**Research Using De-identified**

**Electronic Health Record / Data Analytics Warehouse**

**IRB Protocol Template**

***INSTRUCTIONS:***

* *This template is to be used for research that only involves accessing a historical repository of de-identified electronic health record information that was originally collected for clinical or administrative purposes and not for research purposes.*
* 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.
* *De-identified data means that the source material does not include any of the following 18 categories of personal identifiers of individuals, or of the relatives, employers or household members of such individuals: (1) names; (2) all geographic subdivisions smaller than a state, including street address, city, county, precinct, and their equivalent geocodes, except for the initial three digits of a zip code if the geographic unit represented by these three initial digits contains more than 20,000 people; (3) all elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death, and all ages over 89 and all elements of dates indicative of age over 89, except that such ages and elements may be aggregated into a single category of age 90 or older; (4) telephone numbers; (5) fax numbers; (6) electronic mail addresses; (7) social security numbers; (8) medical record numbers; (9) health plan beneficiary numbers; (10) account numbers; (11) certificate/license numbers; (12) vehicle identifiers and serial numbers, including license plate numbers; (13) device identifiers and serial numbers; (14) web universal resource locators (URLs); (15) internet protocol (IP) address numbers; (16) biometric identifiers, including finger and voice prints; (17) full face photographic images and any comparable images; and (18) any other unique identifying number, characteristic, or code.*

*The IRB must also ensure that there are no readily ascertainable identifiers by means of deductive disclosure (very small number of patients (<5), or disease/scenarios/ data combinations that make the individual identifiable by deductive reasoning).*

**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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# 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** | *Example : descriptive, case series, case control, cohort study, or 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?

**Rationale**

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

#

# 3.0 Methods and Procedures

**Study Design**

This is an (*example: observational, descriptive, case series, case control, cohort, or cross-sectional study)*

The study methodology involves accessing a historical repository of de-identified electronic health record information that was originally collected for clinical or administrative purposes and not for research purposes.

All data that will be accessed and used for this study is in existence (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 Records/Subjects

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

*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 records/subjects that will be screened for inclusion.

Describe what criteria will be used to identify the records that will be screened for subject inclusion.

Indicate the source of the records and data that will be accessed for purposes of 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*.

Clinical data for this study will be obtained by searching for eligible anonymous participants using (*example: xyz discovery tool*) from the (*example: LRH Clinical Data Warehouse*)

See Appendix A for data elements to be included in this study

# 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 not be accessed by any of the study personnel. Therefore, the LRH Application for Waiver of Authorization or Altered Authorization under the HIPAA Privacy Rule is **not applicable and not included.**

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# 15.0 Consent Process

Not applicable.

DO NOT request a waiver of informed consent

# 16.0 Data Management, Security and Confidentiality

**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.

**Data Destruction**

Research records will be retained for six years after the research is completed. 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 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.*

**APPENDIX A.** Data Elements That Will be Included in this Study