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| Protocol #: | Principal Investigator: | |  | Date: |
| Study Title: | | | | |
| New | Pilot | Continuation/Renewal | | Amendment |
| Designated Review | | Full Board Review | | Designated/Primary Reviewer:  Name:  Signature:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Funded/Sponsored Research | | Yes  No | | If Yes, Sponsor**:** |
| Clinical Trial (health/bio medical studies) | | Yes  No | | Exempt:  Expedited (Category: \_\_\_\_\_ ) |

1. **FDA Regulations**. Do FDA regulations apply:

Does this research involve either a) a device that will monitor, diagnose, or affect a biological function or phenomenon; or b) administer/inject a drug or dietary supplement?

Yes No

If yes, ask the following follow-up questions:

1. Will the research study the safety or effectiveness of the device or drug/supplement?

Yes No N/A

1. Will the research pose greater than minimal risks to subjects?

Yes No N/A

1. Will the research involve non-healthy subjects?

Yes No N/A

If yes, to any of the above follow-up questions, then the IRB needs to determine the following:

1. If the research involves a drug, will an Investigational New Drug Application (“IND”) be required? If not exempt from IND requirements, an IND application must be filed with the FDA Center for Drug Evaluation Research (“CDER”).
2. If the research involves a device, is the device a significant risk or non-significant risk device?  **The determination of a significant risk or non-significant risk device must be done by the convened IRB**.  If the convened IRB determines that the device is a significant risk device, then an Investigational Device exemption application must be filed with the FDA Center for Devices and Radiological Health (CDRH).

2. **Purpose** **Background.**

The purpose and background for the study include:

Theoretical framework

Hypothesis or Research Questions

Appropriate Citations

3. **Vulnerable Subjects.**  Are vulnerable subjects involved?

Yes No

If so, have additional safeguards been

Children, wards of the state

Prisoners

Pregnant women, fetuses, neonates

Impaired consent capacity

Students, employees, or laboratory personnel.

4. **Equitable Selection**. Selection of subjects is equitable in relation to each of the following:

Research objectives;

The setting where the research will be conducted;

Vulnerable populations;

Inclusion/exclusion criteria; and

Recruitment methods.

5. **Research Personnel.**

Are the credentials and/or described qualifications of the research staff/ investigators representative of the appropriate expertise needed to perform their responsibilities in the study?

Are all conflicts of interests related to human research protections, if any, appropriately minimized or managed (e.g., limit who obtains informed consent; add disclosure(s) in informed consent process; etc...).

6. **Minimized Risks.** Risks to subjects are minimized:

By using procedures consistent with sound research design;

By using procedures that do not involve unnecessary risk; and

when appropriate, by using diagnostic or treatment procedures already being performed.

7. **Risk/Benefit Ratio**. Risks to subjects are reasonable in relation to anticipated benefits, if any, and

the importance of the knowledge that may reasonably be expected to result

The research plan addresses the likelihood of harm and magnitude of harm, including potential physical, psychological, social, and/or economic risks to subjects; and

The research is likely to achieve its proposed aims; and

The importance of the resulting knowledge expected is clear. (Reviewer should only consider risks/benefits that may result from the research. Do not consider possible long-range effects of applying knowledge gained from research or impact to public policies)

8. **Informed Consent**.

Are there adequate provisions in place to ensure Informed consent is obtained from each subject or legally authorized representative (“LAR”), unless waived by IRB.

Consent document elements:

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| 1. | * Statement that study involves research * Explanation of purposes of research and expected duration of subject's participation * Description of procedures to be followed * Identification of any procedures which are experimental |
| 2. | * Description of risks or discomforts to subject. |
| 3. | * Description of benefits to subject or to others. |
| 4. | * Disclosure of alternative procedures, if appropriate. |
| 5. | * Description of the extent to which confidentiality will be maintained. [If FDA regulated: statement that FDA may inspect records.] |
| 6. | * For research involving more than minimal risk, explanation as to whether compensation and medical treatments are available if injury occurs. |
| 7. | * Explanation of whom to contact if the subject has questions, concerns, suggestions, or input:   + about the research;   + about the subjects' rights; and   + if research-related injury occurs. |
| 8. | * Statement that participation is voluntary, that refusal to participate involves no penalty or loss of benefits, and that subject may discontinue at any time. |

