GIBSON INSTITUTE OF COGNITIVE RESEARCH

Human Subjects Protocol (HSP)

IRB

To complete the form, click the underlined areas and type or paste in your text; double-click checkboxes to check/uncheck.

Indicate the type of review you are applying for:

☐ Convened (Full) IRB *or*

☐ Expedited—See the Expedited Category Review Sheet, and indicate the categories here: ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7 ☐8 ☐9

☐ Exempt—See the Exempt Category Review Sheet, and indicate the categories here: ☐1 ☐2 ☐3 ☐4 ☐5 ☐6

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1. IRB Protocol Title:____

2. Investigator(s)

a. Name of Principal Investigator:____ Degree(s)/Title:____
Dept/Div:____ Mailing Address:____ ZIP:____
Phone:____ E-mail:____

b. Name of Co-Principal Investigator:____ Degree(s)/Title:____
Dept/Div:____ Mailing Address:____ ZIP:____
Phone:____ E-mail:____

INVESTIGATOR ASSURANCE STATEMENT & SIGNATURE

By my signature as Principal Investigator, I acknowledge my responsibilities for this Human Subjects Protocol, including:

- Certifying that I and any Co-Investigators or Other Investigators comply with reporting requirements of the GICR Conflict of Interest Review Board;
- Certifying that the information, data, and/or specimens collected for the research will be used, disclosed and maintained in accordance with this protocol and GICR policies;
- Following this protocol without modification unless (a) the IRB has approved changes prior to implementation or (b) it is necessary to eliminate an apparent, immediate hazard to a participant(s);
- Verifying that all key personnel listed in the protocol and persons obtaining informed consent have completed initial IRB training and will complete continuing IRB training as required;
- Verifying that all personnel are licensed/credentialed for the procedures they will be performing, if applicable;
- Certifying that I and all key personnel have read the *GICR Policy/Procedure to Ensure Prompt Reporting of Unanticipated Problems Involving Risks to Subjects or Others to the IRB, Institutional Officials, and Regulatory Agencies* and understand the procedures for reporting;
- Applying for continuing review of the protocol at least annually unless directed by the IRB to apply more frequently;

- Conducting the protocol as represented here and in compliance with IRB determinations and all applicable local, state, and federal law and regulations; providing the IRB with all information necessary to review the protocol; refraining from protocol activities until receipt of initial and continuing formal IRB approval.

Signature of Investigator:_____ **Date:**_____

3. Funding

Is this study externally funded? □Yes □No

If No, specify that costs of the study will be covered by funds from the GICR or other source named:____

If Yes, complete a-d.

a. Title of Grant or Contract:____

b. PI of Grant or Contract:____

c. Sponsor, Funding Route (*check and describe all that apply*):

□ Gov't Agency or Agencies—Agency name(s):____

□ Private Nonprofit (e.g., Foundation)—Name:____

□ Industry, investigator-initiated—Name:____ Describe the funding arrangement:____

4. Locations Involved

a. Describe the facilities available for the conduct of the research:____

b. Is this study a clinical trial requiring clinical services at a site other than sites listed in Item a above? □Yes □No

c. Is the study to be undertaken within a school, business, or other institution that does not have an institutional review board? □Yes □No
If Yes, attach a statement of any contacts with and approvals from the appropriate institution officials.
Note. Documentation of all such approvals must be received by the GICR IRB before IRB approval will be issued.

d. Has this protocol or project been reviewed by another IRB, similar review board, or departmental review committee(s) that authorizes the use of its patient populations? □Yes □No
If Yes, provide name of the review board(s):____ and for each board listed, enter either the date of latest approval(s) or "PENDING":____ or reasons not approved:____. *If this protocol is subsequently rejected or disapproved by another review board, the GICR IRB must be notified promptly.*
Attach copies of approvals/disapprovals.

5. Drugs: Will any drugs or supplements be used/studied in this protocol? □Yes □No
If Yes, attach the Drug Review Sheet.

6. Devices: Will any devices be studied in this protocol or used for a purpose

other than for which they were approved by the FDA? □Yes □No
If Yes, attach the Device Review Sheet.

7. HIPAA Privacy and Security

Will the PI or others obtain, review, or make other use of participants' "personal health information" (i.e., information, whether oral or recorded in any form or medium that (a) is created or received by a health care provider and (b) relates to past, present, or future physical or mental health or condition of an individual; or provision of health care; or payment for provision of heath care)? □Yes □No

If Yes, complete a-d as described.

a. Will the data/information be stored or managed electronically (on a computer)? □Yes □No

b. Is the principal investigator requesting that the IRB waive patient HIPAA authorization from another institution or entity (e.g., insurance company, collaborating institution). □Yes □No
If Yes, attach copy of privacy notices from institution/entity, and provide the name of institution/entity:____

c. Indicate which of the listed identifiers would be associated/linked with the protected health information (PHI) used for this protocol.

□ Names
□ Geographic subdivisions smaller than a State
□ Elements of dates (except year) related to an individual
□ Telephone numbers
□ Fax numbers
□ Email addresses
□ Social security numbers
□ Medical record numbers
□ Health plan beneficiary numbers
□ Account numbers
□ Certificate/license numbers
□ Vehicle identifiers and serial numbers
□ Device identifiers and serial numbers
□ Biometric identifiers
□ Web universal resource locators (URLs)
□ Internet protocol address numbers
□ Full-face photographic images
□ Any other unique identifying number—Describe:____
Note. Codes are not identifying as long as the researcher cannot link the data to an individual
□ None—**If None, skip to Item 8.**

d. Choose one plan to describe your use of the personal health information:

□ The data collected meet the specifications for a "limited data set"
—Attach Data Use Agreement or Business Associate Agreement

□ Research staff will obtain authorization from each patient to use the information

—Attach Patient Authorization form, complete except for patient name and IRB protocol number

□ PI requests Waiver of Patient Authorization to use the information
—Attach Waiver of Authorization and Informed Consent form

PROPOSED RESEARCH

8. Purpose—in nontechnical, lay language

Summarize the purpose and objectives of this protocol, including any related projects, in one short paragraph.

