IRB Protocol Scientific Review Form

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| All U.S. Army Medical Research and Development Command (USAMRDC) supported/funded research involving human subjects, human data, or human specimens must be reviewed for compliance with Federal, Department of Defense (DOD), and Army human subjects protection requirements and receive approval by the Office of Research Protections (ORP) Human Research Protection Office (HRPO) prior to implementation; this requirement derives from DODI 3216.02 and the Defense Federal Acquisition Regulation Supplement.  |

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| Title of Protocol:       |
| Principal Investigator:       |

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| **Review Criteria** | **Yes** | **No** | **N/A** |
| 1. Is the purpose clear?
 | [ ]  | [ ]  | [ ]  |
| 1. Is the background information appropriate and complete?
 | [ ]  | [ ]  | [ ]  |
| 1. Is the objective clearly defined? Is there a compelling Army need for these data?
 | [ ]  | [ ]  | [ ]  |
| 1. Does the proposed sample size match the experimental design? (Could sample size be smaller yet statistical power adequate?)
 | [ ]  | [ ]  | [ ]  |
| 1. Is the methodology described in sufficient detail (in terms of equipment, procedures, data collection, volunteers, etc.)?
 | [ ]  | [ ]  | [ ]  |
| 1. Can the objectives be achieved with the proposed methodology?
 | [ ]  | [ ]  | [ ]  |
| 1. Has the researcher addressed training issues adequately?
 | [ ]  | [ ]  | [ ]  |
| 1. Is the experimental design clearly stated?
 | [ ]  | [ ]  | [ ]  |
| 1. Can the objectives be achieved with the proposed experimental design?
 | [ ]  | [ ]  | [ ]  |
| 1. Will questionnaires, if any, provide relevant data?
 | [ ]  | [ ]  | [ ]  |
| 1. Are the risks and potential discomforts identified and are the risks reasonable in relation to potential benefits?
 | [ ]  | [ ]  | [ ]  |
| 1. Have study endpoints and criteria for early withdrawal from the study been identified?
 | [ ]  | [ ]  | [ ]  |
| **If you checked No for any of the above criteria, support with rationale.** Use additional sheets if necessary, following the pattern given below. |
| Review Item Number: Item # | Location in protocol: e.g., page number |
| Enter Comments |
| Review Item Number: Item # | Location in protocol: e.g., page number |
| Enter Comments |

**Add any other comments below involving specific points not covered by the criteria listed on page 1:**

**Reviewer:**

 ***Print Name***

**Reviewer:**

 ***Signature Date***

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| **Additional Reviewer’s Information** |
| **Field of Expertise:**  |
| **Affiliation:**       | **Office Symbol:**       |
| **Address:**       |
| **E-mail Address:**  | **Telephone Number:**       |