

**[*Instructions for this template***

*Text in brackets is instructional and should be deleted before submitting your document to the IRB for review.*

*Only the title page and sections I-IV of this document are editable. Complete these sections as applicalble to your grant. You will create an Initial Application in eRA, complete the HRP-211 eForm and upload this document in the submission. DO NOT include any supporting documents with this application.*

*Your Protocol must be submitted to the IRB as an* ***MS Word*** *document.*]

**118 Protocol for applications and proposals lacking definite plans for involvement of human subjects.**

**TITLE:** [Enter full protocol title as listed in eRA]

**PROTOCOL VERSION DATE:**

**PRINCIPAL INVESTIGATOR (PI)**

**Name:** [*PI name here must match the eRA eForm*]

**Telephone:**

**Email:**

# FUNDING

[*Include the funding. (e.g., Funding for this research is pending from [insert name of sponsor].)* ***Include the Proposal Number in this section.*]**

# OBJECTIVES

[*Describe the purpose of the study, including identification of specific primary objectives/hypotheses/research question(s). Describe secondary objectives/hypotheses if there are any.*]

# BACKGROUND AND SIGNIFICANCE

*[Provide the scientific or scholarly background and rationale for the research based on the existing literature.*

*Describe the relevant prior experience and gaps in current knowledge.*

*Explain the significance of the human research in terms of why it is important and how it will add to existing knowledge.*

*This should not be a copy-pasted significance section from a grant. Rather, create a more concise version that highlights the key points and that is accessible to non-scientist reviewers.*]

# PRELIMINARY STUDIES

[*Describe any preliminary studies.*]

# RESEARCH STUDY DESIGN AND PROCEDURES

**Study Design**

The Study Design has not yet been developed pending funding. No human research will be conducted until full IRB Approval has been obtained.

**Study Procedures**

The Study Procedures have not yet been developed pending funding. No human research will be conducted until full IRB Approval has been obtained.

# ABOUT THE PARTICIPANTS

The About the Participants information has not yet been developed pending funding. No human research will be conducted until full IRB Approval has been obtained.

# VULNERABLE POPULATIONS

The Vulnerable Populations information has not yet been developed pending funding. No human research will be conducted until full IRB Approval has been obtained.

# RECRUITMENT METHODS AND PRE-SCREENING

The Recruitment Methods information has not yet been developed pending funding. No human research will be conducted until full IRB Approval has been obtained.

# INFORMED CONSENT

The Informed Consent information has not yet been developed pending funding. No human research will be conducted until full IRB Approval has been obtained.

# COMPENSATION

The Compensation information has not yet been developed pending funding. No human research will be conducted until full IRB Approval has been obtained.

# COST TO PARTICIPANTS

The Cost to Participants information has not yet been developed pending funding. No human research will be conducted until full IRB Approval has been obtained.

# DATA MANAGEMENT

The Data Management information has not yet been developed pending funding. No human research will be conducted until full IRB Approval has been obtained.

# PROVISIONS TO PROTECT THE PRIVACY INTERESTS OF PARTICIPANTS

The Provisions to Protect the Privacy Interests of Participants information has not yet been developed pending funding. No human research will be conducted until full IRB Approval has been obtained.

# WITHDRAWAL OF PARTICIPANTS

The Withdrawal of Participants information has not yet been developed pending funding. No human research will be conducted until full IRB Approval has been obtained.

# RISKS TO PARTICIPANTS

The Risks to Participants information has not yet been developed pending funding. No human research will be conducted until full IRB Approval has been obtained.

# MANAGEMENT OF RISKS

The Management of Risks information has not yet been developed pending funding. No human research will be conducted until full IRB Approval has been obtained.

# POTENTIAL BENEFITS

The Potential Benefits information has not yet been developed pending funding. No human research will be conducted until full IRB Approval has been obtained.

# PROVISIONS TO MONITOR THE DATA FOR THE SAFETY OF PARTICIPANTS

The Provisions to Monitor the Data for the Safety of Participants information has not yet been developed pending funding. No human research will be conducted until full IRB Approval has been obtained.

# DRUGS

The Drugs information has not yet been developed pending funding. No human research will be conducted until full IRB Approval has been obtained.

# DEVICES

The Devices information has not yet been developed pending funding. No human research will be conducted until full IRB Approval has been obtained.

# WORKING WITH OTHER INSTITUTIONS/SINGLE IRB

The Working with Other Institutions information has not yet been developed pending funding. No human research will be conducted until full IRB Approval has been obtained.

# SHARING OF RESULTS WITH PARTICIPANTS

The Sharing of Results with Participants information has not yet been developed pending funding. No human research will be conducted until full IRB Approval has been obtained.

# REFERENCES

The References information has not yet been developed pending funding. No human research will be conducted until full IRB Approval has been obtained.