Retrospective Study Protocol

Study Protocol Title:

_____

Lead Investigator, Research Team, and Study Site

Lead Investigator	
Co-Investigators	

Vascular Low Frequency Disease Consortium (VLFDC) Site Address	David Geffen School of Medicine at UCLA Division of Vascular Surgery 200 Medical Plaza, Suite 526 Los Angeles, CA 90095
Program Director, VLFDC	Peter F. Lawrence, MD UCLA Division of Vascular Surgery pflawrence@mednet.ucla.edu
Associate Director, VLFDC	Karen Woo, MD UCLA Division of Vascular Surgery kwoo@mednet.ucla.edu
Program Coordinator, VLFDC (Contact Person)	Gabriela Flores UCLA Division of Vascular Surgery gabrielaflores@mednet.ucla.edu

A Note From the Lead Investigator

Dear Collaborator,

On behalf of the Vascular Low Frequency Disease Consortium (VLFDC), welcome! We are very excited to be working with you to find ways to improve the diagnosis and management of _____. Thank you for committing to participate in this project.

This document has been prepared to assist you and your team in having a fast, hassle-free IRB experience. In the protocol, you will find information that IRBs commonly request in the review of *retrospective studies* that qualify for *expedited review*.

We understand that every IRB has a unique application and varied review process, and are available to provide any additional information that your IRB may request. Please do not hesitate to contact Gabriela Flores at gabrielaflores@mednet.ucla.edu if you need additional assistance or have any questions.

To begin, please fill out and submit the protocol signature page on the following page (page 3). We look forward to working with you.

Sincerely,

, MD
Lead Investigator

Peter F. Lawrence, MD
VLFDC Director

Protocol Signature Page

The signature below provides the necessary assurances that this _____ study will be conducted according to the stipulations of the protocol, including all statements regarding confidentiality. This is in compliance with the principles outlined in applicable US Federal regulations and Good Clinical Practice Guidelines (ICH E6 Section 4.5.1, 6.2.5, and 8.2.2).

_____
Institution Name (please print)

_____
Investigator Name (please print)

_____ _____
Investigator Signature Date Signed

Please sign and send to vlfdc@mednet.ucla.edu

Table of Contents

List of Abbreviations

Project Title

Brief Description of the Study

Keywords

Background and Significance

Study Objectives

Study Design
Subject Selection

Inclusion Criteria

Exclusion Criteria

Sample Size

Research Design
Retrospective chart review; retrospective cohort study to abstract data from patients treated for ____ during _____.

Study Procedures
Subject Identification
Subjects will be identified with ICD-9-CM or ICD-10-CM and CPT codes.

CPT	DESCRIPTION

ICD-9/ 10 Code	DESCRIPTION

Procedures Involved
The study does not involve any patient contact and will not impact the care patients receive. De-identified data regarding the patients will be compiled and analyzed to accomplish the proposed study objectives. Data collection will include demographic information, patient-related factors and comorbidities, diagnostic imaging information, surgical procedure information, pathology report findings, complications of surgery, and outcomes.

Multi-Institutional Research
Up to __ additional centers may participate in this study. All de-identified data will be compiled at a central repository located at the David Geffen School of Medicine at UCLA.
Study Duration
We anticipate the review to take up to __ year(s) to complete.

Risks and Benefits

Risks to Subjects

As this is a retrospective study, there is no potential for physical risks to subjects. There is a minimal risk of breaches of confidentiality since patient information will be collected and analyzed for the proposed study. However, appropriate measures will be taken to minimize the risk as much as possible. All information entered into the central database will be de-identified. This study will abide by all regulations related to protecting human subjects and protected health information.

Potential Benefits to Subjects

There is no direct benefit to the subjects. However, future patients with may benefit from improved care as a result of this study.

Statistics and Data Analysis

Request for Waiver of HIPAA Authorization

This study consists of a retrospective chart review. We request a waiver of HIPAA authorization as contacting each patient to request their authorization to access their private health information is not practical and may present a bias in the study as patients who fulfill inclusion criteria may have moved to another area or now receive care at a different institution. All data extracted from patient charts will be de-identified and assigned a unique study number prior to entry into the study database. Protected health information will not be re-used or disclosed to any person or entity and the study results will not be communicated to the subjects included in the study. The results of the proposed study will be used to improve the care of future patients.

Data Security

All research personnel involved in the study will act in accordance with HIPAA regulations. All data will be de-identified at each site before being sent to the centralized database for the multi-institutional study. All data contributed will be housed in a secure electronic database located on a password-protected computer at the David Geffen School of Medicine at UCLA. Only the lead investigator, program coordinator, and data analyst will have access to the de-identified, multi-institutional data. PHI will be maintained at participating sites for the purpose of data verification. Any documents with PHI will be stored in a locked room at each study site for a minimum of 3 years after completion of the study.

Compensation to Subjects

Subjects will not be compensated. There will be no direct contact with patients included in this retrospective chart review.

Ethical Considerations

No ethical considerations have been identified, as there will be no direct contact with patients before, during, and after the proposed study.

Conflict of Interest

The investigators have no conflict of interest to report.

Funding Source

There are no plans to apply for grants or additional funding. No funding is required for the

completion of this study.

Publication Plan

The results of this study will be submitted as an abstract to ____ Meeting, which has a deadline of early _____. All research personnel listed on this protocol will be eligible for authorship in any resulting abstracts and publications in accordance with the qualifications outlined by the Journal of Vascular Surgery. The order of authors will be determined prior to manuscript development and depend on each individual's contribution to the study.

References