**PROTOCOL TITLE:**

Epilepsy Genetics Database

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**VERSION NUMBER/DATE:**

Version 1 – 3/24/2021

**REVISION HISTORY**

|  |  |  |  |
| --- | --- | --- | --- |
| **Revision #** | **Version Date** | **Summary of Changes** | **Consent Change?** |
| 2 | 12/16/2021 | Minor wording clarification of 4.0, 6.0, 7.0, and 16.0. No substantive changes of methodology or types of data collected | Y (for change in study personnel only) |
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# Study Summary

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| **Study Title** | Epilepsy Genetic Database |
| **Study Design** | Multi-site data collection (combined prospective & retrospective) |
| **Primary Objective** | Develop a centralized national database of common and rare genetic etiologies of childhood-onset epilepsy  |
| **Secondary Objective(s)** | 1. Creation of common data elements allowing further characterization of distinct genetic etiologies
2. Centralized resource for identifying candidates for further natural history studies, or potentially therapeutic trials based on genetic etiology
 |
| **Study Population** | Childhood-onset epilepsy patients who have undergone genetic testing  |
| **Sample Size** | 4000 subjects |
| **Study Duration for individual participants** |  Participants will provide informed consent and baseline clinical/ genetic information at the time of enrollment. This will be conducted at a single time point over the phone or during a regular standard of care clinical visit. Patients will be given the opportunity to opt-in to further annual follow-up surveys for a period of up to 10 years. If the patient opts-out of annual surveys, there will be no follow-up thereafter. |
| **Study Specific Abbreviations/ Definitions**  |  |
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|  |  |

# Objectives

* + We would like to keep a multi-institutional registry of patients with epilepsy who have pathogenic or likely pathogenic results of genetic testing. This registry will serve as a robust tool that can be used to advance the diagnosis, understanding, and treatment of various genetic epilepsies and improve epilepsy care. It will also allow compilation of data and collaboration between multiple sites in order to better best practices in pediatric epilepsy. In addition, we will be able to demonstrate the utility of genetic testing in the field of pediatric epilepsy. The primary objective is to create a multi-institutional database of patients with genetic epilepsies where common data elements are entered prospectively. The goals are to then use this database to 1) compile anonymized patient data among institutions and 2) serve as a registry whereby patients with genetic epilepsies eligible for other research studies can be identified, for those that have provided proper consent. The data collected can 1) provide information on the natural history of genetic epilepsies, 2) better elucidate the incidence and phenotypic spectrum of rare genetic epilepsies, and 3) understand factors that may influence the phenotypic expression.

# Background

* + Our ability to identify a genetic etiology in epilepsy has grown substantially over the past decade. The current yield of positive results from epilepsy gene panels or whole exome sequencing is approximately 30% in patients with refractory epilepsy of unknown cause. However, while our diagnostic capabilities have flourished, our ability to use this diagnostic information to inform treatment decisions has lagged behind. Surely, there are a known handful of genetic epilepsies where a clear therapy or treatment regimen exists, but this number pales in comparison to the >1000 genes associated with epilepsy. In part, this is because many of these genetic epilepsies are exceedingly rare, such that each institution might only have a few patients with a given genetic diagnosis. Creating a database of patients with various genetic epilepsies will allow clinicians to collaborate and pool our data so that we may develop a more robust data. We hope to ultimately use this information and data gleaned from other research studies fed by this database to improve epilepsy diagnosis and outcomes, similar to what has been accomplished by the Children’s Oncology Group.
	+ Recent large-scale, collaborative studies of epilepsy genetics have led to a rapid advance in identification of pathogenic or likely pathogenic variant genes in epilepsy (PMID:33818783, PMID:31625138), as well as variants classified as “unknown significance” at this time. Though there are some collaborative efforts to collect these genetic variants in large databases (ClinVar), they include little to no information to help guide clinical management. Genetic testing is increasingly being used in clinical practice (PMID: 32201576). Due to the relative rarity of many genetic epilepsies, there is still limited data to support best treatment plans in caring for patients.

# Study Endpoints

* + Descriptive statistics regarding incidence of pathogenic and likely pathogenic variants for rare genetic epilepsies. Phenotypic elements present within these epilepsies will be reflected in supplemental documents representing the REDCap instruments as well as the Human Phenotype Ontology data.

