IRB Checklist – Initial Review

**Date:** Click here to enter text.

**Reviewer** *(name)***:** Click here to enter text.

**Reviewer Type:** [ ]  **Primary** [ ]  **Secondary** [ ]  **Expedited IRB ID#:** Click here to enter text.

**Title of Project:** Click here to enter text.

**Principal Investigator** *(name)***:** Click here to enter text.

**Faculty Advisor, if applicable** *(name)***:** Click here to enter text.

# Reviewer Recommendations Summary

**Level of Risk** *(please check one)***:**

[ ]  **Minimal risk** (the probability and magnitude of harm or discomfort are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests)

[ ]  **Greater than minimal risk**

**Device Category** *(please check one)***:**

[ ]  **Not applicable** [ ]  **Significant risk** [ ]  **Non-significant risk**

**Child Category** *(see also Attachment 1):*

[ ]  **Not applicable**

[ ]  **Cat. 1 (45 CFR 46.404) – minimal risk w/ prospect of direct benefit**

[ ]  **Cat. 2 (45 CFR 46.405) – greater than minimal risk w/ prospect of direct benefit**

**Recommended Total Enrollment Number (upper limit):** Click here to enter text.

**Recommended IRB Action** *(check one)***:**

[ ]  **Approve as submitted**

[ ]  **Modifications required to secure approval (minor contingencies)**

[ ]  **Defer for the reasons described below (major contingencies)**

[ ]  **Table for the reasons described below**

[ ]  **Disapprove for the reasons described below**

[ ]  **Suspend for the reasons described below**

[ ]  **Terminate for the reasons described below**

**Comments or Concerns:** Click here to enter text.

**Continuing Review Frequency** *(check one)***:**

[ ]  **12 months** [ ]  **6 months** [ ]  **Other:** Click here to enter text.

**Type of Review** *(check one)***:**

[ ]  **Expedited Review Categories 1-9 - Category** Click here to enter text.

[ ]  **Expedited Review of Minor Modifications**

[ ]  **Reviewer Recommendations for Convened IRB**

Click here to enter text.

**Signature of Reviewer Date**

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|  | **Check “Yes,” “No” or “N/A”** | **Reviewer Comments Below:** |
| **I. Introduction, Specific Aims, and Background**a) Are the specific aims clearly specified?b) Are there adequate preliminary data to justify the research?c) Is there appropriate justification for this research protocol? | [ ] **YES** [ ] **NO** [ ] **N/A**[ ] **YES** [ ] **NO** [ ] **N/A**[ ] **YES** [ ] **NO** [ ] **N/A** | a) | Click here to enter text. |
| b) | Click here to enter text. |
| c) | Click here to enter text. |
| **II. Scientific Design**a) Is the scientific design adequate to answerthe question?b) Are the objectives likely to be achievablewithin a given time period?c) Is the scientific design (i.e., randomization;placebo controls; Phase 1, 2, or 3)described and adequately justified? | [ ] **YES** [ ] **NO** [ ] **N/A**[ ] **YES** [ ] **NO** [ ] **N/A**[ ] **YES** [ ] **NO** [ ] **N/A** | a) | Click here to enter text. |
| b) | Click here to enter text. |
| c) | Click here to enter text. |
| **III. Inclusion/Exclusion Criteria for Subjects**a) Are inclusion and exclusion criteria clearlyspecified and appropriate?b) If women, minorities, or children are included or excluded, is this justified?c) Is the choice of subjects appropriate for the question being asked?d) Is the principle of distributive justice adequately incorporated into the inclusion and exclusion criteria for the research protocol? Is subject selection equitable? | [ ] **YES** [ ] **NO** [ ] **N/A**[ ] **YES** [ ] **NO** [ ] **N/A**[ ] **YES** [ ] **NO** [ ] **N/A**[ ] **YES** [ ] **NO** [ ] **N/A** | a) | Click here to enter text. |
| b) | Click here to enter text. |
| c) | Click here to enter text. |
| d) | Click here to enter text. |
| **IV. Recruitment of Subjects**a) Are the methods for recruiting potential subjects well defined?b) Are the locations and timing of the recruitment process acceptable?c) Is the individual performing the recruitment appropriate for the process?d) Are all recruitment materials submitted and appropriate?e) Are there acceptable methods for screening subjects before recruitment? | [ ] **YES** [ ] **NO** [ ] **N/A**[ ] **YES** [ ] **NO** [ ] **N/A**[ ] **YES** [ ] **NO** [ ] **N/A**[ ] **YES** [ ] **NO** [ ] **N/A**[ ] **YES** [ ] **NO** [ ] **N/A** | a) | Click here to enter text. |
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| d) | Click here to enter text. |
| e) | Click here to enter text. |

