[This generic sample Research Protocol is intended to serve as a model for PI (Principal Investigator) use.]

[TITLE OF STUDY] Research Protocol

This Research Protocol (Protocol) discusses in detail how the Principal Investigator (herein PI or "Researchers" – "we" "our") plans to carry out the Research, how Researchers will analyze the data that Researchers collect, and what Researchers plan to do with the results. The following are points that we include in this Research Protocol. Hereinafter, the total plan of research is referenced as the Research. The IHR IRB Protocol Number is added to the approval page by the IRB.

[1] Introduction and Background

[1] Title of Study: _____
[2] Goal or Goals of Study: _____
[3] Method of Study (Summary): _____

☐ This Research is necessary or important for human health or wellness. It involves the following human health or wellness concern: _____

Relevant research background includes:

1. The expertise of the PI is: _____

[1] Education: _____

[2] Degrees Held: _____

[3] Practice:_____
[4] Disclosure of Relevant Commercial Interests: _____

2. Relevant previous non-commercial research includes: _____

☐ The positive impact of the Research will be an improvement in the health or wellness of relevant populations, or an increase in scientific knowledge relevant to the health or wellness concerns of such persons.

[2] Study Design & Phases

☐ The following is a description of the study design, sequence, and timing of all study procedures that will be performed:

Study Design: _____

(1) Phase One: _____

(2) Phase Two: _____

(3) Phase Three _____

Sequence and Timing of Study Procedures: _____

_____

The following pilot, screening, intervention, and follow-up Phases will be implemented:

PHASE ONE [A] Any Pilot Study: _____

[B] Analysis of Pilot Study: _____

[C] Screening of Subjects for Main Study _____

PHASE TWO: Intervention & Data Collection _____

_____

PHASE THREE: Analysis of Data & Follow-up: _____

_____

Attached are copies of all materials that will be used in the procedure, such as surveys, scripts, questionnaires, etc. This includes: EXHIBIT GROUP A: _____

_____

Attached are such flow sheets as will help the reader understand the procedures. These include: EXHIBIT GROUP B:_____

_____

☐ The Study Procedures will NOT differ from standard care or procedures (e.g., medical, psychological, educational, etc.), except: _____

_____

☐ Any deception (including placebo) or withholding of complete information is NOT required, except as detailed here. Such deception or withholding is necessary because: _____

_____

☐ The study will take place at the following location(s): _____

_____

☐ A letter of approval and cooperation from each participating site is required by this Protocol; copy attached hereto. EXHIBIT C

[3] Participants

- ☐ The nature of the research, as set forth in this Protocol, requires and justifies using the participant population in the manner set forth in the above Study Design and Phases..
- ☐ The approximate number and ages for the control and experimental groups are:

Number of Persons, Total	Age Range	Other Relevant Characteristics

- ☐ The expected gender and minority representation of the participant population should mirror that of the general population, except: _____.
- ☐ The criteria for selection for each participant group is: _____ _____
- ☐ The exclusion criteria for each participant group is: medically inappropriate individual, due to existing condition or other medical contraindication and the following: _____
- ☐ The primary source for participants is expected to be: _____

Attached hereto are letters of cooperation from agencies, institutions, or others involved in the recruitment. EXHIBIT GROUP D

- ☐ The participants will be approached by the PI and associates or agents through various means of communication, including personal contact by the PI and others. All reasonable steps will be taken to avoid coercion and protect privacy.

Attached are copies of all relevant study-connected web pages, advertisements, flyers, contact letters, and phone contact protocols, or draft versions thereof. EXHIBIT GROUP E

- ☐ if participants will receive payments, services without charge, or extra course credit, set forth here: _____.
- ☐ If participants will be charged for any study procedures or substances, set forth here: _____.

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[4] Risks and Benefits

- ☐ The following is the nature and amount of risk of injury, stress, discomfort, invasion of privacy, and other side effects from all study procedures, drugs, and devices as understood by PI: _____ _____

The amount of risk the community may be subjected to: _____

- ☐ All reasonable due care will be used to minimize risks and maximize benefits.
- ☐ The PI and associates will engage in a continuing reassessment of the balance between risks and benefits and report any doubtful changes to the IHR IRB
- ☐ Data and safety monitoring will be a primary responsibility of the PI.
- ☐ The expected benefits for individual participants, the community, and society include: _____

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[5] Adverse Effects

☐ Any adverse effects or events will be handled in accordance with normal medical procedures. If a dietary supplement is involved in a serious adverse event, a proper report under the FDA AER System will be filed forthwith on FDA Medwatch Form 3500A: http://www.fda.gov/medwatch/SAFETY/3500A.pdf . A "serious adverse event" is defined by law as: "The term "serious adverse event" is an adverse event that-- (A) results in-- (i) death; (ii) a life-threatening experience; (iii) inpatient hospitalization; (iv) a persistent or significant disability or incapacity; or (v) a congenital anomaly or birth defect; or (B) requires, based on reasonable medical judgment, a medical or surgical intervention to prevent an outcome described under subparagraph (A)."