# Study Intervention/Investigational Agent

* + - This study does not involve any intervention or use of an investigational agent.

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|  | ***Applicable to:*** |
| ***FDA Regulation*** | ***IND Studies*** | ***IDE studies*** | ***Abbreviated IDE studies*** |
| ***21 CFR 11*** | ***X*** | ***X*** |  |
| ***21 CFR 54*** | ***X*** | ***X*** |  |
| ***21 CFR 210*** | ***X*** |  |  |
| ***21 CFR 211*** | ***X*** |  |  |
| ***21 CFR 312*** | ***X*** |  |  |
| ***21 CFR 812*** |  | ***X*** | ***X*** |
| ***21 CFR 820*** |  | ***X*** |  |

# Procedures Involved\*

* + Patients will be approached during their regularly scheduled epilepsy clinic visits. Alternatively, subjects established with pediatric neurology may be contacted at other points of care (ER, inpatient) by telephone or through REDCap via their email. A waiver of authorization is necessary for research preparedness, to review charts to determine study eligibility. No further data will be utilized prior to consent. The study team at each individual center will approach families that have already decided to undergo or have undergone genetic testing. They will then provide the family information regarding the study and inform them that research is voluntary. The guardian of the child will need to provide consent. If the child is of age of assent they will have to provide their assent as well. If genetic testing reveals a result including a pathogenic or likely pathogenic variant or a variant of unknown significance, the information will be provided to the site study coordinate to enter necessary information into the study database.
	+ Study participants will be offered the option to enroll in annual study surveys, which they will receive by e-mail. If they choose not to enroll, there will be no further follow-up.
	+ Follow-up surveys will be sent annually to participants with a secure link to a REDCap survey. Surveys will allow for longitudinal evaluation of genetic variants.
	+ Participants will also be offered the option to be contacted for future studies.
	+ Describe:
		- This study involves identifying and consenting eligible patients and recording clinical and genetic data in a HIPAA-compliant redcap database. The main risk for the study is patient confidentiality, as we are recording genetic information. In order to protect this information only study staff will have access to the data. The records will be de-identified as much as possible and stored within a password protected database at individual institutions and at the main study site, No PHI other than genetic information will be sent to the central database. OHSU.
		- The data will be recorded in the REDCap database, see appendix A.
	+ The patient’s general demographic and basic clinical information (age, date of birth, sex, date of epilepsy diagnosis, current medications) along with results of their genetic reports will be collected. The data will be obtained by chart review after obtaining informed consent.
	+ There are no plans for clinical follow-up after enrollment in the study. It is a one-time data collection, followed by annual electronic surveys if the family consents. The information will be stored in a database.

# Data and Specimen Banking\*

* + The data will be stored indefinitely. The only individuals that will have access to this data are those directly involved in the study. Additionally, the data will be stored on a password protected device on a secure network. Once someone is no longer involved in the study their access will be revoked.
	+ List the data to be stored or associated with each specimen: See attached documents detailing REDCap instruments.
	+ Data will be housed in a secure REDCap database, after initial data is collected it may be moved to a password protected excel spreadsheet for data analysis purposes. The data will only be shared between institutions that are housed under the IRB. Additionally, specific study staff will be the only ones that have access to the data. Access will be granted once staff complete study training and with proper IRB approval.

# Sharing of Results with Subjects\*

* + Families will have access to their genetic test results via standard of care procedures, so study staff will not be responsible for reporting the results. Any pertinent clinical findings uncovered on chart review by study staff will be reported to their primary neurology provider.

# Study Timelines\*

* + Describe:
		- The research subject’s duration of participation is a one-time encounter during their previously scheduled epilepsy clinic visit or by telephone, in order to obtain consent.
		- Follow-up annual surveys will be sent yearly for 10 years through REDCap for subjects who agree to participate in this portion of the study. Participants can opt-out at any time. A single reminder email will be sent if the form is not returned within 1 week.
		- The duration anticipated to enroll all study subjects. The initial enrollment period is ten years, with possibility of requesting extension.
		- The estimated date for the investigators to complete this study (complete primary analyses) Primary endpoint analysis will be completed within seven years.

