**Retrospective Chart Review Protocol**

**with**

**Kuali Online Application Generic Responses**

Title (1, 2)

Principal Investigator

Name, MD

**Title:** As stated on department website

LSU Health - New Orleans

Protocol Version: Draft

Date

Study Personnel

|  |  |
| --- | --- |
| **Principal Investigator** | **Name:** **Title:** As stated on department websiteLSU Health - New Orleans**Email:** vdasa@lsuhsc.edu |
| **Student Researcher 1** | **Name:** **Title**: Tx Medical StudentLSU Health - New Orleans**Email**: @lsuhsc.edu |
| **Student Research 2** | **Name:** **Title:** Tx Medical StudentLSU Health - New Orleans**Email**: @lsuhsc.edu |
| **Data Manager** | **Name:** Claudia Leonardi, PhD**Title:** Assistant Professor, Research, Department of Community Health Science & PolicyLSU Health - New Orleans**Email:** cleon1@lsuhsc.edu |
| **Trainee (Resident)** | **Name:** **Title:** TraineeLSU Health - New Orleans**Email:**  |

# SYNOPSIS

|  |
| --- |
| Study PurposeCopy from Section 3.1.  |
| Primary ObjectiveCopy from Section 3.2 |
| Secondary Objectives (if applicable)Copy from Section 3.3 |
| Study DesignCopy from Section 4.1 |
| Study Date Range and DurationCopy from Section 4.2  |
| Study PopulationCopy from Section 4.3. |
| Number of Participants and Sample Size ConsiderationsCopy from Section 4.4 |

Table of Contents

[SYNOPSIS 3](#_Toc2)

[1 - Statement of Compliance 6](#_Toc3)6

[1.1 Statement of Compliance 6](#_Toc4)

[2 - Background & Rationale 7](#_Toc5)7-8

[2.1 Background Information and Relevant Literature 7](#_Toc6)7

 2.1.1 Bibliography…………………………………………………………………………… 8

[2.2 Rationale and Study Significance 7](#_Toc7)9

[2.3 Potential Risks and Benefits 7](#_Toc8)

 [2.3.1 Known Potential Risks 7](#_Toc9)

 [2.3.2 Known Potential Benefits 7](#_Toc10)

[3 - Study Purpose and Objectives 9](#_Toc11)10

[3.1 Study Purpose 9](#_Toc12)

[3.2 Primary Objective 9](#_Toc13)

[3.3 Secondary Objectives (if applicable) 9](#_Toc14)

[4 - Study Design 10](#_Toc15)11

[4.1 Study Design 10](#_Toc16)

[4.2 Study Date Range and Duration 10](#_Toc17)

[4.3 Study Population 10](#_Toc18)

[4.4 Number of Participants and Sample Size Considerations 10](#_Toc19)

[4.5 Inclusion Criteria 10](#_Toc20)

[4.6 Exclusion Criteria 10](#_Toc21)

[4.7 Vulnerable Populations 10](#_Toc22)

[5 - Study Procedures 11](#_Toc23)12

[5.1 Data Sources 11](#_Toc24)

[5.2 Data Collection 11](#_Toc25)

[5.3 Statistical Analyses 11](#_Toc26)

[6 - Records Retention 12](#_Toc27)13

[6.1 Data and Record Handling 12](#_Toc28)

[6.2 Confidentiality & Data Management 12](#_Toc29)

[6.3 Records Retention 12](#_Toc30)

[7 - Regulatory and Ethical Considerations 13](#_Toc31)14

[7.1 Informed Consent/Assent and HIPAA Authorization 13](#_Toc32)

[7.2 Waiver of Informed Consent (if applicable) 13](#_Toc33)

[7.3 Waiver of HIPAA Authorization 14](#_Toc34)

[7.4 Deviations/Unanticipated Problems 15](#_Toc35)

[7.5 Funding Source 15](#_Toc36)

[7.6 Conflict of Interest Management Plan (if applicable) 15](#_Toc37)

[7.7 IRB 15](#_Toc38)

7.8 References

[8 - Publication Plan 16](#_Toc39)15

[8.1 Publication Plan 16](#_Toc40)

# 1 - Statement of Compliance

## Statement of Compliance

<LSU Health Sciences Center (LSUHSC) - New Orleans (NO) has filed a federal-wide assurance (FWA) of compliance with the Office of Human Research Protections under FWA00002762. LSUHSC-NO has assured activities related to human subjects research, regardless of the source of support, will be guided by the Belmont Report as its statement of principles governing the institution for protecting the rights and welfare of human subjects. The LSUHSC FWA includes one registered internal Institutional Review Board (IRB) under IORG000018 for OHRP/FDA Research as IRB00000177.