☐ The expected facilities and equipment are adequate to handle possible adverse effects.

☐ The PI and sponsoring entity will be financially responsible for treatment of physical injuries resulting from study procedures. The IHR IRB is not responsible for such financial requirements.

[6] Confidentiality of Research Data

☐ Prior to publication the PI will take care that all data will be anonymous (no possible link to identifiers).

☐ If identifiable data is maintained it will be coded and the key to the code will be kept separate from the data.

☐ Except as required by law and permitted under HIPPA, no other agency or individual will have access to identifiable data.

☐ All reasonable steps will be taken to protect data, such as: computer with restricted access, locked files, etc.

[7] Informed Consent Forms

☐ The Informed Consent form shall be in writing. [See IHR IRB format for Informed Consent.] Informed Consent shall disclose expected term of the study and shall include a provision providing for method to leave the study.

Attached are copies of all proposed consent and assent forms for each participant group. EXHIBIT GROUP F

[8] Drugs, Substances, and Devices

☐ Attached is a List of all *Non-Investigational Drugs* or other substances (including dietary ingredients and HPUS homeopathic dilutions) that will be used, if any, during the research, including the name, source, dose, and method of administration (lawful substances). EXHIBIT G

☐ Attached is a List of all *Investigational Drugs or Substances* (including New Dietary Ingredient (NDI) and non-HPUS homeopathic dilutions) to be used in the study, if any, including the name, source, dose, method of administration, IND number, and phase of testing. (INDs are to be registered with the appropriate institutional pharmacy) EXHIBIT H

Attached is a Summary of drug information prepared by the PI, including available toxicity data, reports of animal studies, description of studies done in humans, and drug protocol. EXHIBIT I

☐ Attached is a List of all *Investigational or Other Devices or Techniques* to be used, if any, including the name, source, description of purpose, method, and Food and Drug Administration IDE number (if any), and explain why the device qualifies as a Non-Significant Risk. Attach a copy of the protocol, descriptions of studies in humans and animals, and drawings or photographs of the device. EXHIBIT GROUP J

[9] Additional Information

☐ There are no materials with potential radiation risk (e.g., X-rays and radioisotopes).

☐ We will not use materials with potential radiation risk and are not subject to an annual review by a Radiation Safety Committee.

☐ Participant medical, academic, or other personal records that will be used include:

_____

☐ If required by the Study Design and Protocol, above, the type of audio-visual recordings, tape recordings, or photographs that will be made are: _____

_____

☐ All scientific instruments used will be tested at regular intervals by or under the immediate direction of the PI. Other safety testing will include: _____

☐ The data collected will be analyzed by or under PI supervision. The data analysis protocol is:

_____

☐ Do the PI or sponsor have relevant insurance coverage? If so, state company name and policy number.

The PI expects to prepare and submit clinical trial notes, papers and reports to peer reviewed and other publications based on the IRB approved Research Protocol and the outcome of the Research.

This Protocol initially prepared: [Day / Month / Year]

Submitted to IRB: [Day / Month / Year]

Revision Dates: _____

Approved by IHR IRB: [Day / Month / Year] -- The IRB reserves all rights.

IHR IRB Protocol Number _____ [Assigned by IRB upon Approval.]

_____

Principal Investigator

_____

IRB Chairperson

RESEARCH PROTOCOL EXHIBITS

[2] Study Design and Phases

EXHIBIT GROUP A - Procedure Materials

EXHIBIT GROUP B - Flow Charts

EXHIBIT C - Site Approval Letters

[3] Participants

EXHIBIT GROUP D - Cooperation Letters

EXHIBIT GROUP E - Ads and Contact Info

[7] Informed Consent Forms

EXHIBIT GROUP F - Informed Consent Forms [See IHR IRB Sample IC Form]

[8] Drugs, Substances, and Devices

EXHIBIT G - List of Substances

EXHIBIT H - List of Drugs

EXHIBIT I - Drug Information

EXHIBIT GROUP J - List of Devices