# Inclusion and Exclusion Criteria\*

* + At participating institutions, study team members will approach families to participate, as appropriate for their institution, during regularly scheduled clinic visits, or via telephone.
	+ Describe the criteria that define who will be included or excluded in your final study sample.
		- All ages will be included, for genetic testing completed between birth and 100 years of age.
		- Subjects will be included if a) they received genetic testing related to their neurologic/neurodevelopmental symptoms, b) the test result was pathogenic, likely pathogenic, or a variant of uncertain significance relative to seizures/ epilepsy, and c) they have a diagnosis of seizures/ epilepsy. Genetic testing may encompass a broad array of methodologies, including complete genomic hybridization, targeted gene panels, whole exome sequencing, whole genome sequencing, single gene testing, karyotyping, fluorescent in situ hybridization, or methylation analysis. The database may include abnormal genetic test results for subjects of any age.
		- Subjects will be included for abnormal or indeterminant genetic results obtained either prospectively or retrospectively. (Example: a subject with known pathogenic variant who presents for neurologic care after IRB approval may participate in the study even if no new genetic testing is ordered).
		- Subjects may be included if they have a pathogenic or likely pathogenic variant in a gene with high penetrance for epilepsy even if they have not yet clinically manifest with seizures.
		- Subjects will be excluded if no genetic testing has been completed, or the results were interpreted as normal, benign, or likely benign.
		- Subjects will be excluded if genetic testing only demonstrates a single variant in a gene or genes with an inheritance pattern where a single pathogenic variant would not be disease-causing (e.g. a single pathogenic variant in an autosomal recessive gene).
	+ Indicate specifically whether you will include or exclude each of the following special populations: (You may not include members of the above populations as subjects in your research unless you indicate this in your inclusion criteria.)
		- The study will not include parents (adults) who are unable to provide consent due to language barriers, intellectual disabilities or any other extenuating circumstances.
		- Individuals who are not yet adults (infants, children, teenagers) will be required to provide their assent if they are over the age of 9 years old (in absence of a neurodevelopmental disability that would preclude competence to do so).
		- Pregnant women will not be included in this study.
		- Prisoners will not be included in this study.

# Local Number of Subjects

* + Indicate the total number of subjects to be accrued locally. Initial recruitment is anticipated to be 30-50 subjects/month, with a proportional decline annually as retrospective enrollment dissipates. Prospective subject enrollment is anticipated to be 5-10 subjects/month.
	+ If applicable, distinguish between the number of subjects who are expected to be enrolled and screened, and the number of subjects needed to complete the research procedures (i.e., numbers of subjects excluding screen failures.) Subjects may be consented prior to the receipt of genetic study results, and if the test results are negative, then they would essentially be screen failures. Approximately 70% of subjects who are consented at time of genetic testing are anticipated to have a pathogenic variant (15-45%, depending on the type of genetic test) or a variant of unknown significance (~30%).

# Recruitment Methods

* + Subjects established with pediatric neurology will be recruited at any point of care (clinic visit, hospitalization, telephone consultation), or via telephone following an appointment. Consent for study participation will be obtained at the same time as consenting for genetic testing. If the test results return as normal, the subject will be excluded, and if the test results return as pathogenic or a variant of unknown significance, they will be successfully enrolled.
	+ Alternatively, subjects may be recruited retrospectively if genetic testing has already identified a pathogenic or possibly pathogenic variant. Consent for study participation will be obtained at point-of-care (inpatient ward, clinic) or via phone or e-consent through REDCap by a member of the study team.
	+ The subjects will be recruited from participating pediatric neurology patient populations.
	+ Patients will be identified by the study team within the participating pediatric neurology centers.
	+ The study does not intend to use any materials to recruit patients. Patients will be offered participation by their neurology provider(s) and, if interested, consented and enrolled at their regular neurology/ epilepsy clinical encounters or over the phone.
	+ The subjects do not receive any compensation for participating in the study, as there are no procedures or participation required outside of normally scheduled appointments. Annual survey participation is voluntary and the subjects will not receive any additional compensation.

# Withdrawal of Subjects\*

* + If the family does not go through with genetic testing, then they will be withdrawn from the study. However, families will not need to be notified because this will not affect them further.
	+ At any time, the subjects and/or legal guardian may contact the study staff and request to be withdrawn from the study. At this time all recorded information would be deleted from the study database.