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| **V. Research Procedures**a) Are the rationale and details of the research procedures accurately described and acceptable?b) Is there a clear differentiation betweenresearch procedures and standard care?c) Are the individuals performing theprocedures appropriately educated?d) Is the location of where the procedure will be performed acceptable?e) Are there adequate plans to inform subjects about specific research results if necessary (clinically relevant results, risk of depression, risk of suicide, incidental findings, etc.)? | [ ] **YES** [ ] **NO** [ ] **N/A**[ ] **YES** [ ] **NO** [ ] **N/A**[ ] **YES** [ ] **NO** [ ] **N/A**[ ] **YES** [ ] **NO** [ ] **N/A**[ ] **YES** [ ] **NO** [ ] **N/A** | a) | Click here to enter text. |
| b) | Click here to enter text. |
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| d) |  |
| e) | Click here to enter text. |
| **VI. Drugs, Biologics, and Devices**a) Is the status of the drug described and appropriate (investigational, new use of an FDA-approved drug, or an FDA- approved drug within approved indications)?b) Are the drug dosage and route ofadministration appropriate?c) Are the drug or device safety and efficacy data sufficient to warrant the proposed phase of testing?d) Is the significant risk or nonsignificant riskstatus of the device described and appropriate? | [ ] **YES** [ ] **NO** [ ] **N/A**[ ] **YES** [ ] **NO** [ ] **N/A**[ ] **YES** [ ] **NO** [ ] **N/A**[ ] **YES** [ ] **NO** [ ] **N/A** | a) | Click here to enter text. |
| b) | Click here to enter text. |
| c) | Click here to enter text. |
| d) | Click here to enter text. |
| **VII. Data Analysis and Statistical Analysis**a) Is the rationale for the proposed number of subjects reasonable?b) Are the plans for data and statistical analysis defined and justified, including the use of stopping rules and endpoints?c) Are there adequate provisions formonitoring data (DSMB)? | [ ] **YES** [ ] **NO** [ ] **N/A**[ ] **YES** [ ] **NO** [ ] **N/A**[ ] **YES** [ ] **NO** [ ] **N/A** | a) | Click here to enter text. |
| b) | Click here to enter text. |
| c) | Click here to enter text. |
| **VIII. Potential Risks, Discomforts, and Benefits for****Subjects**a) Are the risks and benefits adequatelyidentified, evaluated, and described?b) Are the potential risks minimized and likelihood of benefits maximized?c) Is the risk/benefit ratio acceptable for proceeding with the research?d) If children are involved, which regulatory category of risk/benefit does the protocol fall within, and are all criteria within the category adequately addressed? | [ ] **YES** [ ] **NO** [ ] **N/A**[ ] **YES** [ ] **NO** [ ] **N/A**[ ] **YES** [ ] **NO** [ ] **N/A**[ ] **YES** [ ] **NO** [ ] **N/A** | a) | Click here to enter text. |
| b) | Click here to enter text. |
| c) | Click here to enter text. |
| d) | Click here to enter text. |
| **IX. Compensation and Costs for Subjects**a) Is the amount or type of compensation or reimbursement reasonable?b) Are there adequate provisions to avoid out-of-pocket expenses by the research subject, or is there sufficient justification to allow subjects to pay?c) If children or adolescents are involved,who receives the compensation, and is this appropriate? | [ ] **YES** [ ] **NO** [ ] **N/A**[ ] **YES** [ ] **NO** [ ] **N/A**[ ] **YES** [ ] **NO** [ ] **N/A** | a) | Click here to enter text. |
