**SUB-STUDY SUBMISSION FORM FOR RADIOLOGY DEPARTMENT**

**UMBRELLA PROTOCOL, IRB #2016-6858**

Please fill in the below information for your sub-study (you may delete the descriptive text), and submit to Monene Kamm @ kammmm@ucmail.uc.edu. Your sub-study will be reviewed by the Umbrella Protocol Principal Investigator, Achala Vagal, and members of the Radiology Research Committee.

The Umbrella Protocol is attached for your review. This protocol contains all IRB required elements and all investigators must abide by the protocol. The below is supplemental and specific to your sub-study.

The investigators for the sub-study will be added to the Radiology Umbrella Protocol 2016-6858 in RAP. Addition of Sub-Study Investigators can happen simultaneously with review. You may provide the investigator(s) names for the sub-study before the actual submission to expedite the process. Please review the below before your submission:

* **All research team members must have completed the appropriate CITI Training and have a RAP account prior to being added to the IRB.** Department Research Regulatory Manager(s) can provide instructions.
* **Amendments will be submitted to the IRB on the 10th of each month, provided the previous amendment is approved.**
* **A Regulatory Manager will notify the reseach team once their study is approved through an amendment. No data collection or record review for the sub-study may begin until this notification has been sent.** (Data collection forms may be built and tested while waiting for IRB approval)

|  |
| --- |
| **For Investigator to Complete** |
|  **Date Submitted:** |
| **In order to be successful with this study, I would require support in the following ways (check all that apply):** |
| [ ]  | **Monetary** | [ ]  | **Technical Support** | [ ]  | **Personnel** |
| [ ]  | **Equipment/software** | [ ]  | **Post-processing** | [ ]  | **Statistical Analysis** |
| [ ]  | **None** | [ ]  | **Other (specify):** |  |  |
| **Desire to Present/Publish:** [ ]  **Yes** [ ]  **No****If Yes, likely target conferences/journals:** |

1. **Sub-Study Title:**
2. **Principal Investigator of Sub-study:**
3. **Sub-Study Investigator Team**
4. **Sub-Study Specific Aims:**

Provide a description of the overall purpose/rationale of the research that will be conducted under this umbrella protocol. Include main aims of the study/project. There should be a very clear statement of the main hypothesis and any exploratory hypotheses.

1. **Sub-Study Background and Significance**

Describe in short the scientific basis for this sub-study. There should be reference to the literature to demonstrate the study will contribute new and generalizable knowledge and the significance/impact/clinical relevance of the study. If there are any preliminary data, these should be described here.

1. **Sub-Study Potential Participants**

Describe:

* How the pool of records will be identified. (Records might be identified be by querying a database for all patients with a certain procedure code, DRG code, ICD-9 code, or it might be by exporting data from all patients during a time period, or data that was collected in a previous or ongoing research study or by some other means)
* Approximate number of subjects
* Include any additional data that will be used to augment the records
1. **Sub-Study Screening/Inclusion and Exclusion Criteria**

List the specific criteria that will be used to decide which records will be included and which will not. Include the inclusion and exclusion criteria.

1. **Sub-Study Data Collection**

**Provide a DETAILED description of the data collection. This section must describe how each piece of research data will be obtained from the records, including a detailed plan of how records will be accessed, from where the records will be accessed and how data will be collected. Attaching a data collection form for your sub-study is preferable.**

1. **Sub-Study Timeline**

Briefly describe the expected length of time it will take for you to extract the data you wish you use from the data set. Estimate the length of time for primary analysis and final report writing/publication. Since studies can be delayed for multiple reasons, wording can be designed as such.

Example wording: *Collection will begin within a month of IRB approval. It is expected that collection of the data will take up to 6 months. Analysis of the data is expected to take 6 months to complete. Our goal is to submit a manuscript within 4 months of the end of data analysis.*

1. **Sub-Study Analysis Methods**

Describe how the data will be analyzed to answer the study question, **including the methods to be used and a basis for how you have determined the number of records that are needed to answer the research question (including as appropriate a power analysis or other sample size calculation).** A reasonable statistical approach must be provided. Help for statistical analysis can be obtained from the assigned faculty from CCHMC Department of Biostatistics and Epidemiology, Bin Zhang: Bin.Zhang@cchmc.org or 513-803-8050.

1. **References**

|  |
| --- |
| **For UC Radiology Research and Development Committee Personnel to Complete** |
| **Date Review Completed:** |
| **Determination and Next Steps:** |