# Risks to Subjects\*

* + This study is no greater than minimal risk. Risks involve a breach of confidentiality. All possible measures will be taken in order to protect patient’s PHI; however, we are collecting genetic test results, which has the potential to be identifiable. The information will only be shared within the registry between sites that are covered under the IRB.

# Potential Benefits to Subjects\*

* + There is no anticipated direct benefit to subjects. However, there is potential for indirect benefit in improving diagnosis and treatment of individuals with genetic epilepsies.

# Data Management\* and Confidentiality

* + Basic descriptive analysis will be used to explain the characteristics of the study population including means and standard deviations for continuous variables, and frequencies and percentages for categorical variables; then, a model of best fit will be created. As conclusions arise from data analysis, additional statistical methods may be employed. There is no pre-determined statistical plan for the database aside from descriptive statistics. The anticipated studies that will arise include natural history data for rare genetic epilepsies (regarding onset, % pharmacoresistance, comorbidities, etc.). Alternatively, the database may serve as a springboard for recruitment to other disease-specific conditions (if subject has opted-in to be re-contacted for future studies).
	+ Prior to access to study data, staff will be required to undergo study training as well as institution specific training for protecting patient’s health information. Only study staff that have completed this training will have access to the database. At all times the database will be password protected and only accessible on the institution’s secure network. At any time if a staff member is removed from the study or their institution their access will be revoked immediately.
	+ At any time, each institution will only have access to their patient’s PHI. There are two elements of PHI which institutions will enter into the database (MRN, DOB); the former will remain encrypted to outside institutions participating in the study, and the latter will be converted into age (months) in any distributed reports. Two additional element of PHI may also be included. If there is a paper consent, this will be scanned into REDCap (listing name), but only viewable by enrolling institution. If families opt-in to be recontacted for future studies or to receive annual electronic surveys, an email address will be entered. This will also remain encrypted to external sites.
	+ Each institution will have access to its site’s information to ensure data integrity and that the database is functioning properly. This allows for troubleshooting and a fair distribution of responsibility throughout all sites. Identifiers and study data will be separated as much as possible; however, we do recognize that this is impossible in some cases as we are collecting genetic information.
	+ As mentioned above one institution (OHSU) will be responsible for ensuring proper usage and storage of data collected. Allowing for one site to be solely responsible at a time allows for consistency and data integrity. Individual sites can collect additional data to be stored locally as per each local IRB, but each site will be required to transmit to the central database all necessary data as detailed in Appendix A.
	+ Describe how data or specimens will be handled study-wide:

# Data for this project will be stored in OCTRI's installation of REDCap, a highly secure and robust web-based research data collection and management system.

# Features of REDCap that protect participants' privacy and data security include:

# ·        Physical Security: OCTRI's REDCap software is housed on servers located in ITG's Advanced Computing Center providing locked physical security

# ·        Electronic Security: The REDCap servers are housed behind both the OHSU firewall and a second ACC firewall.  All web-based data transmissions are encrypted with industry-standard SSL methods.

# ·        Controlled User Access: REDCap is employs a robust multi-level security system that enables researchers to easily implement "minimum necessary" data access for their research staff, including specification of data fields that are identifiers. This feature includes “single click” ability to provide completely deidentified (removing all identified data fields and shifting dates) for analysis or other purposes.  User activities are logged to enable auditing of all data access.   Access is integrated with OHSU's network such that users who are also OHSU employees are authenticated against their OHSU network credentials.

# ·        Data Integrity: REDCap is jointly managed in accordance with OHSU Information Security Directives by ACC staff and members of OCTRI's Biomedical Informatics Program, ensuring fidelity of database configuration and back-ups.  User activities are logged to enable auditing of all data changes.

Each participating center will have a reciprocal data use agreement with OHSU allowing selected deidentified data from the central database to be shared with investigators at other participating centers. The data will be stored in REDCap, a secure database. When it is time for analysis the data will be exported to an excel sheet. The excel sheet will be password protected and housed within a secure network.

* + The data will be stored indefinitely, as this is a registry study. However, identifiers will be kept separate as much as possible.
	+ All data will be stored online on a secure network. If the excel spreadsheet ever needs to be shared between sites this will be done as a secure email.

