|  |
| --- |
|  |
| [Type the document title] |
| [Type the document subtitle] |
|  |
| **[Type the main author name]** |
| **[Pick the date]** |

|  |
| --- |
| [Type the abstract of the document here. The abstract is typically a short summary of the contents of the document.] |

**Contact Information of Researchers and Collaborators:**

[Note: for MRPC staff, enter ‘MRPC’ as the Affiliation and leave Address and Office Phone Number fields empty]

**P.I. Information**

Name:

Affiliation (include name of the department if appropriate):

Address:

Office Phone Number:

Cell Number:

E-mail Address:

**Co- Investigators Information**

Name:

Affiliation (include name of the department if appropriate):

Address:

Phone Number:

E-mail Address:

**List ALL co-investigators and their contact information**

 **Introduction**

**Type of Research**

**Background/Rationale of the Study**

**Purpose/Objective of the Study** (why?)

**Participant Selection/Definition** (who?)

 **Study Population Description**

**Inclusion Criteria**

**Exclusion Criteria**
**Gender**
**Racial/Ethnic Origin**

**Vulnerable Populations**
**Age**
**Total Number of Participants to be enrolled**

**Study Design**

**Summary of the Research Design**

**Hypothesis** [a statement about what you believe to be true about nature and relationships of two or more variable to each other – the more specific the better]

**Specific Aims/Objectives**

 **Primary**

 **Secondary**

**Methods and Procedures**

[Include study setting (where?)

Time frame of data collection (when?)

Variables to be measured (what?)

Tools that will be used to measure these variables (how?)]

**Analysis of Study Results**
**Data and Safety Monitoring**

**Storage of Data**

Data will be stored electronically in a restricted-access, password-protected, permission-based data management system, REDCap. Data will be maintained for three (3) years following the conclusion of the investigation.

**Description of REDCap**

Study data will be collected and managed using the Research Electronic Data Capture (REDCap) system hosted at [Methodist LeBonheur Health Care]. REDCap is a secure, web-based application designed to support data capture for research studies, providing 1) an intuitive interface for validated data entry; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for importing data from external sources.

REDCap was developed specifically around HIPAA-security guidelines. All web-based information transmission is encrypted. REDCap has been disseminated for use locally at other institutions and currently supports 240+ academic/non-profit consortium partners and over 26,000 research end-users world-wide (www.project-redcap.org).

Ref.: Paul A. Harris, Robert Taylor, Robert Thielke, Jonathon Payne, Nathaniel Gonzalez, Jose G. Conde, Research electronic data capture (REDCap) – A metadata-driven methodology and workflow process for providing translational research informatics support, J Biomed Inform. 2009 Apr;42(2):377-81.

**Confidentiality of Data**

All personnel will complete training in Human Subjects Research Protections. Only staff approved to work on this study will have access to information gathered as part of this study. All data will be kept secure and confidential. All electronic research records containing identifiable, private information will be kept in password-protected computers. Data will be stored electronically in a restricted-access, password-protected, permission-based data management system, REDCap. Access to the data will be restricted to research personnel only. Data will be shared with the University of Tennessee Health Sciences Center Department of Preventive Medicine biostatistical group for statistical analysis. Data transferred to the biostatistical group will be via secure transfer available within REDCap, and will be kept encrypted and secured by the sponsor.

Each record within the dataset received from the data management team will be assigned a study identification number. The linkage between the identifiers and the study identification number will be maintained separately from the study database in a locked and secured location.

**Risk/Benefit Assessment**

**Risks** (Indicate each procedure and the rate of occurrence of a risk – see ‘Note’ below)

**Prevention of Risks**
**Adverse Events**
**Benefits**

Note:

Risks associated with participation in this research. Include physical, psychological, social, and any other risks. Include the name of the procedure and identify the risks and their rate of occurrence

If the study/project literature or the sponsor cannot provide the rate of occurrence of a risk, make an educated guess as to its rate of occurrence and type the word "Estimated:" before typing in the description of the risk.

Risks

Very Common: occurs 50 times out of every 100

Common: occurs 21-50 times out of every 100

Occasional: occurs 6-20 times out of every 100

Rare: occurs 1-5 times out of every 100

Very Rare: occurs less than 1 time out of every 100

For Example

Procedure: Medical Record Review

Risk: Loss of confidentiality = very rare

**Participant Recruitment and Informed Consent**

**Recruiting**

**Informed Consent / Assent**

**Obtaining and Documenting Consent**

**Participant Comprehension and Capacity**
**Costs to Participants**

**Compensation to Participants**

**References**