## *GIBSON INSTITUTE OF COGNITIVE RESEARCH* INSTITUTIONAL REVIEW BOARD
### REVIEWER CHECKLIST & DECISION

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|---|---|---|
| *Protocol #* | *PI* | *Reviewer* |

***Important Note: Some items may not be applicable to the study.***

| | PURPOSE AND BACKGROUND | YES | NO | N/A | NOTES |
|---|---|---|---|---|---|
| 1 | Statement of purpose is adequate | | | | |
| 2 | Preliminary data are adequate | | | | |
| 3 | Study personnel appear appropriate/qualified | | | | |
| | **STUDY DESIGN** | **YES** | **NO** | **N/A** | |
| 4 | Design is adequate to address research question (risk/benefit analysis) | | | | |
| 5 | Rationale for the number of subjects is justified | | | | |
| 6 | Inclusion/exclusion criteria are appropriate | | | | |
| | **STUDY POPULATION AND RECRUITMENT PROCEDURES** | **YES** | **NO** | **N/A** | |
| 7 | Selection of subjects is equitable | | | | |
| 8 | Screening procedures are acceptable | | | | |
| 9 | Recruitment methods and materials are appropriate | | | | |
| 10 | Verification/permission letters are included from recruitment sites | | | | |
| 11 | Payments/reimbursements are not coercive/unduly influential | | | | |
| 12 | Any coercion/undue influence to participate is avoided or minimized | | | | |
| 13 | Vulnerable subject populations* are identified and adequately protected, and additional safeguards are provided where needed to protect subjects' rights and welfare and minimize coercion or undue influence *[*e.g., children, prisoners, pregnant women, mentally disabled persons, economically or educationally disadvantaged persons]* | | | | |
| | **INFORMED CONSENT** | **YES** | **NO** | **N/A** | |
| 14 | Consent will be sought from each prospective participant or their legal representative | | | | |
| 15 | If consent is waived, or consent process/documentation is altered from standard, appropriate justification is provided. | | | | |
| 16 | The consent process minimizes the possibility of coercion or undue influence | | | | |
| 17 | Consent form language is appropriate/understandable to subjects | | | | |
| 18 | Consent form is accurate and complete and includes all required elements [*See checklist next page.*] | | | | |
| 19 | Consent procedure is adequately described in the IRB Proposal | | | | |
| 20 | Any exception to signed consent by adult subjects (*e.g., surrogates, children*) is justified in protocol and reflected in consent documentation | | | | |
| 21 | Communications with the participant, both written and verbal, will be in language understandable to the participant or representative | | | | |
| 22 | Information communicated during the consent process will not include exculpatory language through which the participant or representative is made to waive or appear to waive legal rights or release or appear to release the investigator, sponsor, institution, or their agents from liability for negligence. | | | | |
| | **PROCEDURES** | **YES** | **NO** | **N/A** | |
| 23 | Study utilizes procedures already performed for diagnosis/treatment | | | | |
| 24 | Frequency and duration are stated | | | | |
| 25 | Research procedures are clearly differentiated from standard of care | | | | |
| 26 | Procedures are performed at acceptable facilities by trained staff | | | | |
| 27 | Data collection/recording methods are explained | | | | |
| 28 | Adverse Event reporting is addressed | | | | |