The LSUHSC-NO IRB is duly constituted with written procedures for initial and continuing review of human subjects research; written minutes of convened IRB meetings, an electronic research application system to adhere to records retention requirements of the review and approval process. All documented processes are in compliance with requirements of FDA regulations 21 CFR Parts 50 and 56, HHS regulations 45 CFR 46, and International Conference on Harmonization (ICH) E6, Good Clinical Practice (GCP) as adopted by the FDA, as applicable. LSUHSC-NO also reviews in compliance with other applicable federal and state laws and regulations governing IRBs and human subjects research.

A full copy of the IRB standard operating procedures can be found on the Human Subjects website at https://www.lsuhsc.edu/administration/academic/ors/irb/. LSUHSC-NO is fully accredited by the Association for the Accreditation of Human Research Protection Programs (AAHRPP).>

# - Background & Rationale

## Background Information and Relevant Literature

<Insert literature review.> Examples are on the [MSK section](https://www.medschool.lsuhsc.edu/ortho/ortho_committee.aspx) of the department website.>

## 2.1.1 Bibliography

Zotero is a free citation manager that has a chrome extension and desktop app. It helps a lot with his!!

## Rationale and Study Significance

Insert study significance and rationale.

## 2.3 Potential Risks and Benefits

## 2.3.1 Known Potential Risks

<Because data will be collected from the patient's electronic medical record, there is a small risk of loss of confidentiality and breech of privacy. Coded data will be entered by research personnel into a password protected and HIPAA-compliant web-based application (REDCap).>

## 2.3.2 Known Potential Benefits

<The major benefit of this study is the potential to increase the quality of patient care associated with decreased or poor patient outcomes. While there are no benefits to the individual patient, future patients and communities may benefit from lessons learned>

# 3 - Study Purpose and Objectives

## 3.1 Study Purpose

The purpose of this study…

## 3.2 Primary Objective: Aim of the study

The primary objective of this study…

## 3.3 Secondary Objectives (if applicable: minor objectives that *could be* studied)

The secondary objective of this study…

.

# 4 - Study Design

## 4.1 Study Design

<This is a retrospective study of orthopaedic patients with (specify injury, diagnosis, surgery, etc.)>

## 4.2 Study Date Range and Duration

Start Date:

End Date:

## 4.3 Study Population

<Adult orthopaedic surgery patients treated at [Institution Name] with (a diagnosis or injury of, etc.)>

## 4.4 Number of Participants and Sample Size Considerations

\_\_\_\_patients

<Discuss target sample size with Dr. Leonardi. Err on the side of generosity.>

## 4.5 Inclusion Criteria

Insert inclusion criteria

## 4.6 Exclusion Criteria

Insert inclusion criteria

## 4.7 Vulnerable Populations

<No vulnerable populations will be included in the study.>

# 5 - Study Procedures

## 5.1 Data Sources

<UMC New Orleans (or other institution) patient health information stored in REDCap.>

## 5.2 Data Collection

<Previously scanned electronic health records will be used to obtain the following information:>

## 5.3 Statistical Analyses

<Data will be analyzed by Dr. Leonardi using SAS/STAT, Version 9.4, SAS System for PC. Copyright © 2014 SAS Institute Inc., Cary, NC, USA.

The preferred statistical method is parametric. Non-parametric and robust alternative methods will be considered based on model assumptions. Primary tools will be Pearson correlation, Spearman-rank correlation, WilcoxonMann-Whitney test and one-way ANOVA. They may be supplemented by other tools depending on the nature of the data (continuous, binary, ordinal etc.) and its distribution (Normal, log-normal etc.). Significance will be declared at p-value <0.05.>

# 6 - Records Retention

## 6.1 Data and Record Handling

<Data will be collected retrospectively through noninvasive procedures routinely employed in clinical practice.

Patient health information (PHI) will be used only to assess eligibility and identify potential participants. All research documents containing PHI will be stored in a locked/password protected area accessible only to study staff. Study data will be coded or de-identified prior to distribution external to the study team.