Additional elements to consider, unless the item(s) does not apply given the nature of the research or the proposed procedures:

* Information concerning payment;
* Statement that procedure may involve unforeseeable risks;
* Description of circumstances under which subject's participation may be terminated by the investigator without subject's consent;
* Description of additional costs to subject resulting from participation in research;
* Description of consequences of subject's decision to withdraw from research;
* Statement that significant new findings developed during research which may relate to subject's willingness to continue will be provided to subject;
* Approximate number of subjects involved in study.
* For applicable FDA-regulated clinical trials, a statement to inform subjects the clinical trial will be registered with a national clinical trial registry data bank ([clinicaltrials.gov](http://clinicaltrials.gov/)).
* For FDA-regulated clinical trials, a statement to inform subjects that if he/she should choose to withdraw early from the study, the data collected to the point of withdrawal remains in the study database and may not be removed.

9. **Consenting Process**.

The proposed consent process provides the subject/subject’s LAR with sufficient opportunity to consider whether to participate;

The information to be relayed during the consent process is in a language understandable to the subject/subject’s LAR;

The information being communicated during the consent process does not include exculpatory language through which the subject/subject’s LAR waives or appears to waive any of the subject’s legal rights;

The information being communicated during the consent process does not include exculpatory language through which the subject/subject’s LAR releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

When appropriate (i.e., participants include children, individuals with intellectual or developmental delay), appropriate assent forms are included.

10. **Data**

Data Monitoring Plan (required for all studies with greater than minimal risk). Does project plan properly identify the type of information being collected and ensure adequate protection and security?

Privacy/confidentiality is protected. Is there adequate provisions to protect subjects privacy and maintain data confidentiality?

Procedures are stated clearly regarding what happens to data when subjects withdraw from a study prior to its conclusion.

11. **Miscellaneous.**

For greater than minimal risk research or NIH-funded/FDA-regulated clinical investigations, consider the following to determine if the data security is adequate:

* Is the proposed plan commensurate with the nature, size, and complexity of the research as well as the degree of risk involved?
* Does proposal include procedures for promptly detecting harm and mitigating potential injuries?
* What safety information will be collected? How will safety information be collected (e.g. at study visits, by monthly telephone calls, etc.)?
* What data will be monitored and who will monitor the data?
* What is the frequency of review or analysis of cumulative safety data to determine whether harm is occurring?
* Are there procedures for ensuring appropriate reporting of findings to the IRB?
* Are there any conditions or criteria that could trigger an immediate suspension/ termination of the research and if so are their procedures for reporting the suspension/ termination to the appropriate entities?
* Is establishment of an independent individual or data and safety monitoring board (“DSMB”) warranted? If so, is there a plan for providing DSMB reports, (routine and urgent), to the IRB?

Studies including video or audio recording include appropriate media release forms.

Proposed payment to subjects and/or cost to subjects for participation is appropriate

Confirm that all measures discussed in the protocol are present in the submitted protocol package.

If all assessments are not included with submission, is reasonable explanation provided.

Review and approval by other committees/units, as applicable for biomedical research (e.g., IBC, laser safety officer, radiation safety officer), has been conducted.

Approval from external institutions has been obtained from an authorized official.

A signature assurance sheet signed by the Principal Investigator and his/her Department Chairperson (or appropriate equivalent) is on file.

12. **General Data Protection Regulation (“GDPR”). Research that collects personal/identifiable information or data from anyone who is living or traveling in one of the countries of the European Economic Area. (Anonymous data and use of already deidentified data is not subject to the GDPR.)**

Consent form includes all necessary GDPR elements:

* PI’s name
* data processing purpose and/or transferring information
* type of data collected
* identification of all parties that will have access to the data
* explanation of rights
* Data security information
* How long data will be stored (can be indefinite)
* Whether and under what conditions data may be used for future research
* express consent statement in signature block section).

Adequate data protection in association with the risk (consider a data protection plan)

13. **Reviewer Comments: Summary Table**

**Significant Risk to Human Subjects: (**Please use the space below to summarize any significant problems):

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**Methodological or Secondary Areas of Concern: (**Please use the space below to summarize but do not put subjects at risk).

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