**ERICH data flow and management process**

**SCREENING LOGS**

An email is generated to all the sites at the beginning of the month reminding them to submit the monthly screening log. The log is due at the beginning of each month. Once the screening log is submitted to the Coordinating Center it gets reviewed for completeness. The Administrative Coordinator enters the screening log into the sites screening log database which is password protected. The screening log is then filed into the SCREENING LOG BINDER under the sites tab.

**CASE REPORT FORMS**

**CASE/CONTROL INTERIVEWS AND FOLLOW-UPS:** Case report forms are submitted to the Coordinating Center within five days of completion. Once forms are received, they are reviewed for completeness, logistics, and accuracy by the study staff. The study staff stamps the bottom of page 1 with a “received” stamp. The interview is entered into the site database. Once entered into the database the study staff stamps the bottom of page 1 with an “entered” stamp and initials.

**CHART ABSTRACTS:** Chart abstracts are submitted to the Coordinating Center within 2 months discharge if the patient was not a transfer from another institution. If the patient was transferred from another institution then the site has 3 months from discharge to submit the chart abstract to the Coordinating Center. Once forms are received, they are reviewed for completeness, logistics, and accuracy by the study staff. The study staff stamps the bottom of page 1 with a “received” stamp. The interview is entered into the site database. Once entered into the database the study staff stamps the bottom of page 1 with an “entered” stamp and initials.

**DATA FLOW:** Once the CRFs are pre-data queried they are placed in a locked filing cabinet and sorted by case interview, control interview, chart abstract, and follow-up. Forms are sent to data entry three times a week. The forms are placed in a locked ERICH specific filing cabinet and sorted by case interview, control interview, chart abstract and follow-up and wait to be data entered. Julie Brock first-data enters the ERICH data. Data queries are flagged. When first entry is completed it is stamped and initialed. Bonnie Combs second-data enters the ERICH data. Data queries are flagged. When second entry is completed it is stamped and initialed. Once the CRFs are double entered they are brought back to the ERICH office and placed in a locked filing cabinet.

**DATA QA/DATA QUERIES/MISSING DATA:** All case report forms are pre-data queried by the Coordinating Center prior to being data entered. Pre-data queries are flagged and sent to data entry. As the case report forms are being entered, data entry flags the pages that have missing data, logistic check or clarify. Data queries are typed up monthly by the Coordinating Center and emailed to the site at the end of each month. Data queries are due by the end of the following month. Otherwise, they are added to the next month’s queries. If the site fails to answer two months of data queries the PI is notified.

Once the data queries are submitted to Coordinating Center the study staff makes the necessary corrections in red ink, initial and date the correction. The data queries are flagged and sent to data entry for entry. When data entry has entered in all the queries they are transferred back to the ERICH office and entered into the site database as entered, then filed in the site specific drawer/#ID folder.

Monthly: Data Entry requests a “clean and compare” from data management. Data management generates a report of what data between first entry and second entry doesn’t match. The CRFs are pulled and checked for accuracy and clarity.

**MISSING DATA:** A monthly report is generated to the sites informing them of what items are outstanding. The items are to be submitted by the end of the month. If they are not, the missing data gets added to the next month’s report. If the items are still not submitted the PI is notified.

**CONTROL ENROLLMENT PATHWAY:** The Institute for Policy Research (IPR) will use random-digit-dial telephone survey methods to identify one control of the same gender, race, ethnicity and age as cases (±5 years) from the same city/region that the cases are obtained. The IPR also includes Spanish speaking call operators that will allow for identification of controls from Spanish-only speaking households. Each of the random digit dialing (RDD) samples of telephone numbers used in this study will be purchased from Survey Sampling International (SSI) in Fairfield, Connecticut. Samples for each city/region will be stored in separate databases specific to each city/region. Three types of samples may be used to identify potential respondents. IPR interviewers will first attempt to reach potential controls at telephone numbers drawn using SSI’s RDD landline sample methodology that spans the entire adult population. Because previous control identification using RDD methods has revealed difficulty in reaching both minority and older populations, two additional types of samples may be employed to assist in reaching harder-to-find controls as the study progresses: SSI’s RDD ethnic density sampling (African-American and Hispanic respondents) and SSI’s RDD age density sampling (older respondents); both use exchange density methodology to generate telephone numbers included in each sample (More information about these methodologies can be found at <http://www.surveysampling.com/?q=en/respondents/>).

