

## PM - 307

# STANDARD OPERATING PROCEDURE FOR IRB EXEMPT UMBRELLA

### I. INTRODUCTION AND PURPOSE

This standard operating procedure (SOP) describes the processes followed at this investigative site for studies operating under an IRB exempt umbrella, and the management of the data obtained under authorization of that umbrella exemption.

### 2. SCOPE

This SOP applies to all research conducted under an IRB exempt umbrella at the University of Utah Department of Orthopaedics.

### 3. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.101(b)	Categories of Exempt Human Subject Research
IRB SOP 401(b)	Research Activities Exempt from IRB Review

### 4. REFERENCES TO OTHER APPLICABLE SOPS

DM-501	Data Management
DM-502	Management of Electronic Records and Signatures
DM-503	Data Requests and Data Pulls

### 5. ATTACHMENTS

None

### 6. RESPONSIBILITY

This SOP applies to those members of the clinical research team and others involved in research conducted under one of the University of Utah Department of Orthopaedics IRB Exempt Umbrellas.

This includes the following:

- Principal investigator
- Sub-investigator
- Research director
- Research coordinator
- Support staff

## 7. DEFINITIONS

**Umbrella Compliance Officer:** Individual who has been appointed to review umbrella protocols and determine if the research meets one or more of the Exempt Categories of Research criteria.

**Exemption Umbrella:** A study that adheres to principles of sound research design and ethics to protect the rights and welfare of participants, while also fitting into at least one of the Exempt Categories of Research (<http://irb.utah.edu/guidelines/exemption-umbrellas.php>)

**Enterprise Data Warehouse Form (EDW):** This form is used to request data/information from the University of Utah Health Sciences Center through the University Enterprise Data Warehouse (EDW). Data received from this source is covered under HIPAA regulation (46 CFR 164) and is subject to privacy law. Data requested for use in human subject research is also subject to review by the Institutional Review Board (IRB) under applicable federal regulation. For guidance completing this form, please see the document titled **Guidance for Accessing Protected Health Information** at <http://irb.utah.edu/guidelines/investigator.php>.

**Umbrella Regulatory Coordinator:** Individual who has been appointed to coordinate all regulatory functions for the assigned IRB exempt umbrella. These regulator functions include, but are not limited to IRB amendments, report forms, electronic and paper filing of protocols, data management, and correspondence with faculty and staff.

**Umbrella Protocol:** Mandatory document for all research conducted under a University of Utah Department of Orthopaedics IRB Exempt Umbrella. This document requires a

**Umbrella Checklist:** Document required for each umbrella protocol that serves as a checklist for items that need to be complete prior to study procedures beginning. This document can be completed by anyone on the study team, the umbrella compliance officer, or the umbrella regulatory coordinator.

## 8. PROCESS OVERVIEW

- A. Setup, training and maintenance
- B. Research Site Responsibilities
- C. Collection and Management of the data

## 9. PROCEDURES

### A. SETUP, TRAINING, AND MAINTAINENCE

- Principal investigator
- Sub-investigator
- Research director
- Research coordinator
- Support staff

All research conducted under an IRB exempt umbrella must meet the following criteria:

- Retrospective research only
- Protocol/Checklist complete and signed off prior to conducting research and filed in the regulatory binder and eFile under: U:\Ortho Clinical Research\ - Saltzman, Charles\ - Umbrella\Umbrella Support Documents\Current Protocol, Checklist, EDW
- All documents required to conduct research should be maintained in the eFile. Format located under: U:\Ortho Clinical Research\ - Saltzman, Charles\ - Umbrella\Umbrella Support Documents\Archive

### B. RESEARCH SITE RESPONSIBILITIES

- Support staff

Maintain the IRB exempt umbrella according to University of Utah IRB policy. Please see <http://irb.utah.edu/guidelines/exemption-umbrellas.php> for additional information.

### C. COLLECTION AND MANAGEMENT OF DATA

- Principal investigator
- Sub-investigator
- Research director
- Research coordinator
- Support staff


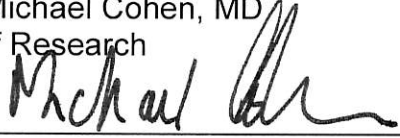
All data collected under an IRB exempt umbrella, should follow the process outlined in SOP DM-503.

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## 10. REVISION HISTORY

**Version 1.0 14 June 2016: Original date of approval**

Prepared by: Ashley Neese, BS	Date: 05/09/2016
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