# Provisions to Protect the Privacy Interests of Subjects

* + The study entails a one-time interaction with study staff which ensures that the family has minimal additional interaction as to not disrupt their regularly scheduled visit. Also, the family does not have to provide any personal information to study staff as research is always voluntary.

Utilizing study team members during clinic visits helps to aid in any intrusiveness the family may feel. All data will be gathered via chart review, so the family will not need to disclose any information beyond providing their consent.

* + After study staff identifies and consents participants, the study team will perform chart review. Data in most cases will be entered at a single time point. A change in genetic classification may be updated if there is a reinterpretation of the significance of a variant.

# Compensation for Research-Related Injury

* + The research does not involve more than Minimal Risk to subjects; therefore, research related injury is not anticipated.

# Economic Burden to Subjects

* + There will be no additional costs to the participants, the genetic testing is being done as standard of care, so they are not receiving additional care outside of their normal visit.

# Consent Process

* + Indicate whether you will you be obtaining consent, and if so describe:
		- The consent process will take place during the regularly scheduled Neurology Clinic visit or by telephone or e-consent via REDCap.
		- The consent process is estimated to take about 15-20 minutes. However, if the family would like more time to think about it, we will also offer the phone consent or e-consent option.
		- Informed Consent Process for Research (HRP-090) will be followed thoroughly

**Subjects who are not yet adults (infants, children, teenagers)**

* + - Parental permission will be obtained from one parent even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child.
		- The only other individual able to provide consent is a legal guardian of the patient. The status will be assessed within the patient’s chart to ensure legal guardianship.
		- Children will be required to provide assent if they are over the age of 8 years old and also intellectually capable.
			* When assent of children is obtained, they will provide their signature as well as the date and time beneath the consent line. The genetic counselor will go through the consent with the child as well and answer all questions prior to any procedures.
			* Assent will be required of all, some, or none of the subjects. If some, indicated, which subjects will be required to assent and which will not.
			* If assent will not be obtained from some or all subjects, an explanation of why not.
			* Describe whether assent of the subjects will be documented and the process to document assent. The IRB allows the person obtaining assent to document assent on the consent document and does not routinely require assent documents and does not routinely require subjects to sign assent documents.

# Process to Document Consent in Writing

* + Informed consent is a process that is initiated prior to the individual’s agreeing to participate in the study. It continues throughout the individual’s study participation. Consent and assent forms will be IRB-approved. The participant/LAR will be asked to read, review, and sign the consent document(s). Extensive discussion of risks and possible benefits of participation will be provided to the participants and their families/LAR in a language they understand. An IRB approved short form consent and a translator will be used when consenting participants who do not speak English. Illiterate subjects will have the consent form read to them aloud. Participant consent will then be documented by having participants make their “mark” on the consent document in the presence of a non-study team member witness to avoid any possible coercion. The investigator will explain the research study to the participant/LAR and answer any questions that may arise. All participants will receive a verbal lay consent.
	+ Written consent will be scanned into REDCap (alternatively a hard copy will be kept in a study binder for the duration of the study and standard period of time thereafter). Telephone and e-consent will be documented and stored within REDCap.

# Setting

* + Describe the sites or locations where your research team will conduct the research.
		- The study team will approach families during their regularly scheduled visits.
		- The consent process will take place within the private clinic room. The data collecting portion of the study will take place within the offices of the site-specific study teams.

# Resources Available

* + Describe the resources available to conduct the research: For example, as appropriate:
		- Justify the feasibility of recruiting the required number of suitable subjects within the agreed recruitment period. For example, how many potential subjects do you have access to? What percentage of those potential subjects do you need to recruit?
		- Collectively, identifiable genetic causes are high, with rates approaching 30-45% (Berg, JAMA Neurol, 2018; Sanchez-Fernandez, Neurol, 2019). However, there are >100 single gene causes, and dozens of copy number variants that are overrepresented in the epilepsy population. This has resulted in a phenomenon where many tertiary epilepsy centers have a sizeable population of subjects with a known genetic etiology, but the absolute number for any specific genetic etiology remains low except in the cases of the most common genetic disorders (e.g. tuberous sclerosis, SCN1A). Merging data from single centers to a collective database will enhance the ability to identify larger cohorts for rare disorders. A 5-year period with multi-center participation will yield sub-populations of various size. The common data elements in this database will allow for some initial characterizations, and the database also serves as a resource for identifying potential subjects for subsequent condition-specific studies and trials (separate recruitment and enrollment).
		- Due to most of the study-related process being conducted during a clinical interaction, we do not estimate the additional time to exceed 30 minutes.
		- The recruitment process will take place in the patient’s room during their visit to ensure privacy or via telephone.
		- We do not expect the study to require patients to need additional medical or psychological resources. Additionally, the genetic testing will occur regardless of participation, so all results will be disseminated to the appropriate people.
		- Prior to completing any study processes staff will be required to complete in-person training and acknowledge understanding by signing and dating a training and delegation log. If study processes change all staff will be updated and required to sign the training log again for the new information.

