**Instructions:**

* Keep an electronic copy. You will need to modify this copy when making changes.
* All referenced checklists, templates, and policies, can be found on the IRB website.
* **Remove all instructions in italics so 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 deletethe section headers.
* *When you save and upload this document, add the protocol version date to the title.*

**PROTOCOL TITLE:**

**PRINCIPAL INVESTIGATOR:**

Name

Department

Telephone Number

Email Address

**STUDY SUMMARY:**

*Please provide a brief summary of the study in the table below.*

|  |  |
| --- | --- |
| **Research Site** |  |
| **Primary Objective** |  |
| **Secondary Objective(s)** |  |
| **Records Review Type** |  |
| **Study Population** |  |
| **Type of Consent** |  |
| **Sample Size** |  |
| **Study Duration** |  |
| **Funding Source** |  |

**REVISION HISTORY:**

***\*This table should only be used during submission of an Amendment application to the IRB.***

|  |  |  |  |
| --- | --- | --- | --- |
| **Version #** | **Version Date** | **Summary of Changes** | **Consent Change?** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

**PRIMARY OBJECTIVES:**

*Describe the purpose, specific aims, objectives, and/or hypotheses.*

*(There should be one or two primary objectives with additional objectives listed as secondary.)*

**SECONDARY OBJECTIVES:**

*Secondary objectives may or may not be hypothesis-driven, may include secondary outcomes, and general non-experimental objectives (e.g. to develop a registry, to collect natural history data).*

**BACKGROUND:**

*Provide the scientific or scholarly background for, rationale for, and significance of the research based on the existing literature and how this project will add to existing knowledge.*

*Describe any relevant preliminary data (e.g. pilot data).*

*Note: this section should be limited to only information directly related to the research questions and objectives. Do not include your thesis/dissertation proposal.*

**STUDY DESIGN AND PROCEDURES:**

|  |
| --- |
| Select one of the following: |
| Retrospective chart review |
| Prospective chart review |
| Both: retrospective and prospective chart review |

*To qualify as retrospective, the data and/or biospecimens must exist when the study is submitted to the IRB for initial review. If the data and/or biospecimens do not exist when the study is submitted to the IRB for initial review, it is defined as prospective.*

*Briefly describe the study design and indicate, in general terms, how the design will fulfill the intent of the study.*

**SOURCE OF RECORDS/RECRUITMENT:**

*Source of records (be specific).*

*Estimated minimum number of charts to be reviewed.*

**DATE RANGE:**

*Date range from which chart data will be reviewed.*

**INCLUSION AND EXCLUSION CRITERIA:**

*Describe the criteria that determine which charts will be included or excluded in the study.*

*Example: All patients (18 years and older) who have undergone total knee arthroplasty at MVH between Jan.1, 2005 and March 31, 2015 will be eligible for inclusion.*

*Indicate whether you will include or exclude each of the following special populations:*

* *Adults unable to consent*
* *Individuals who are not yet adults (infants, children, teenagers)*
* *Pregnant women*
* *Prisoners*
* *Vulnerable Populations*

**DATA COLLECTION PROCEDURES:**

*Who will be accessing the medical records?*

*Briefly describe clinical site responsibilities in data collection and management.*

*Describe the procedure for obtaining data.*

*Describe the general type of data to be collected and timeframe*

*Attach the database elements and/or data points to be collected (i.e. Excel file) or Data Collection Form. Please be certain any form contains page numbers and a place for the person collecting the information to sign and date.*

**DATA TO BE COLLECTED:**

*Indicate what information will be retained for each subject and by whom.*

*Will you be recording identifiers (PHI) from charts? List them here.*

**DATA ANALYSIS:**

*Describe the data analysis plan, including any statistical procedures or power analysis.*

*What sample size will you be able to get and is your suggested samples size sufficient for your primary objective?*

*Describe any procedures that will be used for quality control of collected data.*

