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| InstitutionalReviewBoardOHRP 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):

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| [ ]  Full IRB Review | [ ]  Expedited IRB Review | [ ]  Review Exemption | [ ]  Secondary Data Use |

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| --- | --- |
| 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. |