**PROTOCOL TITLE:**

*Include the full protocol title.*

**PRINCIPAL INVESTIGATOR:**

*Name*

*Department*

*Telephone Number*

*Email Address*

**VERSION NUMBER/DATE:**

*Include the version number and date of this protocol.*

**REVISION HISTORY**

|  |  |  |  |
| --- | --- | --- | --- |
| **Revision #** | **Version Date** | **Summary of Changes** | **Consent Change?** |
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Table of Contents

[1.0 Study Summary 3](#_Toc496162129)

[2.0 Objectives\* 3](#_Toc496162130)

[3.0 Background\* 3](#_Toc496162131)

[4.0 Study Endpoints\* 3](#_Toc496162132)

[5.0 Study Intervention/Investigational Agent 3](#_Toc496162133)

[6.0 Procedures Involved\* 3](#_Toc496162134)

[7.0 Data and Specimen Banking\* 3](#_Toc496162135)

[8.0 Sharing of Results with Subjects\* 4](#_Toc496162136)

[9.0 Study Timelines\* 4](#_Toc496162137)

[10.0 Inclusion and Exclusion Criteria\* 4](#_Toc496162138)

[11.0 Vulnerable Populations\* 4](#_Toc496162139)

[12.0 Local Number of Subjects 4](#_Toc496162140)

[13.0 Recruitment Methods 4](#_Toc496162141)

[14.0 Withdrawal of Subjects\* 4](#_Toc496162142)

[15.0 Risks to Subjects\* 4](#_Toc496162143)

[16.0 Potential Benefits to Subjects\* 4](#_Toc496162144)

[17.0 Data Management\* and Confidentiality 4](#_Toc496162145)

[18.0 Provisions to Monitor the Data to Ensure the Safety of Subjects\* 5](#_Toc496162146)

[19.0 Provisions to Protect the Privacy Interests of Subjects 5](#_Toc496162147)

[20.0 Compensation for Research-Related Injury 5](#_Toc496162148)

[21.0 Economic Burden to Subjects 5](#_Toc496162149)

[22.0 Consent Process 5](#_Toc496162150)

[23.0 Process to Document Consent in Writing 5](#_Toc496162151)

[24.0 Setting 5](#_Toc496162152)

[25.0 Resources Available 5](#_Toc496162153)

[26.0 Multi-Site Research\* 5](#_Toc496162154)

# Study Summary

|  |  |
| --- | --- |
| **Study Title** |  |
| **Study Design** |  |
| **Primary Objective** |  |
| **Secondary Objective(s)** |  |
| **Research Intervention(s)/ Investigational Agent(s)**  |  |
| **IND/IDE #**  |  |
| **Study Population** |  |
| **Sample Size** |  |
| **Study Duration for individual participants** |  |
| **Study Specific Abbreviations/ Definitions**  |  |

# Objectives\*

# Background\*

# Study Endpoints\*

# Study Intervention/Investigational Agent

# Procedures Involved\*

# Data and Specimen Banking\*

# Sharing of Results with Subjects\*

# Study Timelines\*

# Inclusion and Exclusion Criteria\*

# Vulnerable Populations\*

# Local Number of Subjects

# Recruitment Methods

# Withdrawal of Subjects\*

# Risks to Subjects\*

# Potential Benefits to Subjects\*

# Data Management\* and Confidentiality

# Provisions to Monitor the Data to Ensure the Safety of Subjects\*

# Provisions to Protect the Privacy Interests of Subjects

# Compensation for Research-Related Injury

# Economic Burden to Subjects

# Consent Process

# Process to Document Consent in Writing

# Setting

# Resources Available

# Multi-Site Research\*