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# IRB Reviewer Summary & Checklist for eProtocol Submissions

(Review the entire list before starting)

| Reviewer | PI | Protocol ID | Date |
|---|---|---|---|
| | | | |
| **Study Title:** | | | |

| Application Type |
|---|
| ☐ Not Human Subjects Research |
| ☐ Exempt |
| ☐ Expedited |
| ☐ Full |
| ☐ Limited Activity Determination |

**Summary of Review:**

**A. Application Component Checklist**

Application contains:

- ☐ CITI Training Certificate for PI
- ☐ CITI Training Certificate(s) for other participant(s)
- ☐ Conflict of Interest information (i.e., Form VI COI Disclosure Form)
- ☐ Copies of consent documents
- ☐ Copies of any instruments

***Note:*** *If the study application is incomplete, please notify the IRB chair.*

**B. Research Design**

- ☐ Research design is sufficient for review
- ☐ Research design is insufficient to review

***Note:*** *If the research design is insufficient, please notify the IRB chair.*

**C. Reviewer Recommendations:**

- ☐ Approve for one year
- ☐ Approve with stipulations for one year
- ☐ Defer decision making pending receipt of additional information and/or documents
- ☐ Disapprove

**Detailed Checklist:**

| **1. Study Purpose & Objectives** | | **YES** | **NO** | **N/A** | **OHRP Guidance** |
|---|---|---|---|---|---|
| I. | Is the research question clearly stated? | ☐ | ☐ | ☐ | *OHRP Guidance*: Research Involving Human Subjects |
| II. | Is the significance of the study well justified? | ☐ | ☐ | ☐ | |
| III. | Are the aims appropriate and aligned with the background? | ☐ | ☐ | ☐ | |

| 2. Study Design & Methods | | YES | NO | N/A | OHRP Guidance |
|---|---|---|---|---|---|
| I. | Are the study design and methods appropriate for addressing the research question? | ☐ | ☐ | ☐ | OHRP Guidance: Protection of Human Subjects (45 CFR 46 Subpart A) |
| II. | Is there adequate time to conduct and complete the research proposed? | ☐ | ☐ | ☐ | |
| III. | Are potential conflicts of interests disclosed and described? | ☐ | ☐ | ☐ | |
| IV. | For biomedical research: Are interventions well-defined and feasible? | ☐ | ☐ | ☐ | |
| V. | For social/behavioral research: Are instruments (e.g., surveys, interviews) justified and suitable? | ☐ | ☐ | ☐ | |
| VI. | Are all other study materials attached (e.g., questionnaires, interview questions, treatment protocol if applicable) and deemed acceptable after review? | ☐ | ☐ | ☐ | |
| **3. Participant Selection & Recruitment** | | **YES** | **NO** | **N/A** | **OHRP Guidance** |
| I. | Are the inclusion and exclusion criteria clearly stated and reasonable? | ☐ | ☐ | ☐ | OHRP Guidance: Equitable Selection of Subjects |
| II. | Is the subject population described in sufficient detail? | ☐ | ☐ | ☐ | |
| III. | Is participant selection equitable? | ☐ | ☐ | ☐ | |
| IV. | Are screening procedures described in adequate detail and acceptable? | ☐ | ☐ | ☐ | |
| V. | Are recruitment methods appropriate and not coercive? | ☐ | ☐ | ☐ | |
| VI. | Are all procedures from recruitment, screening, data collection, data analysis, writing of manuscripts accurately described and acceptable? | ☐ | ☐ | ☐ | |
| VII. | Are all recruitment materials attached (e.g., subject pool website posting, flyers letters of introduction) and deemed acceptable after review? (possible coercion such as excessive compensation or unequal relationships should be considered) | ☐ | ☐ | ☐ | |
| VIII. | Is compensation (if any) reasonable and not so high as to be coercive? | ☐ | ☐ | ☐ | |
| IX. | Is the timing and location of recruitment appropriate and respectful of potential participants? | ☐ | ☐ | ☐ | |
| **4. Informed Consent Process** | | **YES** | **NO** | **N/A** | **OHRP Guidance** |
| I. | Is the consent process described clearly? | ☐ | ☐ | ☐ | OHRP Guidance: Informed Consent FAQs |
| II. | Does the consent form include all required elements (e.g., purpose, procedures, risks, benefits, confidentiality)? | ☐ | ☐ | ☐ | |
| III. | Are there adequate plans to inform subjects about specific research results that might affect the subject's health/safety and/or decision to continue participation? | ☐ | ☐ | ☐ | |
| IV. | Is the consent process culturally appropriate and understandable to participants? | ☐ | ☐ | ☐ | |
| **5. Risks & Risk Minimization** | | **YES** | **NO** | **N/A** | **OHRP Guidance** |
| I. | Are the risks to participants (physical, psychological, legal, etc.) adequately described? | ☐ | ☐ | ☐ | |

| | | | | | |
|---|---|---|---|---|---|
| II. | Have steps been taken to minimize risks? | ☐ | ☐ | ☐ | 🔗 *OHRP Guidance:* Minimizing Risks in Research |
| **6. Potential Benefits** | | **YES** | **NO** | **N/A** | **OHRP Guidance** |
| I. | Are the potential benefits to participants or society clearly outlined? | ☐ | ☐ | ☐ | 🔗 *OHRP Guidance*: Balancing Risks and Benefits |
| II. | Do benefits outweigh the risks? | ☐ | ☐ | ☐ | |
| **7. Data Confidentiality & Privacy Protections** | | **YES** | **NO** | **N/A** | **OHRP Guidance** |
| I. | Are data storage, retention, and confidentiality practices clearly described? | ☐ | ☐ | ☐ | 🔗 *OHRP Guidance*: Privacy and Confidentiality |
| II. | For sensitive data, are protections (e.g., encryption, coding, de-identification) in place? | ☐ | ☐ | ☐ | |
| III. | Will data be placed in the participant's medical records? | ☐ | ☐ | ☐ | |
| **8. Vulnerable Populations** | | **YES** | **NO** | **N/A** | **OHRP Guidance** |
| I. | Are additional safeguards in place if the study involves vulnerable groups (e.g., children, prisoners, pregnant individuals)? | ☐ | ☐ | ☐ | 🔗 *OHRP Guidance*: Subpart B – Pregnant Women and Fetuses 🔗 *OHRP Guidance*: Subpart C – Prisoners 🔗 *OHRP Guidance*: Subpart D – Children |
| **9. Data Monitoring & Safety** | | **YES** | **NO** | **N/A** | **OHRP Guidance** |
| I. | For biomedical research: Is there a data and safety monitoring plan? | ☐ | ☐ | ☐ | 🔗 *OHRP Guidance*: Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events |
| II. | For social/behavioral research: Are procedures in place to handle participant distress or disclosure of sensitive information? | ☐ | ☐ | ☐ | |
| **10. Training** | | **YES** | **NO** | **N/A** | **OHRP Guidance** |
| I. | Do the PI and key personnel have appropriate training that is up to date (e.g., CITI)? | ☐ | ☐ | ☐ | 🔗 *OHRP Guidance*: Institutional and Investigator Responsibilities |

**Recommended Stipulations:**

**For deferred applications, please list any additional information and/or documents to be provided prior to continued IRB review:**

**Additional Comments:**