HRP-211 | 2/2/2024

FORM: Basic Study Information

Use for new proposals[1] (Make copies of pages as needed)

BASIC INFORMATION

Basic Study Information	Study Details
IRB Number (if known):	Click or tap here to enter text.
Study Title:	Click or tap here to enter text.
Short Title:	Click or tap here to enter text.
Investigator:	Click or tap here to enter text.
Primary Contact:	Click or tap here to enter text.
Brief Description:	Click or tap here to enter text.

IRB OVERSIGHT

IRB Oversight Information	Study Details
Which IRB at this institution should oversee this research?	Click or tap here to enter text.
Will this institution's IRB act as the IRB of record for other participating sites?	☐ Yes ☐ No
Will an external IRB act as the IRB of record?	☐ Yes ☐ No
What kind of study is this?	☐ Multi-Site Study or Collaborative Study ☐ Single-Site Study

FUNDING SOURCES

Name of Funding Source	Funding Source ID	Grant Office ID
Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.
Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.
Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.

FINANCIAL INTEREST DECLARATION

See HRP-001 - SOP - Definitions for definitions of Immediate Family and a financial interest Related to the Research.

Do any personnel (or an immediate family member of personnel) involved in the design, conduct, or reporting of the research have a financial interest Related to the Research?

☐ Yes ☐ No

[1] This document satisfies AAHRPP elements I.6.B, I-9, II.2.A, II.3.A, II.3.C-II.3.C.1, III.1.B, III.2.B

If yes, provide the institution's evaluation of the financial interest below.

Name	Role	Involved in consent?	Evaluation (You may attach a separate page describing the outcome of the evaluation.)
Click or tap here to enter text.	Click or tap here to enter text.	☐ Yes ☐ No	Click or tap here to enter text.
Click or tap here to enter text.	Click or tap here to enter text.	☐ Yes ☐ No	Click or tap here to enter text.
Click or tap here to enter text.	Click or tap here to enter text.	☐ Yes ☐ No	Click or tap here to enter text.
Click or tap here to enter text.	Click or tap here to enter text.	☐ Yes ☐ No	Click or tap here to enter text.
Click or tap here to enter text.	Click or tap here to enter text.	☐ Yes ☐ No	Click or tap here to enter text.

PROTOCOL INFORMATION

Provide an Investigator Protocol (See HRP-503 - TEMPLATE PROTOCOL for instructions)

Provide the following documents when they exist or are applicable (see [2] for items marked *):

- Point-by-point response (For a response to modifications to secure approval, deferral, or disapproval)
- Evaluation of any Related Financial Interest
- Appendix A: Personnel
- Appendix B: Research Locations
- Appendix C: External Sites
- Appendix D: Drugs, Biologics, Dietary Supplements, and Foods, and Device and associated attachments*
- Appendix E: Devices and associated attachments
- Written materials to be provided to or meant to be seen or heard by subjects
    - Evaluation instruments and surveys*
    - Advertisements (printed, audio, and video)
    - Recruitment materials and scripts
    - Consent documents (The IRB does not require an informed consent document for HUD use.)
    - If consent will not be documented in writing, a script of information to be provided orally to subjects
    - Foreign language versions of the above
- Complete sponsor protocol*
- Grant application
- DHHS protocol and DHHS-approved sample consent document*

[2] Omit this item if this is the activation of a previously approved protocol at a new site or sites that will be overseen by a principal investigator who will take separate and full responsibility for that site or those sites.

Investigator Acknowledgement

I will conduct this protocol in accordance with requirements in the HRP-103 - INVESTIGATOR MANUAL.

Investigator Signature

Date of Signature: Click or tap here to enter text.

X_____

Appendix A: Personnel

- Name all personnel involved in this protocol's design, conduct, or reporting.
- Include the Principal investigator named above.

Name	Role	Involved in consent?
Click or tap here to enter text.	Click or tap here to enter text.	☐ Yes ☐ No
Click or tap here to enter text.	Click or tap here to enter text.	☐ Yes ☐ No
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Click or tap here to enter text.	Click or tap here to enter text.	☐ Yes ☐ No
Click or tap here to enter text.	Click or tap here to enter text.	☐ Yes ☐ No

Appendix B: Research locations

- Complete for local research location (e.g., an elementary where an investigator for this institution will intervene or interact with students).
- Do not include other institutions participating in a Collaborative Study or Multi-Site Study.

