Rev 02/08/23 cbj

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 at irb@nunm.edu.

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

☐ No	
☐ Yes ☐ N/A	Script(s): include for all interactions that are part of the Protocol No. of items: _____ Specify Type (e.g., Telephone): _____
☐ Yes ☐ N/A	**Informed Consent Form(s)** Yes ☐ N/A ☐ Adult Informed Consent (Grade 8) (# forms: _____) Yes ☐ N/A ☐ Genetic Informed Consent (# forms: _____) Yes ☐ N/A ☐ Child Assent (# forms: _____)
☐ Yes ☐ N/A	**Investigator's Brochure/Package Inserts/Safety Sheets for Food Supplements, Herbs, Etc.**
☐ Yes ☐ N/A	**Advertisements/Recruitment Letters** No. of Items: _____ Specify Type (e.g., paper flyer, electronic posting, letters to patients): _____
☐ Yes ☐ N/A	**Survey Instrument(s)/Data Collection Form(s)** No. of items: _____ Specify Type (e.g., Adverse events, phone screen, SF-36): _____
☐ Yes ☐ No	**Will you be compensating any of the participants for their time in monetary form?** If yes, please note the following: • A completed W-9 is required in order to issue any type of compensation (check, gift card, etc.) to study participants. • Do NOT submit the W-9 form to the SR 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 to the business office at the time that a check is requested, or when another type of compensation is provided to the participant.
☐ Yes ☐ N/A	Collaborative Agreement(s) No. of items: _____
☐ Yes ☐ N/A	*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: http://helfgott.nunm.edu/institutional-review-board/responding-to-the-irb/.) ☐ All document edits have been captured in tracked changes. ☐ Clean versions of edited documents are submitted with track-change versions.
☐	**PI emailed completed checklist and IRB submission documents to: irb@nunm.edu**

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: _____/_____/_____