

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 <i>one copy</i> of each item.	
<input type="checkbox"/>	<p>Scientific Advisory Committee Review, Date Completed: Completed by</p> <hr style="border: 0; border-top: 1px solid black; margin: 5px 0;"/> <div style="display: flex; justify-content: space-between;"> Printed Name Signature/Date </div>
<input type="checkbox"/>	Full Title of Study:
<input type="checkbox"/>	<hr style="border: 0; border-top: 1px solid black; margin: 5px 0;"/> <p>Short Study Name/Acronym (<i>Limit 54 characters</i>) <i>Please use this Short Title/Acronym in all IRB email correspondence for the duration of this project.</i></p>
<input type="checkbox"/>	<div style="display: flex; justify-content: space-between; margin-bottom: 10px;"> <div style="width: 45%;"><hr style="border: 0; border-top: 1px solid black;"/></div> <div style="width: 45%;"><hr style="border: 0; border-top: 1px solid black;"/></div> </div> <div style="display: flex; justify-content: space-between;"> <div style="width: 45%; text-align: center;">Principal Investigator Name & Degree(s)</div> <div style="width: 45%; text-align: center;">Principal Investigator Signature/Date</div> </div> <hr style="border: 0; border-top: 1px solid black; margin: 5px 0;"/> <div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"><hr style="border: 0; border-top: 1px solid black;"/></div> <div style="width: 45%;"><hr style="border: 0; border-top: 1px solid black;"/></div> </div> <div style="display: flex; justify-content: space-between;"> <div style="width: 45%; text-align: center;">Co-Principal Investigator Name & Degree(s)</div> <div style="width: 45%; text-align: center;">Co-Principal Investigator Signature/Date</div> </div>
<input type="checkbox"/>	<p>All submission documents are on NUNM forms/templates (which can be found here: https://nunm.edu/research/resources/irb/documents/)</p>
<input type="checkbox"/>	<p>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.</p>
<input type="checkbox"/>	<p>Label all document in the following format according to IRQ attachment numeric: Attachment number _PI last name_ short study name_ document title_ version date mm.dd.yy.</p> <ul style="list-style-type: none"> • Example 1: 1-3_Kubitz_Zwickey_For Example Study_IRQ_02.12.23 • Example 2: 6_Bradley_Microbiome_John Smith Fully Executed DSFI Form_04.12.24
<input type="checkbox"/>	Initial Review Questionnaire (IRQ)
<input type="checkbox"/> Yes <input type="checkbox"/> No	<p>Expedited study? If so, please add at the end of your document labels “EXPEDITE.”</p> <ul style="list-style-type: none"> • Example: 1-3_Kubitz_Zwickey_For Example Study_IRQ_EXPEDITE_04.11.24 • Example: 6_Bradley_Microbiome_John Smith Fully Executed DSFI Form_EXPEDITE_04.12.24

<input type="checkbox"/> Yes <input type="checkbox"/> No	Exempt study? If so, please add at the end of your document labels "EXEMPT." <ul style="list-style-type: none"> Example 1: 1-3_Kubitz_Zwickey_For Example Study_IRQ_EXEMPT_02.12.23
<input type="checkbox"/> Yes <input type="checkbox"/> N/A	Data Safety Monitoring Plan for NIH-sponsored studies
<input type="checkbox"/> Yes <input type="checkbox"/> 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.
<input type="checkbox"/> Yes <input type="checkbox"/> No	All study personnel completed required RCR and HIPAA training , required every 5 years. <ul style="list-style-type: none"> Up to date completion confirmation must be on file at NUNM.
<input type="checkbox"/> Yes <input type="checkbox"/> No	All study personnel filed a Disclosure of Significant Financial Interest (DSFI) form , required annually. <ul style="list-style-type: none"> Fully executed DSFI forms must be on file at NUNM.
<input type="checkbox"/> Yes <input type="checkbox"/> N/A	Script(s): include for all interactions that are part of the Protocol No. of items: _____ Specify Type (e.g., Telephone):
<input type="checkbox"/> Yes <input type="checkbox"/> N/A	Informed Consent Form(s) All forms have been edited to Grade 8 reading level Yes <input type="checkbox"/> N/A <input type="checkbox"/> Adult Informed Consent (Grade 8) (# forms: _____) Yes <input type="checkbox"/> N/A <input type="checkbox"/> Genetic Informed Consent (# forms: _____) Yes <input type="checkbox"/> N/A <input type="checkbox"/> Child Assent (# forms: _____)
<input type="checkbox"/>	Consent forms were reviewed and edited to an 8 th Grade reading level
<input type="checkbox"/> Yes <input type="checkbox"/> N/A	Investigator's Brochure/Package Inserts/Safety Sheets for Food Supplements, Herbs, Etc.
<input type="checkbox"/> Yes <input type="checkbox"/> N/A	Advertisements/Recruitment Letters No. of Items: _____ Specify Type (e.g., paper flyer, electronic posting, letters to patients):
<input type="checkbox"/> Yes <input type="checkbox"/> N/A	Survey Instrument(s)/Data Collection Form(s) No. of items: _____ Specify Type (e.g., Adverse events, phone screen, SF-36):
<input type="checkbox"/> Yes <input type="checkbox"/> No	Will you be compensating any of the participants for their time in monetary form? If yes, please note the following: <ul style="list-style-type: none"> A completed W-9 is required in order to issue any type of compensation if the overall total per person per year is over \$599 (check, gift card, etc.). <u>Do NOT submit the W-9 form to the SRC or IRB.</u> 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.
<input type="checkbox"/> Yes <input type="checkbox"/> N/A	Collaborative Agreement(s) No. of items: _____
<input type="checkbox"/> Yes <input type="checkbox"/> N/A	<i>Resubmissions to the IRB:</i> 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

IRB Checklist
 Short Study Name/Acronym:
 PI:

	<p>https://nunm.edu/research/resources/irb/process/.)</p> <ul style="list-style-type: none"><input type="checkbox"/> All document edits have been captured in tracked changes.<input type="checkbox"/> Clean versions of edited documents are submitted with track-change versions.
<input type="checkbox"/>	Emailed completed checklist and IRB submission documents to: IRB@nunm.edu