IRB Retrospective Study Protocol Template

### LENI & PETER W. MAY DEPARTMENT OF ORTHOPEDICS

#### Instructions

All research personnel need to

* be up to date on their [IRB Required Trainings](https://icahn.mssm.edu/research/pphs/training)
* have an account in [Ideate](https://ideate.mssm.edu/home/) *(PRO Tip: Use Firefox on campus)*
* have an account in [InfoEd](https://eresearch.mssm.edu/) *(request access*[***here***](http://osticket.mssm.edu/support/open.php)*)*

Send this completed **form**, research personnel **CVs/Resumes**, **data collection sheet**, **linking sheet**,and **Education Completion Certificates** to the [Ortho Clinical Research Team](mailto:OrthoResearch@mountsinai.org)

# Study Basics and Logistics

**Title:**

**PI:**

**Is there external funding for this study?:** [Yes]\* / [No]\*If so, please elaborate

**Research Team Members and Roles on Study:**

**Estimated Study Timelines (from IRB Application to Publication)**

*Please describe…*

**Objectives:**

*Please describe…*

**Background (*Include References*):**

*Please describe…*

**Endpoints (*Primary and Secondary*):**

*Please describe…*

**At what sites in Mount Sinai will the research take place?  Where all is the data from?**

*Please describe…*

# Human Subjects & Data Protection

**How does the study involve minimal risk to participants:**

*Please describe…*

**How the Waivers of HIPAA Authorization and Consent Will Not Adversely Affect the Rights and Welfare of Participants:**

*Please describe…*

**Why is it not practical to conduct this research without a waiver or alteration of informed consent?**

*Please describe…*

**Plans for Providing Participants with Additional Pertinent Information After Participation Where Appropriate?**

*Please describe…*

# Study Data, Data Collection & Record/Data Storage

**Health Related Information Will be Viewed, Recorded, or Generated?**

[Yes] / [No]

**Description of Health Information that will be viewed, recorded or generated:**

*Please describe…*

**Non-Health related information (Identifying information like Name, MRN, DOB etc) will be viewed or recorded?**

[Yes] / [No]

**Description of Non-Health information that will be viewed or recorded:**

*Please describe…*

**HIV/AIDS Related Information Will Be Viewed or Recorded?**

[Yes] / [No]

#### Data That Will Be Viewed, Recorded, or Generated Contains ANY of the Following Directly Identifiable Information

## **Identifiers:**

## Name

## Fax #

## Web URL

## Social Security Number (SSN)

## MRN

## Address (by Street Location)

## TelephonE #

## IP Address

## HEalth Plan Beneficiary #

## Account #

## Certificate

## License #

## Vehicle IDentification # (VIN)

## License Plates

## Full Face Photographic Images

## Biometric Identifiers (finger prints or voice prints)

## Geographical subdivisions (Smaller than a state)

## All elements of dates for dates directly related to an individual **(DOB, DOS, Date of Discharge, Admissions Date etc)**

## E-mail Addres

**Will Be Viewed:** *Please note from list above…*

**Will Be Recorded:** *Please note from list above…*

**Data Collection Source(s):**

*Please describe…*

**How PHI Will Be Protected from Improper Use or Disclosure:**

*Please describe…*

**When will PHI will be Destroyed?**

*Please describe…*

**Will PHI will be Shared?**

[Yes]\* / [No]*\*If Yes, please elaborate*

**Location Where Data Will be Stored (both physical and electronic):**

*Please describe…*

**How will the data be stored (select one)?**

* With a code that can be linked to the identity of the participant
* Completely de-identified (absolutely no identifiers will be used in the study)
* Other: **Please detail**

## Please note that data must be stored for 7 years post the completion of data analysis per the IRB

**Steps that will be taken to secure the data during storage, use and transmission**

*Please describe…*

**Data analysis plan including any statistical procedures:**

*Please describe…*

# Retrospective Review

**Number of Records to be reviewed:**

**Justification for Number of Records to be reviewed:** *Please describe…*

**Data generation period:** Records starting from **XX/XX/XXXX** and ending at **XX/XX/XXXX** will be reviewed

## The latest possible end date for Record review/data generation is **prior to the initial application IRB submission** for a **retrospective study –** this date cannot be typically extended

# Regulatory

**Data Regarding Subject or Control Subjects will be submitted to or Held for Inspection by FDA as Part of an application for a research or marketing permit:** [Yes] / [No]

**A device will be used on specimens to collect data that will be submitted to or held for inspection by FDA as part of an application for a research or marketing permit**: [Yes] / [No]