**SHARING OF RESULTS WITH PARTICIPANTS:**

*Describe whether results (study results or individual subject results, such as results of investigational diagnostic tests, genetic tests, or incidental findings) will be shared with participants or others (e.g., the participant’s primary care physicians).*

*Describe how the results will be shared If applicable (e.g. for studies involving scans and/or panels of exploratory testing on specimens).*

**PRIVACY & CONFIDENTIALITY OF DATA:**

*Describe the plan to protect privacy of subjects and confidentiality of data.*

*What identifiers will be kept with the data?*

*If codes, where will the key linking the codes to identifiers be kept?*

*Will other parties help with statistical analysis, and if so, will identifiers be stripped off first?*

*What are plans for protecting the data or disposing of it once the study is completed?*

**SECURE STORAGE OF DATA:**

*Describe the steps that will be taken to secure the data (e.g., training, authorization of access, password protection, encryption, physical controls, certificates of confidentiality, and separation of identifiers and data) during storage, use, and transmission.*

*Where and how data will be stored?*

*How long the data will be stored?*

*Who will have access to the data?*

*How data will be transported and/or transmitted?*

**STUDY TIMELINES:**

*Describe:*

* *The estimated duration anticipated to review all charts.*
* *The estimated date that the investigators will complete the data analysis.*

**CONSENT PROCESS:**

*Most retrospective medical records review will qualify for exempt review; thus informed consent is not necessary.*

*However, many prospective medical records reviews are reviewed at the expedited review level. Thus a request for a waiver of informed consent may be necessary. Please state if you are doing so for your study.*

*If applying for a waiver, please address how your request meets the following criteria:*

* *The research involves no more than minimal risk to the subjects.*
* *The waiver or alteration will not adversely affect the rights and welfare of the subjects.*
* *The research could not practicably be carried out without the waiver or alteration (impracticability normally requires justification beyond inconvenience or cost)*
* *Whenever appropriate, the subjects will be provided with additional information about their participation in the research (often not necessary).*

*If your study does not meet the criteria for waiver of informed consent , explain how and when consent will be obtained.*

**HIPAA:**

*List the specific HIPAA identifiers you will record in your research files.*

* *Names*
* *Postal address* 
  + *All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code, if, it contains more than 20,000 people.*
* *Dates* 
  + *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, except that such ages may be aggregated into a single category of age 90 or older.*
* *Telephone numbers/Fax numbers*
* *Electronic mail address*
* *Social security numbers*
* *Medical record numbers and/or Account numbers*
* *Health plan beneficiary number*
* *Certification/license numbers*
* *Vehicle identifiers and serial numbers, including license plate numbers*
* *Device identifiers and serial numbers*
* *Name of relative*
* *Web Universal Resource Locator (URL) and or Internet Protocol (IP) address number*
* *Biometric identifiers, including fingers and voice prints*
* *Full face photographic images and any comparable images*
* *Any other unique identifying number, characteristic, or code*

*HIPAA waiver: If you are recording identifiers from subjects who are still living, and it is not practicable to obtain their HIPAA authorization for your study, state that you are requesting a HIPAA waiver.*

*If applying for a waiver, please address how your request meets the following criteria:*

* *The use or disclosure of PHI involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements:*
  + *An adequate plan to protect the identifiers from improper use and disclosure;*
  + *An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers, or such retention is otherwise required by law; and*
  + *Adequate written assurances that the PHI will not be reused or disclosed to any other person or entity, except as required by law, or for authorized oversight of the research study, or for other research for which the use or disclosure of PHI would be permitted by this subpart.*
* *The research could not practicably be conducted without the waiver or alteration.*
* *The research could not practicably be conducted without access to and use of the protected health information.*

**RESOURCES AVAILABLE:**

*Describe the resources available to conduct the research:*

* + - *Describe the time that you will devote to conducting and completing the research.*
    - *Describe your facilities.*
    - *Describe your process to ensure that all persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties and functions.*

**REFERENCES:**

*Add references*