***BIOMEDICAL TEMPLATE WITHOUT INSTRUCTIONS:***

* *Use this protocol template for BIOMEDICAL research*
* *Depending on the nature of what you are doing, some sections may not be applicable to your research. If a section is not applicable, mark NA.*
* *When you write the protocol, keep an electronic copy. You will need to modify this copy when making changes.*
* If your study will ONLY involve secondary use of data and/or specimens. See **HRP-503b TEMPLATE** **SECONDARY USE PROTOCOL**.
* *Use the BIOMEDICAL research template WITH instructions for a guide.*
* Remove above instructions in red before submitting to the IRB.

# PROTOCOL TITLE: (Include the full protocol title.)

Protocol Version Date: *<Enter Information Here>*

|  |
| --- |
| Check if this research has U.S. Federal government funding via one or more direct awards or a sub-award. Provide the source of federal support: |
| All other sources of funding: |

# PRINCIPAL INVESTIGATOR:

*Name <Enter Information Here>*

*Department <Enter Information Here>*

*Telephone Number <Enter Information Here>*

*Email Address <Enter Information Here>*

# Co- INVESTIGATORS:

*Name <Enter Information Here>*

*Department <Enter Information Here>*

*Email Address <Enter Information Here>*

# Objectives:

*<Enter Information Here>*

# Background:

*<Enter Information Here>*

# Inclusion and Exclusion Criteria:

*<Enter Information Here>*

# Number of Local Participants:

*<Enter Information Here>*

# Study-Wide Number of Participants:

*<Enter Information Here>*

# Study Timelines:

*<Enter Information Here>*

# Study Endpoints:

*<Enter Information Here>*

# Procedures Involved:

*<Enter Information Here>*

# Data and Specimen Banking:

*<Enter Information Here>*

# Data and Specimen Management:

*<Enter Information Here>*

# Provisions to Monitor the Data to Ensure the Safety of

### Participants:

*<Enter Information Here>*

# Withdrawal of Participants:

*<Enter Information Here>*

# Risks to Participants

*<Enter Information Here>*

# Potential Benefits to Participants:

*<Enter Information Here>*

# Vulnerable Populations:

*<Enter Information Here>*

# Sharing of Results with Participants:

*<Enter Information Here>*

# Setting:

*<Enter Information Here>*

# Resources Available:

*<Enter Information Here>*

# Prior Approvals:

*<Enter Information Here>*

# Confidentiality:

*<Enter Information Here>*

# Provisions to Protect the Privacy Interests of Participants:

*<Enter Information Here>*

# Compensation for Research-Related Injury:

*<Enter Information Here>*

# Economic Burden to Participants:

*<Enter Information Here>*

# Recruitment Methods:

*<Enter Information Here>*

# Study-Wide Recruitment Methods:

*<Enter Information Here>*

# Consent Process

*<Enter Information Here>*

*(****For Non-English Speaking Participants****,*

*<Enter Information Here>*

***Waiver or Alteration of Consent Process***:

*<Enter Information Here>*

***Participants who are not yet adults (infants, children, teenagers***)

*<Enter Information Here>*

***Cognitively Impaired Adults***

*<Enter Information Here>*

***Adults Unable to Consent***

*<Enter Information Here>*

# Process to Document Consent in Writing:

*<Enter Information Here>*

***Waiver of Documentation of Consent:***

*<Enter Information Here>*

# Drugs or Devices:

*<Enter Information Here>*

# Waiver of IND or IDE

*<Enter Information Here>*

# Multi-Site Research:

*<Enter Information Here>*