Site name	Location/Address and contact name	Contact phone or email	Will this location provide a letter of support?
Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.	☐ Yes ☐ No
Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.	☐ Yes ☐ No
Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.	☐ Yes ☐ No
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Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.	☐ Yes ☐ No
Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.	☐ Yes ☐ No

Appendix c: External Sites locations

- Complete for each external site at which the investigator will conduct or oversee the protocol.

Site name	Contact Name	Contact phone or email	IRB Oversight
Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.	☐ Site's IRB will review the protocol ☐ Site will rely on this institution's IRB
Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.	☐ Site's IRB will review the protocol ☐ Site will rely on this institution's IRB
Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.	☐ Site's IRB will review the protocol ☐ Site will rely on this institution's IRB
Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.	☐ Site's IRB will review the protocol ☐ Site will rely on this institution's IRB
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Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.	☐ Site's IRB will review the protocol ☐ Site will rely on this institution's IRB

Appendix D: Drugs, Biologics, Dietary Supplements, and Foods

List all:

- Unapproved drugs/biologics being used in the protocol
- Approved drugs/biologics whose use is specified in the protocol[3]
- Foods or dietary supplements whose use is specified in the protocol[4]
- Submit a package insert or investigator brochure for each listed drug

Generic Name	Brand Name	Type[5]
Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.
Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.
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Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.
Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.
Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.

Protocol is being conducted (select one of the following):

☐ Under IND# IND#(s): Click or tap here to enter text. Submit evidence of IND#(s)[6]	☐ Without IND# What is the basis for determining an IND is not required[7]? Click or tap here to enter text.

Who holds the IND?

☐ Sponsor
☐ Investigator (Submit approved IND application(s) (Form 1571) and FDA approval letter(s) for IND#(s))

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[3] "Specified in the protocol" means that the protocol requires the one or more subjects to use the drug, biologic, dietary supplement, or food as part of study participation, regardless of whether its use is standard of care. For example, if the protocol indicates that "subjects in group 1 will take 650 mg of aspirin in response to a headache" the use of aspirin is specified by the protocol. If the protocol indicates that "subjects in group 1 may take 650 mg of aspirin in response to a headache" the use of aspirin is not specified by the protocol.
[4] Ibid
[5] Drug, Biologic, Food Product, Dietary Supplement, or Other.
[6] Acceptable evidence includes: Sponsor protocol with the IND#, communication from the sponsor documenting the IND#, or FDA approval letter indicating IND#.
[7] IRBs should ask the clinical investigator whether the sponsor determined that an IND is or is not required and the basis for the determination. If the sponsor has determined that an IND is not required, the IRB may request that the investigator provide a copy of any available supporting documentation (e.g., letter from the sponsor or FDA, other basis for that determination). FDA Guidance August 2013, IRB Responsibilities for Reviewing the Qualifications of Investigators, Adequacy of Research Sites, and the Determination of Whether an IND/IDE is needed.

☐ Other (Specify): Click or tap here to enter text.

APPENDIX E: DEVICES

List all:

- Devices being evaluated for safety or effectiveness
- Humanitarian Use Devices (HUD)

Submit product labeling for each item listed

Device Name
Click or tap here to enter text.
Click or tap here to enter text.
Click or tap here to enter text.
Click or tap here to enter text.
Click or tap here to enter text.
Click or tap here to enter text.
Click or tap here to enter text.
Click or tap here to enter text.

Protocol is being conducted (select one of the following):

☐ Under IDE#(s): Click or tap here to enter text. **Submit evidence of IDE#(s)[8]**
☐ Under HDE#(s): Click or tap here to enter text. **Submit evidence of IDE#(s)[9]**
☐ Under abbreviated IDE requirements **Submit an explanation of why the device is a non-significant risk device**
☐ None of the above

Who holds the IDE?

☐ Sponsor
☐ Investigator **Submit approved IDE application(s) and FDA approval letter(s) for IDE#(s)**
☐ Other: Click or tap here to enter text.
☐ None of the above

[8] Acceptable evidence includes: Sponsor protocol with the IDE#, communication from the sponsor documenting the IDE#, or FDA approval letter indicating IDE#
[9] Ibid