| | RISKS AND BENEFITS | YES | NO | N/A | |
|---|---|---|---|---|---|
| 29 | Risks are well described, including physical, psychological, social, legal, or economic risks | | | | |
| 30 | Risks are minimized | | | | |
| 31 | Risks and benefits are well described | | | | |
| 32 | Risks are reasonable in relation to potential benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result | | | | |
| | **STUDY RESOURCES** | **YES** | **NO** | **N/A** | |
| 33 | Study personnel are sufficient in numbers and qualifications | | | | |
| 34 | Study personnel have all completed an IRB Training Course | | | | |
| | **PRIVACY AND CONFIDENTIALITY** | **YES** | **NO** | **N/A** | |
| 35 | Measures to protect privacy are adequate | | | | |
| 36 | Measures to protect confidentiality of identifiable data are adequate | | | | |
| 37 | HIPAA privacy policy is addressed if accessing medical records | | | | |
| | **BASIC REQUIRED ELEMENTS OF INFORMED CONSENT [45 CFR 46.116(A) AND 21 CFR 25 (A)]** | **YES** | **NO** | **N/A** | |
| 1 | A statement that the study involves research;<br>an explanation of the purpose of the research;<br>an explanation of the expected duration of the research;<br>a description of the procedures to be followed; and<br>identification of any procedures that are experimental. | | | | |
| 2 | A description of any reasonable foreseeable risks or discomforts to the subject. | | | | |
| 3 | A description of the benefits to the subject or to others that may be expected from the research. | | | | |
| 4 | A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject. | | | | |
| 5 | A statement describing the extent, if any, to which confidentiality of the records identifying the subject will be maintained; and<br>A statement that the records may be inspected by the Sponsor (CRO or other designee), the FDA (for FDA-regulated research), the OHRP, the IRB or other authorized parties; and<br>A statement that a description of this study will be on the ClinicalTrials.gov website (for FDA-regulated clinical trials) | | | | |
| 6 | For research involving more than minimal risk, an explanation as to whether any compensation will be paid, whether any medical treatments are available if injury occurs, and, if so, what those treatments consist of or where further information may be obtained. | | | | |
| 7 | An explanation of whom to contact:<br>for questions about the research;<br>for questions about rights as a research subject; and<br>in the event of a research-related injury. | | | | |
| 8 | A statement that participation is voluntary, and<br>that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue at any time without penalty. | | | | |
| | **ADDITIONAL ELEMENTS (IF APPLICABLE) [45 CFR 46.116 (B)]** | **YES** | **NO** | **N/A** | |
| 1 | Anticipated circumstances under which the subject's participation may be terminated by the investigator. | | | | |
| 2 | Any additional costs to the subject that may result from participation in the research. | | | | |

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|---|---|---|---|---|---|
| 3 | The consequences of and procedures for withdrawing from the research study. | | | | |
| 4 | The approximate number of subjects in the study. | | | | |

## IRB DETERMINATIONS AND CONDITIONS OF APPROVAL (NOT ALL WILL APPLY)

### INFORMED CONSENT DETERMINATIONS

- ☐ Informed Consent is required
- ☐ Child Assent is required
- ☐ Parental Consent is required
- ☐ HIPAA Research Authorization is required
- ☐ Waiver of HIPAA Research Authorization is granted
- ☐ Waiver of Signed Consent is acceptable [46.117(c)(1)or 46.117(c)(2)]
- ☐ Waiver of Child Assent is acceptable [46.116(d)]
- ☐ Waiver of Parental Consent is acceptable [46.116(d)]
- ☐ Waiver of Informed Consent is acceptable [46.116(d)]
- ☐ Additional Conditions – Specify:_____

**WAIVER OF INFORMED CONSENT JUSTIFICATION**

- ☐ Not possible to contact all participants
- ☐ Sample size so large not feasible to obtain consent
- ☐ Consent may introduce systematic bias into data
- ☐ Risk of contacting participants greater than risk of study procedures
- ☐ Design of study does not allow possibility of obtaining consent

**WAIVER OF SIGNED INFORMED CONSENT JUSTIFICATION**

- ☐ Only record linking participants and research data would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. [46.117(c)(1)]
- ☐ Research is minimal risk; no procedures for which written consent is normally required outside research setting. [46.117(c)(2)]

**REVIEW DECISION:**

☐ **Approve** ☐ **Approve Pending Modification(s)**

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IRB Member Signature Date

☐ **Disapprove** (use only after multiple attempts have been made to resolve issues and IRB and PI have reached an impasse *or* if IRB determines that science is clearly inadequate, sufficient resources are unavailable, or research is inappropriate). Disapproval cannot be used for Exempt/Expedited reviews).