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.

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

**Faculty Advisor** *(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 Reviewer Acting on Behalf of the IRB**

**Recommendations to Convened IRB by Expedited Reviewer**

**Recommendations by 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 answer  the question?  b) Are the objectives likely to be achievable  within 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 clearly  specified 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. |
| b) | Click here to enter text. |
| c) | Click here to enter text. |
| 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 between  research procedures and standard care?  c) Are the individuals performing the  procedures 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. |
| c) | Click here to enter text. |
| 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 of  administration 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 risk  status 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 for  monitoring 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 adequately  identified, 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. |
| c) | Click here to enter text. |

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 and  code the data?  c) Is the use of identifiers or links to  identifiers 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-Related  Injury (required)  8. Contacts for additional information  (required)  9. Voluntary participation and the right  to 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 discontinuing  research participation (if applicable)  14. Notification of significant new  findings (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 Consent  possible?  e) Is a plan for the data of participants who  discontinue the study or who are removed  from the study described?  f) Does it state that the UM has no funds set  aside for research related injuries? | **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. |
| b) | Click here to enter text. |
| c) | Click here to enter text. |
| 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:

Click here to enter text.