# Multi-Site Research\*

* + *Study-Wide Number of Subjects\**

*If this is a multicenter study, indicate the total number of subjects to be accrued across all sites.* The initial goal is to recruit 4000 subjects within the 10-year period. Because there are numerous genetic etiologies that are rare, there is no ceiling at which all study goals are necessarily accomplished as each novel case added is potentially meaningful.

* + Study-Wide Recruitment Methods\*
		- If this is a multicenter study and subjects will be recruited by methods not under the control of the local site (e.g., call centers, national advertisements) describe those methods.
			* Local recruitment methods are described later in the protocol.
		- Describe when, where, and how potential subjects will be recruited.
			* Recruitment sites include out-patient clinic or during an in-patient admission, at time of clinical care. A member of the study team will consent subjects about participation. This could be for a previously identified genetic variant, or at the time of consent for a new genetic test.
		- Describe the methods that will be used to identify potential subjects.
			* Chart review at point-of-care, or identification of potential subject by neurology provider at time genetic testing is recommended
		- Describe materials that will be used to recruit subjects. (Attach copies of these documents with the application. For advertisements, attach the final copy of printed advertisements. When advertisements are taped for broadcast, attach the final audio/video tape. You may submit the wording of the advertisement prior to taping to preclude re-taping because of inappropriate wording, provided the IRB reviews the final audio/video tape.)
			* N/A
		- If this is a multi-site study where you are the lead investigator, describe the processes to ensure communication among sites. See “WORKSHEET: Communication and Responsibilities (HRP-830).” All sites have the most current version of the protocol, consent document, and HIPAA authorization. All site PIs belong to PERC genetics working group and will be invited to participate in monthly conference calls for 2021, potentially spacing to bimonthly calls in 2022 and after.
		- All required approvals (initial, continuing review and modifications) will be obtained at each site (including approval by the site’s IRB of record).
		- All modifications will be communicated to sites, and approved (including approval by the site’s IRB of record) before the modification is implemented.
		- All engaged participating sites will safeguard data, including secure transmission of data, as required by local information security policies.
		- All local site investigators conduct the study in accordance with applicable federal regulations and local laws.
		- All non-compliance with the study protocol or applicable requirements will reported in accordance with local policy.
	+ Describe the method for communicating to engaged participating sites.
		- Problems (inclusive of reportable events). Any study problems will be communicated via monthly or bimonthly meetings of the site PIs, or via e-mail.
		- Interim results. Interim results will be communicated via monthly or bimonthly meetings of the site PIs, or via e-mail.
		- The closure of a study. Closure of the study will be determined by a meeting of the site PIs when adequate data has been obtained.
	+ If this is a multicenter study where you are a participating site/investigator, describe the local procedures for maintenance of confidentiality.
		- Where and how data or specimens will be stored locally? Chart review data and genetic testing results will be entered into a secure REDCap database, maintained at OHSU. Individual site study teams will have access to data acquired at their own site. Multi-site data will be accessed and queried by the study PI.
		- How long the data or specimens will be stored locally? Data will be stored in the REDCap database indefinitely.
		- Who will have access to the data or specimens locally? Study team members at individual sites will have access to their site data.
		- Who is responsible for receipt or transmission of the data or specimens locally? The study PI will be responsible for receipt of multi-site data. The site PIs will be responsible for local data.
		- How data and specimens will be transported locally? N/A

# ****27.0 Protected Health Information Recording****

1. **Indicate which subject identifiers will be recorded for this research.**

[x]  Name

[ ]  Complete Address

[ ]  Telephone or Fax Number

[ ]  Social Security Number (do not check if only used for ClinCard)

