**Medical Record Review of Existing Data**

**IRB Protocol Template**

***INSTRUCTIONS:***

* When you write a protocol, keep an electronic copy, clean (all changes accepted, all comments deleted). Modify this copy when making changes.
* As you are writing the protocol, **remove all instructions in italics so that they are not contained in the final version of your protocol.**
* Depending on the nature of your study, some sections may not be applicable to your research. If so mark as “N/A.” **Do not delete** the section numbers.
* Sample text has been added to some sections to assist investigators in some sections.

**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.*

*\*The version number should remain unchanged during pre-review until initial approval. The version date can be updated to reflect changes that are made.*

**REVISION HISTORY**

**Only use this table for submissions of a Modification application to the IRB.**

|  |  |  |  |
| --- | --- | --- | --- |
| **Revision #** | **Version Date** | **Summary of Changes** | **Consent Change?** |
|  |  |  |  |
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**Table of Contents** (Add page numbers)

1. Study Summary
2. Background and Rationale
3. Methods and Procedures
4. Objectives
5. Endpoints
6. Study Population
7. Number of Subjects
8. Setting
9. Study Timeline
10. Data Sources
11. Data Collection
12. Potential Benefits
13. Risks to Subjects
14. Provisions to Protect the Privacy Interests of Subjects
15. Consent Process
16. Data Management, Security and Confidentiality
17. Data Storage for Future Research
18. Statistical Procedures
19. Publications
20. References

# 1.0 Study Summary

*Please provide a brief summary of the study in the table below. A complete description of the study with detailed information should be provided in the body of the protocol. For sections not applicable to the study, mark them as N/A.*

|  |  |
| --- | --- |
| **Study Title** |  |
| **Study Design** | *Note: a retrospective medical record review is NOT a study design, rather it is a study methodology.  The study design for a medical record review is always observational, and can be a case series, a case control study, a cohort study, or a cross-sectional study.* |
| **Primary Objective** | *This is the main purpose of performing this study, focused on one question and is used to determine the sample size.* |
| **Secondary Objective(s)** |  |
| **Study Population** | *Provide a brief description such as health status, gender, age, etc.* |
| **Sample Size** |  |
| **Study Specific Abbreviations/ Definitions** |  |

# 2.0 Background Information and Rationale

**Background**

Provide the scientific background for the research based on the existing literature. Describe what is currently known and why the topic is important. This may also include local data or information that supports the benefit of doing the study.

Present the current problem. Is there a current gap in knowledge or a challenge to previous work?

Note: The HIPAA Privacy Rule requires that researchers use the minimal necessary protected health information necessary to conduct the research. Therefore, the background information provided must scientifically justify the need for all data requested for use for the study.

**Rationale**

Explain how this study will add to existing knowledge and what benefits this will provide.

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# 3.0 Methods and Procedures

**Study Design**

This is an observational (*select one of the following:* *case series, a case control study, a cohort study, or a cross-sectional study)*

The study methodology is a retrospective medical record review of existing data that was collected for the purpose of routine medical care. All data that will be accessed and used for this study is in existence (on the shelf) prior to the original IRB application date.

*Note: ALL prospective outcome data (e.g. 30-day readmissions, etc.) must also be pre-existing (on the shelf) prior to the original IRB application date.*

**4.0 Objectives**

*Describe the purpose, specific aims, objectives or research questions*

* **Primary Objectives**
* **Secondary Objectives**

**5.0 Endpoints**

*Endpoints refer directly to the objectives are the specific expression of what will be measured and compared in the study. The statistical methods should address each endpoint. Example: “The primary objective is to determine if tonsillectomy increases weight gain. The primary endpoint will be the difference in weight two months after surgery compared to the two months before surgery.”*

* **Primary Endpoints**
* **Secondary** **Endpoints**

*State the measurable hypothesis to be tested. (Note: Descriptive studies usually do not include a hypothesis.)*

# 6.0 Study Population

* **Inclusion Criteria**

Describe the criteria that will be used to determine if subjects will be included in your study.

* **Exclusion criteria**

Describe the criteria that will be used to determine if subjects will be excluded from your study.

# 7.0 Number of Subjects

*Describe the enrollment goal. Provide justification that the enrollment goal is feasible within the specified timeframes and the population available.*

*Indicate the number of subjects who are expected to be screened and the number of charts to be reviewed.*

*Describe the rationale for the targeted sample size (e.g. effect size, expected screen failures, etc.)*

# 8.0 Setting

*Describe the sites or locations where your research team will conduct the research and obtain the data.*

**9.0 Study Timeline**

*Describe the estimated date for the investigators to complete this study (primary analysis)*

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# 10.0 Data Sources

Indicate the source of the list of subjects that will be screened for enrollment. Describe what criteria will be used to identify the records that will be screened for subject enrollment. (Example: Data analytics will query the LRH Cerner Data Warehouse to provide a list of subject FIN numbers with an ICD-10 diagnosis of X that were admitted and discharged between the dates of Y and Z.)

