active researchers; add new researchers).
	Protocol Deviation / Violation Report	**** Protocol Deviations Report.pdf**	Use this form to record protocol deviations that occurred since last IRB review.
	Abstract/Summary **Publication Materials**	**** Abstracts.doc/.pdf** **** Publications.doc/.pdf**	Project Findings, Interim Findings
	Other	**** Other Supporting Documents.doc/.pdf**	Related Event Report, DSMB Report, Report(s) to Funders

* Required ** Required if applicable

Closure Submission Checklist

NOTE: Documents required for a Closure depend on progress and status of the project.

✔	Document Type	Document Description (Name)	Notes
	Application Form	*** Closure Application.pdf**	Must be signed by Principal Investigator of Record.
	Protocol Deviation / Violation Report	**** Protocol Deviations Report.pdf**	Use this form to record protocol deviations that occurred since last IRB review.
	Abstract/Summary **Publication Materials**	**** Abstracts.doc/.pdf** **** Publications.doc/.pdf**	Project Findings, Interim Findings
	Other	**** Other Supporting Documents.doc/.pdf**	Related Event Report, DSMB Report, Report(s) to Funders

* Required ** Required if applicable

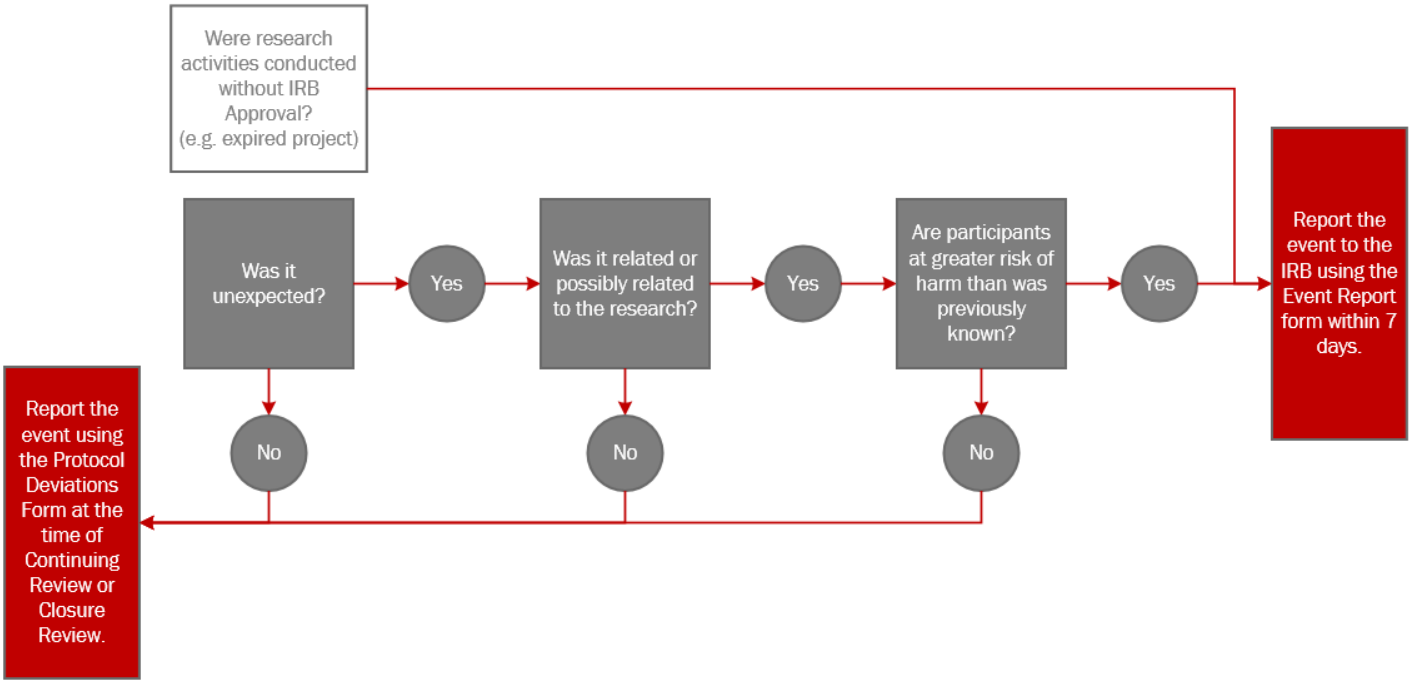
Event Report Submission Checklist

NOTE: 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.

✔	Document Type	Document Description (Name)	Notes
	Application Form	**Event Report.pdf**	Must be signed by Principal Investigator of Record.
	Other	**** Other Supporting Documents.doc/.pdf**	Sponsor Memo for Events, any Supporting Documents

* Required ** Required if applicable

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



Response to Modification Request Checklist

After your submission (NP, AM, CR, RA, C, ER) has been reviewed, the IRB may ask you to make modifications or provide additional information, clarifications, or documentation.

Modifications must be submitted as a new package in the existing IRBNet project. See the IRBNet Submission Instructions for how to create a new package.

✔	Document Type	Document Description (Name)	Notes
	Cover Sheet	*** Modification Response.doc/.pdf**	Provide a letter containing a point-by-point response to the requested changes.
	See New Project Submission Checklist for appropriate document type	**** Revised Documents with tracked changes and new version date.doc**	Examples: Protocol, Consent/Assent Document/Script, HIPAA Authorization, Recruitment Materials, Data Collection Tools, Other Participant Documents
	See New Project Submission Checklist for appropriate document type	**** New documents requiring IRB review and approval before implementation.doc**	Examples: Consent Document/Script, HIPAA Authorization, Recruitment Materials, Project Instruments, others…

* 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.***

Human Subjects Research Determination, Request for External IRB Review

Should you have a special circumstance when the standard submission process is not appropriate (e.g. HSR determinations, request for external IRB review), the OIRB will accept an abbreviated submission. Researchers are encouraged to consult with the OIRB prior to requesting reliance on an external IRB.

✔	Document Type	Document Description (Name)	Notes
	Application Form	*** Project Information.pdf**	This form must be signed by the Principal Investigator of Record.
	Protocol	*** Protocol.doc**	This document should explain the project procedures. If requesting external IRB review, make sure it explains what research activities involve UNM, include the specific request and justification for deferring IRB oversight.
	Other	**** Request for External IRB Review Form.pdf**	Required when requesting review by an external IRB.
	Other	**** Project Team Form.doc**	Required for external IRB requests. Must include all UNM researchers; All are required to complete the UNM FCOI Survey: http://researchcompliance.unm.edu/coi
	Other	**** Other Supporting Documents.doc/.pdf**	Letters of Support, Contract(s), Data Transfer Agreements, Consent form(s), etc.

* Required ** Required if applicable

Grant Funded Research NOAs/JITs without full IRB Applications

For federally funded projectss that receive a Notice of Award (NOA) or Just in Time (JIT) notice where the funding agency requests IRB review determination before the human subjects research components of the project are fully developed, an abbreviated submission can be reviewed to meet the funding requirement. Note that no HSR activities can be conducted under this determination until a complete new project submission has been reviewed and approved by the IRB.

✔	Document Type	Document Description (Name)	Notes
	Application Form	*** Project Information.pdf**	This form must be signed by the Principal Investigator of Record.
	Proposal	*** Grant Proposal.doc**	The proposal submitted to the funding agency. **Do not include budget information.**
	Other	**** Other Supporting Documents.doc/.pdf**	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.