Only team members will have access to retained data, identifiers and the database.>

## 6.2 Confidentiality & Data Management

<Data will be managed using these protocols:

* Restricted access to authorized study personnel
* Secure computer/laptop
* Individual ID plus password protection
* Network restrictions
* Security software (firewall, antivirus, anti-intrusion) installed and regularly updated on all servers, workstations, laptops, and other devices used in the study
* Restrictions on reproducing study related materials
* Access rights will be terminated when authorized study personnel leave the study

Data will be obtained via Citrix using an encrypted connection. It will be stored within the password protected REDCap database. No local copies of data will be stored on laptops. Only team members will have access to retained data, identifiers and the database.>

## 6.3 Records Retention

<The link between study participants and study ID numbers will be destroyed (shredded/purged) when study activities are complete. Identifiers will be retained until the manuscript has been accepted for publication as reviewers sometimes inquire about additional variables to be collected or the PI declares the project "closed". Projects are evaluated yearly and will be closed and identifiers will be destroyed when the project is no longer active which usually happens within 5 years of its start.>

# 7 - Regulatory and Ethical Considerations

Apply the following text in the Kuali Research online application.

## 7.1 Informed Consent/Assent and HIPAA Authorization

< A waiver of informed consent is requested to allow the study team to conduct secondary research without having to inform the subjects of the activities.>

* 1. **Waiver of Informed Consent (if applicable)**

## <A waiver of informed consent is requested to allow the study team to conduct secondary research without having to inform the subjects of the activities.> (LSU Health New Orleans Human Research Protection Program, 2024)

* 1. **Waiver of HIPAA Authorization**

<The research will not access or collect PHI for recruitment purposes. HIPAA authorization will not be obtained from subjects. Only the minimum amount of PHI necessary to conduct the research will be utilized, accessed, collected and generated.>

**Copy this text to the Kuali Online Waiver of HIPAA Authorization section (then delete this section)**

1. List all data elements to be used or disclosed (do not refer to an attachment).

Dr. Leonardi or the coordinating center (in the case of a multi-center study) will provide. List the variables and attach the data sheet.

1. Explain how this research involves no more than minimal risk to loss of confidentiality of the subject.

<Since this study is a retrospective chart review, investigators will have no physical contact with patients. Potential known risks are no greater than minimal except for the possible loss of data confidentiality.>

1. Describe the plan for protecting identifiers from improper use and disclosure

<Patient health information (PHI) will be used only to assess eligibility and identify potential participants. All research documents containing PHI will be stored in a locked/password protected area accessible only to study staff. Study data will be coded or de-identified prior to being sent outside the study team.>

1. Taking into consideration the purpose of the research and local data retention requirements, describe the plan to destroy identifiers at the earliest opportunity appropriate for the research.

<The identifiers will only be available to the database manager after data has been entered into the database.>

1. Explain how the research could not be practicably conducted without
	1. waiver of authorization or alteration of authorization requirements
	2. access to and use of identifiable PHI

## <PHI is required to identify potential participants who meet the eligibility criteria. It is not feasible to individually contact the large numbers of participants. A Waiver of Informed Consent and HIPAA Authorization will be requested.>

## Explain how the research could not be practicably conducted without access to and use of identifiable PHI:

<PHI is required to identify potential participants who meet the eligibility criteria. The data required for this study is only available in the PHI / medical records.>

## 7.4 Deviations/Unanticipated Problems

<Loss of confidentiality via a data breach is possible but unlikely. Patient data will be de-identified, password protected and only available to investigators. If a data breach occurs, the patients will be notified, passwords will be changed and all involved parties will be investigated.>

## 7.5 Funding Source

<Unfunded>

## 7.6 Conflict of Interest Management Plan (if applicable)

<Not applicable. The study personnel have no conflicts of interest. If a potential conflict arises, this information will be submitted for formation of a management plan.>

## 7.7 IRB

<Institutional Review Board approval will be sought. The conduction of the study will be in accordance with the approved protocol and performed by approved research personnel. The IRB will be notified promptly in writing in accordance with all stated guidelines of any deviations to this protocol, reportable events, or unanticipated problems>

**7.8 References**

# 8 - Publication Plan

## 8.1 Publication Plan

<When the work is complete, abstracts will be submitted as presentations at orthopaedic meetings and manuscripts in peer reviewed publications.  LSU Health will be stated as the author affiliation.  If a conflict-of-interest management plan is required during the course of the study, publication stipulations will be followed accordingly.>