Indicate the source of the records and data that will be accessed for purposes of the retrospective medical record review. Example: Study personnel listed on the LRH Application for Waiver of Authorization or Altered Authorization under the HIPAA Privacy Rule will access patient medical records in Cerner in order to abstract the data for the study.

**11.0 Data Collection**

The time interval for the population involved for screening and enrolling subjects for this study will be *MM/DD/YY* to *MM/DD/YY*.

*Note: ALL prospective outcome data (e.g. 30-day readmissions, etc.) must also be pre-existing (on the shelf) prior to the original IRB application date.*

*If this note applies include:* The time interval in/for the prospective outcome data for this study will be *MM/DD/YY* to *MM/DD/YY*.

*Describe the data that will be collected from the medical record (e.g. demographics, medical history, medications, etc.).*

A copy of the paper data collection log and/or electronic spreadsheet that will be used for data entry has been attached to this application.

*Describe measures to be taken to avoid potential bias. Examples: 1) a radiologist blinded to the diagnosis might read the radiographic studies 2) abstractors are blinded to the study hypothesis, 3) a procedure by which all available charts will have an equal chance of selection, 4) measures to handle missing or conflicting data.*

# 12.0 Potential Benefits

This study does not present any direct benefits to the participants. However, the study provides an opportunity to gain a better understanding of \_\_\_\_\_\_\_.

# 13.0 Risks to Subjects

Possible risks include loss of privacy and/or confidentiality. Improper disclosure of PHI has the potential to affect insurability, employability, social standing, legal liability, or cause anxiety about what the recipient of an unauthorized disclosure might do with the information.

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# 14.0 Provisions to Protect the Privacy Interests of Subjects

In the conduct of this research, PHI will only be accessed by the study personnel specified on the LRH Application for Waiver of Authorization or Altered Authorization under the HIPAA Privacy Rule. Complete the Waiver of Authorization or Altered Authorization and include it in this application packet.

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# 15.0 Consent Process

Complete the Request for Waiver of Informed Consent and include this in the application packet.

Complete a request for waiver of assent and/or parental permission if you will be accessing the records of neonates, children or minors.

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# 16.0 Data Management, Security and Confidentiality

A completed LRH Application for Waiver of Authorization or Altered Authorization under the HIPAA Privacy Rule has been included in the application.

Research data management and confidentiality applies to ALL medical record research data and is not limited to HIPAA identifiers. This is because other unique elements of data also have the potential to make participants identifiable. Examples include: when different data elements are used in combination, when the population is known to the investigator, individuals with rare diagnosis/clinical characteristics and/or treatments.

If the research involves the collection of sensitive information (e.g. HIV, STDs, mental health diagnosis, substance abuse, etc.) describe additional data safeguards that will be included to protect the rights and welfare of subjects. Consider using a key stored on a separate document or described in the protocol for categories of sensitive information. For example: a category of HIV status (Y/N) could be categorized as “a” (Y/N) on the data collection form with a key located on a separate document denoting that column “a” indicates HIV status.

**Data Access**

Only study personnel who are listed on the approved LRH Application for Waiver of Authorization or Altered Authorization under the HIPAA Privacy Rule will access identifiable information.

**Data Storage**

Electronically stored data files will be stored on a password protected LRH-approved device according to the requirements specified in Research: LRH Data Management AD.0159.

Paper data collection forms will be secured in a key pad secured office or locked file cabinet.

*It is best practice to store direct identifiers (i.e. name, FIN, MRN) separate from research data. It is required however when collecting sensitive information.*

**Data Destruction**

Research records will be retained for six years after the research is completed and the study is closed with the IRB. Data will be destroyed at the conclusion of the 6-year period.

# 17.0 Data Storage for Future Research

If any data will be banked for **future research studies**, describe the storage and release processes:

**Data Storage for Future Research**

1. Where the data will be stored

2. How long it will be stored

3. How the data will be labelled

4. How the stored data can be accessed

5. Who will have access to the data

6. Describe/list the data points to be stored – you may refer to the data collection form

7. Describe how the data will be destroyed if non-permanent retention is planned

**Data Release for Future Research**

1.The process to request a release

2. The approvals required for release

3. Who can obtain the data

**18.0 Statistical Procedures**

Describe the data analysis plan.

Describe the statistical procedures/tests that will be used to describe the sample and/or answer the research questions.

Specify what software will be used and who will do the analysis.

Describe the statistical considerations for determining the sample size.

If applicable, describe plans for an interim analysis.

If applicable, describe the plan for interrater reliability determination.

**19.0 Publications**

Describe any plans to offer the results of this study for publication or presentation.

# 20.0 References

*Cite sources to information provided in the background information section.*