| b) | Click here to enter text. |
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| **X. Privacy and Confidentiality**a) Are there adequate provisions to protect the privacy and ensure the confidentiality of the research subject?b) Are there adequate plans to store andcode the data?c) Is the use of identifiers or links toidentifiers necessary, and how is this information protected? | [ ] **YES** [ ] **NO** [ ] **N/A**[ ] **YES** [ ] **NO** [ ] **N/A**[ ] **YES** [ ] **NO** [ ] **N/A** | a) | Click here to enter text. |
| b) | Click here to enter text. |
| c) | Click here to enter text. |
| **XI. Informed Consent /Assent**a) Are all the elements of informed consent contained in the consent document?1. Research Purpose (required)2. Research Procedures (required)3. Risks and Discomforts (required)4. Potential Benefits (required)5. Alternative procedures or treatment(required)6. Provisions for Confidentiality(required)7. Management of Research-RelatedInjury (required)8. Contacts for additional information(required)9. Voluntary participation and the rightto discontinue participation without penalty (required)10. Unforeseeable risks (if applicable)11. Termination of participation by the investigator (if applicable)12. Additional Costs (if applicable)13. Consequences of discontinuingresearch participation (if applicable)14. Notification of significant newfindings (if applicable)15. Approximate number of subjects (if applicable)b) Is the process of obtaining consent adequately described?c) Is assent required?d) Is Waiver or Modification of Consentpossible?e) Is a plan for the data of participants who  discontinue the study or who are removed  from the study described? | [ ] **YES** [ ] **NO** [ ] **N/A**[ ] **YES** [ ] **NO** [ ] **N/A**[ ] **YES** [ ] **NO** [ ] **N/A**[ ] **YES** [ ] **NO** [ ] **N/A**[ ] **YES** [ ] **NO** [ ] **N/A**[ ] **YES** [ ] **NO** [ ] **N/A**[ ] **YES** [ ] **NO** [ ] **N/A**[ ] **YES** [ ] **NO** [ ] **N/A**[ ] **YES** [ ] **NO** [ ] **N/A**[ ] **YES** [ ] **NO** [ ] **N/A**[ ] **YES** [ ] **NO** [ ] **N/A**[ ] **YES** [ ] **NO** [ ] **N/A**[ ] **YES** [ ] **NO** [ ] **N/A**[ ] **YES** [ ] **NO** [ ] **N/A**[ ] **YES** [ ] **NO** [ ] **N/A**[ ] **YES** [ ] **NO** [ ] **N/A**[ ] **YES** [ ] **NO** [ ] **N/A**[ ] **YES** [ ] **NO** [ ] **N/A**[ ] **YES** [ ] **NO** [ ] **N/A**[ ] **YES** [ ] **NO** [ ] **N/A**[ ] **YES** [ ] **NO** [ ] **N/A** | a) | Click here to enter text. |
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| d)e) | Click here to enter text. |
| e) | Click here to enter text. |
| f) | Click here to enter text. |
| **XII. Other Issues**a) Are adequate references provided?b) When should the next review occur? If frequent reviews are necessary, how should the interval be determined? | [ ] **YES** [ ] **NO** [ ] **N/A**[ ] **YES** [ ] **NO** [ ] **N/A** | a) | Click here to enter text. |
| b) | Click here to enter text. |

Please attach any additional comments or required findings:

Click here to enter text.