

Institutional Review Board (IRB) Checklist

This checklist is intended to aid investigators in providing the documentation necessary to submit a research proposal involving human subjects to the Institutional Review Board (IRB). **Required items are in bold below.** If this study requires a grant application, a copy of the complete grant may be submitted as the study protocol. Other materials may be required depending upon the specifics of your protocol. If after review the IRB requires modifications to the study, you must include the IRB Summary Statement in the resubmission along with an indication of how all IRB stipulations were addressed. Any document requiring signatures must be fully signed by all parties before submitting to the IRB.

If you have any questions, please email the IRB Liaison: IRB@nunm.edu.

Check all that apply and submit one copy of each item.					
☐	Full Title of Study: (prohibited characters include: “ * : > < ? / \)				
☐	Short Study Name/Acronym (Limit 54 characters) <i>Please use this Short Title/Acronym in all IRB email correspondence for the duration of this project.</i> Prohibited characters include: “ * : > < ? / \				
☐	<table style="width: 100%; border: none;"> <tr> <td style="width: 50%; border-bottom: 1px solid black; text-align: center;">Principal Investigator Name & Degree(s)</td> <td style="width: 50%; border-bottom: 1px solid black; text-align: center;">Principal Investigator Signature/Date</td> </tr> <tr> <td style="border-bottom: 1px solid black; text-align: center;">Co-Principal Investigator Name & Degree(s)</td> <td style="border-bottom: 1px solid black; text-align: center;">Co-Principal Investigator Signature/Date</td> </tr> </table>	Principal Investigator Name & Degree(s)	Principal Investigator Signature/Date	Co-Principal Investigator Name & Degree(s)	Co-Principal Investigator Signature/Date
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☐	All submission documents are on NUNM/Helfgott forms/templates (which can be found here: https://nunm.edu/research/resources/irb/documents/)				
☐	Protocol Date/Version: _____ (Format: mm.dd.yy) This date indicates your submission date or the date of your latest set of edits. This ensures that IRB members are reviewing the correct set of documents. This date should be updated with each submission and added to the title of each submission document as described below.				
☐	File Naming Convention. Label all documents/attachments in the following format according to IRQ attachment numeric: 2-digit attachment number _PI last name_ short study name_ document title_ version date mm.dd.yy Examples: • 01_Jackson_For Example Study_Checklist_02.12.23 • 02_Jackson_For Example Study_IRQ_02.12.23 • 03_Jackson_For Example Study_Protocol_02.12.23 • 13_Jackson_For Example Study_Jon Smith COI Mgmt Plan_02.12.23				
☐	Yes Expedited study? If so, please add at the end of your document labels “EXPEDITE.” Examples:				
☐	No • 01_Jackson_For Example Study_Checklist_EXPEDITE_02.12.23				

	02_Jackson_For Example Study_IRQ_EXPEDITE_02.12.23 03_Jackson_For Example Study_Protocol_EXPEDITE_02.12.23 13_Jackson_For Example Study_Jon Smith COI Mgmt Plan_EXPEDITE_02.12.23
☐ Yes ☐ No	Exempt study? If so, please add at the end of your document labels “EXEMPT.” Examples: 01_Jackson_For Example Study_Checklist_EXEMPT_02.12.23 02_Jackson_For Example Study_IRQ_EXEMPT_02.12.23 03_Jackson_For Example Study_Protocol_EXEMPT_02.12.23 13_Jackson_For Example Study_Jon Smith COI Mgmt Plan_EXEMPT_02.12.23
☐	Document Order of first 4 documents 01_Checklist 02_IRQ 03_Protocol 04_Consent Form
☐	Initial Review Questionnaire (IRQ)
☐	Disclosure of Significant Financial Interest (DSFI) form/dates. All study personnel completed the DSFI process within the past year. They are required annually or sooner if there are changes to an individual’s significant financial interest status. While DSFI Forms themselves are confidential, up to date and fully executed DSFI forms must be on file at NUNM. - A DSFI Form can be initiated via REDCap here: DSFI Form - A list of current DSFI Form execution dates is accessible to NUNM staff here: DSFIs -Public List
☐ Yes ☐ N/A	The DSFI Process may result in a Conflict of Interest Management Plan (COI-MP). COI-MP are not confidential and are required to be filed with each IRB submission. Only choose N/A if none of your study personnel has a COI-MP determination
☐	All study personnel completed required RCR and HIPAA training, required every 5 years. - Up to date completion confirmation must be on file at NUNM. - External personnel (not NUNM staff), RCR and HIPAA/HSR completion certificates required within the IRB submission packet
☐ Yes ☐ N/A	Data Safety Monitoring Plan for NIH-sponsored studies
☐ Yes ☐ N/A	Does this study require an IND (Investigational New Drug) application? Please visit the NUNM website (https://nunm.edu/research/resources/irb/documents/) and the FDA regulated webpage on IND applications (https://www.fda.gov/drugs/investigational-new-drug-ind-application/investigator-initiated-investigational-new-drug-ind-applications) for more information.
☐	All study personnel completed required RCR and HIPAA training, required every 5 years. - Up to date completion confirmation must be on file at NUNM. - For external personnel (not NUNM staff), include all RCR/HSR certifications within the IRB submission packet
☐ Yes ☐ N/A	Script(s): include for all interactions that are part of the Protocol No. of items: _____ Specify Type (e.g., Telephone):

☐ Yes	Informed Consent Form(s) All forms have been edited to Grade 8 reading level
☐ N/A	Yes ☐ N/A ☐ Adult Informed Consent (Grade 8) (# forms: _____) Yes ☐ N/A ☐ Genetic Informed Consent (# forms: _____) Yes ☐ N/A ☐ Child Assent (# forms: _____)
☐	Consent forms were reviewed and edited to an 8 th Grade reading level
☐ Yes	Investigator's Brochure/Package Inserts/Safety Sheets for Food Supplements, Herbs, Etc.
☐ N/A	
☐ Yes	Advertisements/Recruitment Letters
☐ N/A	No. of Items: _____ Specify Type (e.g., paper flyer, electronic posting, letters to patients):
☐ Yes	Survey Instrument(s)/Data Collection Form(s)
☐ N/A	No. of items: _____ Specify Type (e.g., Adverse events, phone screen, SF-36):
☐ Yes	Will you be compensating any of the participants for their time in monetary form?
☐ No	If yes, please note the following: - A completed W-9 is required in order to issue any type of compensation if the overall total per person per year is \$2000 or more (check, gift card, etc.). <u>Do NOT</u> submit the W-9 form to the SRC or IRB. - It is recommended that participants fill out the W-9 at the same time they sign the consent form. - The W-9 forms should be submitted securely to the administrator at the time that a check is requested, or when another type of compensation is provided to the participant.
☐ Yes	Collaborative Agreement(s) No. of items: _____
☐ N/A	
☐ Yes	Resubmissions to the IRB: Include IRB Committee Summary Statement with all the investigating team's responses composed in a different font color (preferably blue). (Please see the following webpage for further guidance https://nunm.edu/research/resources/irb/process/ .)
☐ N/A	☐ All document edits have been captured in tracked changes. ☐ Clean versions of edited documents are submitted with track-change versions.
☐	Emailed completed checklist and IRB submission documents to: IRB@nunm.edu