

|  |  |
| --- | --- |
| Institutional  Review  Board  OHRP IRB# IRB00011406 |  |

FORM A: IRB PROTOCOL REVIEW APPLICATION FORM

Fill in each line as is appropriate. Asterisked sections are not mandatory for Secondary Data Use application (**concept notes** and a complete **data request form** are required however).

Review applied for (please click one below as appropriate):

|  |  |  |  |
| --- | --- | --- | --- |
| Full IRB Review | Expedited IRB Review | Review Exemption | Secondary Data Use |

|  |  |  |  |
| --- | --- | --- | --- |
| 1. Title of Study |  | | |
| 2. Name of Principal Investigator |  | | |
| 3. Affiliation contact address |  | | |
| 4. Contact email |  | | |
| 5. Contact phone |  | | |
| 6. Contact Fax |  | | |
| 7. Background |  | | |
| 8. Hypothesis, Aims and Objectives |  | | |
| 9. Study justification |  | | |
| 10. Research design and study methods |  | | |
| 11. Statistical Analysis |  | | |
| 12. References |  | | |
| 13. Potential benefits to participants |  | | |
| 14. Study participant risk assessment\* |  | | |
| 15. Study participant assent and language considerations\* |  | | |
| 16. Voluntariness of participants\* |  | | |
| 17. Study participant inclusion / exclusion criteria\* |  | | |
| 18. Study population description and sample size calculation |  | | |
| 19. Data collection, storage and confidentiality protection. State future use of data if any\* |  | | |
| 20. Potential benefit to APIN |  | | |
| 21. Contribution to generalized knowledge and any limitations of study |  | | |
| 22. Dissemination of findings |  | | |
| 23. Funding source |  | | |
| 24. Conflict of interests |  | | |
| 25. Attachments checklist\* | NIH bio-sketch formatted CV of study investigator(s)  Evidence of Bio-ethics training from PI  Letter of Intent to IRB Chairman for Ethical Approval  Full written protocol / data use concept notes (see guidelines for format)  Consent form(s)  Secondary Data Use DA form  Other supporting document(s) | | |
| **Internal Use Only** | | | |
| IRB Application ID |  | Application date | Click to Enter |
| Reviewer |  | | |
| Reviewer Comment |  | | |
| Determination | Choose an item. | | |