[x]  Dates (treatment dates, birth date, date of death)

[x]  Email address, IP address or URL

[x]  Medical Record Number or other account number

[ ]  Health Plan Beneficiary Identification Number

[ ]  Full face photographic images and/or any comparable images (x-rays)

[ ]  Account Numbers

[ ]  Certificate/License Numbers

[ ]  Vehicle Identifiers and Serial Numbers (e.g. VINs, License Plate Numbers)

[ ]  Device Identifiers and Serial Numbers

[ ]  Biometric identifiers, including finger and voice prints

[ ]  Other number, characteristic or code that could be used to identify an individual

[ ]  None (Complete De-identification Certification Form)

**2.0  Check the appropriate category and attach the required form\* on the Local Site Documents, #3. Other Documents, page of the application.  (Choose one.)**

[x]  Patient Authorization will be obtained. (Include the appropriate HIPAA language (see Section 14 of consent template) in the consent form OR attach the HRP-900, HIPAA AUTHORIZATION

form.)

[ ]  Protocol meets the criteria for waiver of authorization. (Attach the HRP-901, WAIVER OF HIPAA AUTHORIZATION REQUEST form.)

[x]  Protocol is using de-identified information. (Attach the HRP-902, DE-IDENTIFICATION CERTIFICATION form.) (Checked "None" in 1.0 above)

[ ]  Protocol involves research on decedents. (Attach the HRP-903, RESEARCH ON DECEDENTS REQUEST form.)

[ ]  Protocol is using a limited data set and data use agreement. (Contact the Office of Technology Commercialization to initiate a Limited Data Use Agreement.

**\*Find the HIPAA forms in the IRB Website Library, Templates.**

**Attach the appropriate HIPAA form on the “Local Site Documents, #3. Other Documents”, page of the application.**

1. **How long will identifying information on each participant be maintained?**

**Identifying information will be maintained by the site PI for 5 years beyond the end of the study protocol.**

1. **Describe any plans to code identifiable information collected about each participant.**
	1. **DOB will be entered and available by site PI, but this will only be viewable as age (to nearest month) in REDCap database to investigators from other sites**
	2. **MRN will be maintained in a separate, password-secured document by site PI and site study coordinators for correlation with unique study number.**
2. **Check each box that describes steps that will be taken to safeguard the confidentiality of information collected for this research:**

X **Research records will be stored in a locked cabinet in a secure location**

**X Research records will be stored in a password-protected computer file**

**X The list linking the assigned code number to the individual subject will be maintained separately from the other research data**

**X Only certified research personnel will be given access to identifiable subject information**

**6.0 Describe the provisions included in the protocol to protect the privacy interests of subjects, where "privacy interests" refer to the interest of individuals in being left alone, limiting access to them, and limiting access to their information. (This is not the same provision to maintain the confidentiality of data.)**

**Confidential Health Information**

1. **Please mark all categories that reflect the nature of health information to be accessed and used as part of this research.**

[x]  Demographics (age, gender, educational level)

[x]  Diagnosis

[x]  Laboratory reports

[x]  Radiology reports

[ ]  Discharge summaries

[x]  Procedures/Treatments received

[ ]  Dates related to course of treatment (admission, surgery, discharge)

[ ]  Billing information

[ ]  Names of drugs and/or devices used as part of treatment

[ ]  Location of treatment

[ ]  Name of treatment provider

[ ]  Surgical reports

[ ]  Other information related to course of treatment

[ ]  None

1. *Please discuss why it is necessary to access and review the health information noted in your response above.*

Site-specific identifiers, such as MRN, will not be included in the REDCap database, but will be available for the site PI and site study team. 2-point identification with MRN and DOB will be used to identify subjects who may be eligible for participation in additional, related gene-specific studies (for a separate consent process).

3.0 Is the health information to be accessed and reviewed the minimal necessary to achieve the goals of this research? [x]  Yes [ ]  No

4.0 Will it be necessary to record information of a sensitive nature? [x]  Yes [ ]  No

5.0 Do you plan to obtain a federally-issued Certificate of Confidentiality as a means of protecting the confidentiality of the information collected? [ ]  Yes [x]  No