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| **Protocol Template for Chart Review Studies** |
| **Project Title:** Click here to enter text. |
| **Principal Investigator:** Click here to enter text. |
| **Co-Investigator(s):** Click here to enter text. |
| **THR Facility:** Click here to enter text. |
| **Department:** Click here to enter text. |
|  |
| 1. **Purpose of the Study**
 |
| Please describe: Click here to enter text. |
| 1. **Background and Significance**
 |
| Please describe: Click here to enter text. |
| 1. **Research Plan**
 |
| [ ] Retrospective Chart Review (records already in existence at the time of this IRB Application will be studied)[ ] Prospective Chart Review (medical records/data not yet in existence at the time of this IRB Application will be studied)[ ] Both Retrospective and Prospective |
| When was the medical information originally obtained from the patients (i.e. timeframe of your chart review)?From: (Month/Date/Year)Click here to enter text. To: (Month/Date/Year) Click here to enter text.***\*\*Note that this is not the timeframe when you plan to conduct the research\*\**** |
| Where will the chart review activities occur (i.e. the physical location): Click here to enter text. |
| Will you obtain data from multiple THR Entities? [ ] Yes[ ] No If yes, please list those THR facilities: Click here to enter text. |
| Number of Charts to be reviewed: Click here to enter text. |
| Number of times the charts will be accessed during the review: Click here to enter text. |
| What is the source of the medical information? [ ] Entire Medical Record[ ] Billing[ ] Laboratory Results[ ] Pathology Records[ ] Radiology Records[ ] Patient Interviews, Surveys or Questionnaires [ ] Other (please describe): Click here to enter text. |
| Please describe who will be accessing the charts and recording the data as part of this study: Click here to enter text.Are all persons accessing medical records THR employees? [ ] Yes [ ] No*If no, please describe:* Click here to enter text. |
| Please describe the process/procedures for how the medical data will be accessed and recorded (i.e. when and where): Click here to enter text. |
| Please list what data items will be collected for research purposes from the medical record (***note that you will need to create and upload a data collection form for IRB review and approval):*** Click here to enter text. |
| **4. Protected Health Information (PHI)**Protected health information (PHI) is any information in the medical record or designated record set that can be used to identify an individual and that was created, used, or disclosed in the course of providing a health care service such as diagnosis or treatment. HIPAA regulations allow researchers to access and use PHI when necessary to conduct research. |
| You will be accessing PHI when you review the medical records. Please indicate if you will be recording any of the 18 HIPAA Identifiers listed below: 1. [ ] Names;
2. [ ] All geographical 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 according to the current publicly available data from the Bureau of the Census: (1) The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and (2) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.
3. [ ] 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 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older;
4. [ ] Phone numbers;
5. [ ] Fax numbers;
6. [ ] Electronic mail addresses;
7. [ ] Social Security numbers;
8. [ ] Medical record numbers;
9. [ ] Health plan beneficiary numbers;
10. [ ] Account numbers;
11. [ ] Certificate/license numbers;
12. [ ] Vehicle identifiers and serial numbers, including license plate numbers;
13. [ ] Device identifiers and serial numbers;
14. [ ] Web Universal Resource Locators (URLs);
15. [ ] Internet Protocol (IP) address numbers;
16. [ ] Biometric identifiers, including finger and voice prints;
17. [ ] Full face photographic images and any comparable images; and
18. [ ] Any other unique identifying number, characteristic, or code (note this does not mean the unique code assigned by the investigator to code the data)

[ ] I will not be recording any of these 18 identifiers.  |
| Please list any of these 18 identifiers that you will be recording on your data collection form: Click here to enter text. |
| Do you plan to keep a Master List or Key as part of this study that includes a link between a unique case ID and identifiable patient information (i.e. name, medical record number, etc.)? [ ] Yes\* [ ]  No***\*If yes, please create and submit a template pf the master list/key for IRB review*** |
| If yes, please describe the identifiable information that will be on the master list/key: Click here to enter text. |
| Are there plans to transfer PHI or any data that you collect to an institution, facility, or person outside of THR? [ ]  Yes [ ] NoIf yes, please describe the measures that you will have in place to protect the confidentiality of the PHI: Click here to enter text.Please describe who will be the owner of the data: Click here to enter text.  |
| Is the PI the data steward (person responsible for creating, maintaining, and storing any documents or databases that contain PHI)? [ ] Yes [ ]  No If no, please describe who will be the data steward: Click here to enter text.Please describe who will have access to any PHI that is collected as part of this study. This includes the master list/key, and data collection forms that contain PHI, and any databases that contain PHI): Click here to enter text.  |
| **5. Provisions to Maintain the Privacy and Confidentiality of the Data**  |
| **Confidentiality-**Please describe the measures/steps that you will take to protect the study data (and PHI if applicable) from unauthorized use or disclosure. This includes the master list/key, any data collection forms, and any electronic databases. If you have both paper-based and electronic information, make sure to describe each.  |
| Click here to enter text. |
| **Privacy**-Please describe how you will protect the patient’s privacy (e.g. discussions about any patient data will occur in a private location):  |
| Click here to enter text. |
| **5a. Master List/Key** |
| If you are maintaining a master list/key, please describe the plans for how the master list will be stored separately from the data collection form(s).  |
| Click here to enter text. |
| How long do you plan to keep this master list/key (note that the study may be closed out once all identifiers have been destroyed):  |
| Click here to enter text. |
| **6. Risks and Benefits**  |
| **Risks-**while this study is not likely to create any physical risks to patients, there is the potential for informational risks (e.g. breach of privacy, loss of confidentiality, unauthorized access of research documents/PHI, etc.). Please describe any risks.  |
| Click here to enter text. |
| **Benefits**-Please describe any potential benefits to subjects, society, and or science that may result from this research project.  |
| Click here to enter text. |