**OBSERVATIONAL OR NON-INVASIVE INTERVENTIONAL PROTOCOL TEMPLATE**

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| --- | --- | --- |
| Title: |  | |
| Version Date: |  | |
| IRB Number: |  | |
|  |  | |
| Principal Investigator: |  | |
| Sub-Investigator(s): |  | |
|  |  | |
| Performance Site(s): |  | |
|  |  | |
| Sponsor: |  | |
|  |  | |
| Amendment 1 Date: | | Amendment 4 Date: |
| Amendment 2 Date: | | Amendment 5 Date: |
| Amendment 3 Date: | | Amendment 6 Date: |

**STATEMENT OF COMPLIANCE**

This study will be conducted in full accordance with all applicable LSU Health Sciences Center Policies and Procedures and all applicable Federal and state laws and regulations including 45 CFR 46, and the HIPAA Privacy Rule. Any episode of noncompliance will be documented.

The investigators will perform the study in accordance with this protocol, will obtain consent/assent/ HIPAA authorization (unless waivers are granted), and will report unexpected problems in accordance with LSU Health Sciences Center - New Orleans IRB Policies and Procedures and all federal requirements. Collection, recording, and reporting of data will be accurate and will ensure the privacy, health, and welfare of research subjects during and after the study.

**ABBREVIATIONS AND DEFINITIONS OF TERMS**

|  |  |  |
| --- | --- | --- |
|  |  | Insert and delete terms as relevant [Examples Below] |
| EMR |  | Electronic Medical Record (i.e. EPIC) |
| MRN |  | Medical Record Number |
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**PROJECT SUMMARY/ABSTRACT**

**This section should summarize the central elements of the protocol and be able to stand on its own. It should be no more than one page.**

|  |  |
| --- | --- |
| **Background** | *Include 1-3 sentences about the importance of the condition and the importance of the research question.* |
| **Primary Objective** | *Include primary objective and outcome measures* |
| **Secondary Objective(s)** | *Include secondary objectives and outcome measures* |
| **Study Population** | *Include a brief description of the population such as health/disease status, gender, age, etc.* |
| **Study Design** | *Present an overview of the study design. For example:*   * *Cohort, Case-Control or Cross-Sectional* * *Survey, Specimen Collection, Observational* |
| **Sample Size** | *Include total number of patients for the study* |

1. **BACKGROUND AND RATIONALE**

This section is based on your research question. The background and rationale should:

* Outline the current knowledge about the research topic
* Include a statement for the need/problem the research topic will address
* Answer why the research needs to be done
* Answer what the relevance is of the research

Include references with citations from the literature. This section should be no more than 2-3 pages.

1. **STUDY OBJECTIVES**

The purpose of this study is to…

**2.1 Primary Objective (or Aim)**

This should be specific. For example: “The primary object of this study is to determine whether adults with a hearing impairment have enough resources in their workplace.”

**2.2 Secondary Objectives (or Aims)**

The secondary objectives are to [include any additional objectives, if applicable]

1. **INVESTIGATIONAL PLAN**

**3.1 Study Design**

This study is a [include a description of the study type]

**3.2 Study Duration**

The IRB needs the date range for when the study will take place and the date range for the records to be included.

**3.3 Study Sites**

The study will be conducted at [number] sites. Local sites include…

**3.4 Study Population**

The study team will enroll approximately [number] subjects.

**3.4.1 Inclusion Criteria**

[Examples…

* Hearing impaired
* Age 18 or older]

**3.4.2 Exclusion Criteria**

[Examples…

* Under age 18
* No known hearing impairment]

1. **STUDY PROCEDURES**

**4.1 Recruitment**

Describe the approach to recruit subjects.

* How will subjects be identified?
* How will subjects be approached?
* Will advertising be used?

**4.2 Screening Visit** *[Delete if screening is performed by medical chart review]*

*This section lists the procedures, observations, and measures included as a simple bullet point list. This section is focused on what will be done, while Section 5 addresses how it will be done.*

**4.3 Visit 1**

*This section lists the procedures, observations, and measures included as a simple bullet point list. This section is focused on what will be done, while Section 5 addresses how it will be done.*

**4.4 Visit 2**

*This section lists the procedures, observations, and measures included as a simple bullet point list. This section is focused on what will be done, while Section 5 addresses how it will be done.*

**4.5 Visit 3**

*This section lists the procedures, observations, and measures included as a simple bullet point list. This section is focused on what will be done, while Section 5 addresses how it will be done.*

**4.6 Follow-Up/End of Study**

*This section lists the procedures, observations, and measures included as a simple bullet point list. This section is focused on what will be done, while Section 5 addresses how it will be done.*

**4.7 Subject Withdrawl**

Criteria for withdrawl of subjects:

1. **STUDY EVALUATIONS AND MEASUREMENTS**

Every procedure and measurement listed in section 4 should have a corresponding description of what will happen during the procedure or how the measurement will be made.

**5.X Data Sources**

This description should be specific but not overly detailed. For example: “EPIC will be queried for demographic information, admission dates, and diagnosis codes. Tissue diagnosis will be obtained from pathology records.”

**5.X Data Collection and Management**

This section should include the following information:

* How data will be collected and the system (i.e., REDCap, Excel) used for data storage.
* How confidentiality of the data will be ensures
* Plan for anonymization or de-identification of the data
* Plan for retention and destruction of the data

1. **STATISTICAL CONSIDERATIONS**

**6.1 Primary and Secondary Endpoints**

The primary objective is to determine… The primary endpoint will be…

**6.2 Statistical Methods**

State how data will be validated and describe the statistical methods used for analysis.

**6.3 Sample Size and Power**

The sample size should be justified based on the study objectives.

1. **REGULATORY AND ETHICAL CONSIDERATIONS**

**7.1 Risks to Participant**

Describe the risks of participation in this section. All studies have at least some risk. For chart reviews, the primary risk is the breach of confidentiality of data.

Address how the study design and data management plan will minimize the risks of harm.

**7.2 Potential Benefits to Participant**

Summarize potential benefits of participation, if any.

**7.3 Informed Consent/Assent and HIPAA Authorization**

Either informed consent must be obtained, or a waiver must be requested.

* If consent will be obtained, describe the procedures that will be used to obtain consent (who, when, where, how).
* If a waiver is requested, provide sufficient justification for why the research meets the criteria for a waiver.

**7.4 Safety Reporting**

Describe the plan for reporting any issues to the IRB.

**7.5 Payment to Subjects**

If subjects are to be paid for participation in the study, the amount and method of payment should be outlined.

1. **PUBLICATION**

Describe the plan for publication and presentation of the results.

1. **REFERENCES**

[Insert references/citations]