As cases are identified, their demographic information will be sent to the IPR. Once approximately 20–30 cases are identified or every year at minimum, random digit dialing in the region will commence to obtain controls. From prior studies, we have learned that identifying controls for 20 or more different demographics is far more efficient than sequentially identifying controls for one subject at a time. The control information is then forwarded to the study coordinator at the appropriate site for recruitment.

**ENROLLMENT QA:** Ensuring accurate and consistent phenotyping of ICH cases across ERICH sites is of importance. As part of the QA process, each ERICH site was asked to submit chart abstractions and radiographs for five consecutive enrolled cases and five consecutive subjects who were screened but excluded from enrollment in accordance with ERICH inclusion/exclusion criteria (no hemorrhage, traumatic hemorrhage, hemorrhage due to AVM, etc). These documents are reviewed at the coordinating center in Cincinnati and any discrepancies between the ERICH site and coordinating center are resolved via communication with the ERICH site PIs. Quality assurance will also be enhanced through other mechanisms such as “challenging phenotype cases” presented on ERICH conference calls and comparison of ICH location as identified by local ERICH sites and the central CT and MRI reviews.

**BLOOD DRAW SPECIMEN TRACKING:** Site tracks the specimen through FedEx. The Study Coordinator and Administrative Coordinator are cc’d on the FedEx tracking notices. The notices are received via email. Once the notices are received the Coordinating Center enters the specimen in the site database (case or control) under blood sample received. The blood samples received are compared against Miami’s weekly comprehensive list. This is to ensure all blood samples are received without interruption.

**MRI UPLOAD:** A monthly update is received from MGH on which images they have received from the centers. The Coordinating Center updates the sites tracking database to reflect the images that were sent. A “yes” in documented in the MRI received column when MGH has received the images. The sites have two months from the time the patient was enrolled to submit the images.

**CASE CHALLENGE:** A monthly case challenge is used as a learning experience on the ERICH monthly conference calls. The Coordinating Center requests a case challenge from Houston at the beginning of every month.

**ERICH MONTHLY CONFERENCE CALLS:** The monthly conference calls are held the second Wednesday of every month. They begin at 11:00 am EST. The Coordinators Call follows. The conference call reminder and agenda are sent out to all ERICH study staff and NIH the Tuesday before the meeting. Phone # 513-621-0220 or 1-877-621-0220 Passcode 8333132.

**IMAGING REPORTS:** Imagining reports from MGH and Georgetown are sent to the Coordinating Center monthly. The reports are discussed on the monthly ERICH conference calls.

**IMAGING CORES CONFERENCE CALLS:** Held quarterly. Participants: MGH, Georgetown, and UC

QA: Discussion

**RECRUITMENT COMMITTEE CALLS:** Held semi-annually (see list)

**STEERING COMMITTEE CALLS:** Held monthly (see list)

**COORDINATING CENTER MEETINGS:** Held weekly in PI’s office

**PASSWORDS:**

**MRI PARTNERS UPLOAD:** Study staff has to complete CITI and HIPAA training and submit certificates to the Coordinating Center prior to receiving Partners access. The Coordinating Center notifies Anastasia Vashkevich [avashkevich@partners.org](mailto:avashkevich@partners.org) of who needs access.

**ERICH WEBSITE:** Study staff has to complete CITI and HIPAA training and submit certificates to the Coordinating Center prior to receiving ERICH website access. The Coordinating Center notifies Laurie Russell [lrussell@wakehealth.edu](mailto:dgoff@wakehealth.edu) of who needs access.

**INVOICING:** Sites invoice quarterly for Part A. Coordinating Center submit payment for Part B once the sites hits their 50% of their yearly recruitment goal.

**START-UP VISITS:** Site specific start-up visits are performed once Coordinating Center has received IRB approval letter (see attached forms).

**MONITORING VISITS:** Random annual site visits are performed by the Coordinating Center (see attached forms).

**ENROLLMENT PAYMENT:** Case and control reimbursement is site specific.