

## 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.

*If you have any questions, please email the IRB Liaison: Veronica Rydze, [vrydze@ncnm.edu](mailto:vrydze@ncnm.edu)*

Check <b>all</b> that apply and submit <b>one copy</b> of each item.		GRAY AREA FOR OFFICE USE ONLY
<input type="checkbox"/>	<b>Scientific Advisory Committee Review, Date Completed</b> _____ <b>Completed by (Print name and sign next to printed name):</b> _____ _____	
<input type="checkbox"/>	<b>Title of Study:</b> _____	
<input type="checkbox"/>	<b>Principal Investigator</b> (Print Name with Degrees) _____ (Signature and Date) _____	
<input type="checkbox"/>	<b>Protocol Date/Version:</b> _____	
<input type="checkbox"/>	<b>All submission documents are on NUNM/Helfgott forms/templates</b> (which can be found here: <a href="http://helfgott.nunm.edu/institutional-review-board/irb-documents/">http://helfgott.nunm.edu/institutional-review-board/irb-documents/</a> )	
<input type="checkbox"/>	<b>Label all document in the following format according to IRQ attachment numeric:</b> attachment number_student last name_PI last name_study short name_document title on IRQ. (Example: 1-3_Kubitz_Zwickey_For Example Study_IRQ.)	
<input type="checkbox"/>	<b>Initial Review Questionnaire (IRQ)</b>	
<input type="checkbox"/> Yes <input type="checkbox"/> No	Expedited study? If so, please add at the end of your document labels “expedite.” (Example: 1-3_Kubitz_Zwickey_For Example Study_IRQ_expedite.)	
<input type="checkbox"/> Yes <input type="checkbox"/> No	Exempt study? If so, please add at the end of your document labels “exempt.” (Example: 1-3_Kubitz_Zwickey_For Example Study_IRQ_exempt.)	
<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	<b>Does this study require an IND (Investigational New Drug) application?</b> Please visit the NUNM website ( <a href="http://helfgott.nunm.edu/institutional-review-board/irb-documents/">http://helfgott.nunm.edu/institutional-review-board/irb-documents/</a> ) and the FDA regulated webpage on IND applications ( <a href="http://www.fda.gov/drugs/developmentapprovalprocess/Howdrugsaredevelopedandapproved/approvalapplications/investigationalnewdrugindapplication/default.htm#preIND">http://www.fda.gov/drugs/developmentapprovalprocess/Howdrugsaredevelopedandapproved/approvalapplications/investigationalnewdrugindapplication/default.htm#preIND</a> ) for more information.	
<input type="checkbox"/> Yes <input type="checkbox"/> No	<b>All study personnel completed required RCR and HIPAA training</b> , required every 5 years.	
<input type="checkbox"/> Yes	<b>All study personnel filed a Disclosure of Significant Financial Interest form</b> , required annually.	

IRB Checklist  
Study Title:  
PI:

<input type="checkbox"/> No	
<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	<b>Informed Consent Form(s)</b> 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"/> Yes <input type="checkbox"/> N/A	<b>Investigator's Brochure/Package Inserts/Safety Sheets for Food Supplements, Herbs, Etc.</b>
<input type="checkbox"/> Yes <input type="checkbox"/> N/A	<b>Advertisements/Recruitment Letters</b> No. of Items: _____ Specify Type (e.g., paper flyer, electronic posting, letters to patients): _____
<input type="checkbox"/> Yes <input type="checkbox"/> N/A	<b>Survey Instrument(s)/Data Collection Form(s)</b> No. of items: _____ Specify Type (e.g., Adverse events, phone screen, SF-36): _____
<input type="checkbox"/> Yes <input type="checkbox"/> No	<b>Will you be compensating any of the participants for their time in monetary form?</b> If yes, please note the following: <ul style="list-style-type: none"> <li>• A completed W-9 is required in order to issue any type of compensation (check, gift card, etc.) to study participants.</li> <li>• <u>Do NOT submit the W-9 form to the SRC or IRB.</u></li> <li>• It is recommended that participants fill out the W-9 at the same time they sign the consent form.</li> <li>• The W-9 forms should be submitted to the business office at the time that a check is requested, or when another type of compensation is provided to the participant.</li> </ul>
<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: <a href="http://ncnm-helfgott.ncnm.edu/institutional-review-board/responding-to-the-irb/">http://ncnm-helfgott.ncnm.edu/institutional-review-board/responding-to-the-irb/</a> .) <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"/>	<b>Emailed completed checklist and IRB submission documents to: <a href="mailto:kkubitz@ncnm.edu">kkubitz@ncnm.edu</a></b>

ACTIONS TAKEN:	Originals filed	Initials: _____	Date: ____/____/____
	Sent to IRB chair	Initials: _____	Date: ____/____/____
	IRB review	Initials: _____	Date: ____/____/____
	IRB report generated	Initials: _____	Date: ____/____/____
	Investigator notified	Initials: _____	Date: ____/____/____

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