9. Background—in nontechnical, lay language

Summarize in 2-3 paragraphs past experimental and/or clinical findings leading to the formulation of this study. Include any relevant past or current research by the Principal Investigator.

10. Participants (Screening and Selection)

a. How many participants are to be enrolled? _____
If multi-center study, total number at all centers:_____

b. Describe the characteristics of anticipated or planned participants.
Sex:_____
Race/Ethnicity:_____
Age:_____
Health status:_____

c. From what population(s) will the participants be derived?

_____

Describe your ability to obtain access to the proposed population that will allow recruitment of the necessary number of participants:

_____

Describe the inclusion/exclusion criteria:

_____

d. If participants will comprise more than one group or stratification, describe each group (e.g., treatment/intervention, placebo, controls, sham treatment) **and** provide the number of participants anticipated in each group.

_____

e. Indicate which, if any, of the special populations listed below will be involved in the protocol. Include the Special Populations Review Form (SPRF) if indicated.

□ Minors (<18 years old): Attach Special Populations Review Form—Minors
□ Employees or students at institution where research conducted
□ Persons who are temporarily decisionally impaired
□ Persons who are permanently decisionally impaired (e.g., mentally retarded)
□ Non-English Speakers

f. List any persons other than those directly involved in the study who will be at risk.
If none, enter "None":_____

g. Describe the process (e.g., recruitment, chart review) that will be used to seek potential participants (e.g., individuals, records, specimens).

h. If you will use recruitment materials (e.g., advertisements, flyers, letters) to reach potential participants, attach a copy of each item. If not, identify the source (e.g., databases) from which you will recruit participants.

i. Describe the procedures for screening potential participants.

11. Protocol Procedures, Methods, and Duration of the Study—in nontechnical language

a. Describe the procedures for all aspects of your study. Tell us what you are doing.

b. What is the probable length of time required for the entire study (i.e., recruitment through data analysis to study closure)?

c. What is the total amount of time each participant will be involved?

d. If different phases are involved, what is the duration of each phase in which the participants will be involved? If no phases are involved, enter "not applicable."

e. Will an interview script or questionnaire be used? ☐Yes ☐No
If Yes, attach a copy.

f. Will participants incur any costs as a result of their participation? ☐Yes ☐No
If Yes, describe the reason for and amount of each foreseeable cost.

g. Will participants be compensated? ☐Yes ☐No
If Yes, complete i-v:
i. Type: (e.g., cash, check, gift card, merchandise):
ii. Amount or Value:
iii. Method (e.g., mail, at visit):
iv. Timing of Payments: (e.g., every visit, each month):
v. Maximum Amount of Payments per Participant:

12. Describe the potential benefits of the research.

13. Risks

a. List the known risks—physical, psychological, social, economic, and/or legal—that participants may encounter as a result of procedures required in this protocol. Do not list risks resulting from standard-of-care procedures. *Note. Risks included in this protocol document should be included in the written consent document.*

b. Is this a therapeutic study or intervention? ☐Yes ☐No

If Yes, complete the following items:

i. Describe the standard of care in the setting where the research will be conducted:____

ii. Describe any other alternative treatments or interventions:____

iii. Describe any withholding of, delay in, or washout period for standard of care or alternative treatment that participants may be currently using:____

c. Do you foresee that participants might need additional medical or psychological resources as a result of the research procedures/interventions? □Yes □No

If Yes, describe the provisions that have been made to make these resources available.

____

d. Do the benefits or knowledge to be gained outweigh the risks to participants? □Yes □No

If No, provide justification for performing the research:____

e. Describe precautions that will be taken to avoid risks and the means for monitoring to detect risks.

____

14. Informed Consent

a. Do you plan to obtain informed consent for this protocol? □Yes □No

If Yes, complete the items below.

If No, complete and include the Waiver of Informed Consent or Waiver of Authorization and Informed Consent, as applicable.

b. Do you plan to document informed consent for this protocol? □Yes □No

If Yes, complete the items below.

If No, complete the items below **and** include the Waiver of Informed Consent Documentation.

c. How will consent be obtained?____

d. Who are the persons who will provide consent or permission? ____

e. What steps will be taken to minimize the possibility of coercion or undue influence?

____

f. What language will the prospective participant or the legally authorized representative understand? ____

g. What language will be used to obtain consent? ____

15. Procedures to Protect Privacy

Describe the provisions included in the research to protect the privacy interests of participants (e.g., others will not overhear your conversation with potential participants, individuals will not be publicly identified or embarrassed).

____

16. Procedures to Maintain Confidentiality

a. Describe the manner and method for storing research data and maintaining confidentiality. If data will be stored electronically anywhere other than a server

maintained centrally by GICR, identify the departmental and all computer systems used to store protocol-related data, and describe how access to that data will be limited to those with a need to know.

_____

b. Will any information derived from this study be given to any person, including the subject, or any group, including coordinating centers and sponsors? □Yes □No
If Yes, complete i-iii.

i. To whom will the information be given? _____
ii. What is the nature of the information? _____
iii. How will the information be identified, coded, etc.? _____

17. Additional Information

In the space below, provide any additional information that you believe may help the IRB review the proposed research, or enter "None."

_____