# IRB Initial Application (Version 1.0)

## 1.0 General Information

***Please enter the full title of your study:**

Copy of Example IRB Application - Retrospective (chart review)

***Please enter the acronym or short title you would like to use to reference the study (not the IRB number):**

Example
* This field allows you to enter an abbreviated version of the Study Title to quickly identify this study.

## 2.0 Add Department(s)

**2.1 Select the clinical specialty(ies) associated with this study:**

| Primary Dept? | Department Name |
|---|---|
| ○ | **Beaumont Health System** - Administrative/non-clinical |
| ◉ | **Beaumont Health System** - Emergency Medicine |

## 3.0 Assign key study personnel(KSP) access to the study

**3.1 *Please add a Principal Investigator for the study:**

Tracy Wunderlich

**3.2 If applicable, please select the Research Staff personnel:**

A) Additional Investigators

Mecca, Lauren
Co-Investigator

B) Research Support Staff

Branoff-Wargo, Mara
Clinical Research Nurse Manager
Jankowski, Michelle
Biostatistician
Karabon, Patrick
Biostatistician
Wunderlich, Tracy
Other role - not employed by the Research Institute

**3.3 *Please add a Study Contact:**

Branoff-Wargo, Mara
Mecca, Lauren
Wunderlich, Tracy

The Study Contact(s) will receive all important system notifications along with the Principal Investigator. (e.g. The project contact(s) are typically either the Study Coordinator or the Principal Investigator themselves).

## 4.0 Study Information 1/21/19

**4.1 Form being completed by:**

Name:

Tracy Wunderlich

Title:

Medical Student

Department:

OUWB School of Medicine

Phone number:

2483703621

Email address:

wunderli@oakland.edu

**4.2 Describe the purpose of this application: If this is International Research select External IRB**

- (•) Entering a new study application for review by Beaumont Health IRB
- ( ) Entering a request to submit study to External IRB

**4.4 Is this a Nursing Evidence Based Project, Quality Project or Research (e.g., a nurse, Nurse Practitioner is the PI of the study)? All nursing Evidence Based Projects (EBP)/Quality Projects/Research must be approved by the Corporate Nursing Inquiry Evidence Based Practice, and Research Council prior to IRB submission.**

( ) Yes (•) No

**4.5 Is this project part of a training or educational requirement (i.e., degree requirement, residency, fellowship)?**

(•) Yes ( ) No

**4.6 Are there students, trainees, residents or fellows working on this study?**

(•) Yes ( ) No

**4.7 Complete the Educational Requirement Table below:**

If Yes, complete table below:

| Resident/Fellow /Student Name | Program | University (enter N/A for residents & fellows) | Describe the activities the individual will be participating in |
|---|---|---|---|
| Wunderlich, Tracy | ○ Residency<br>○ Fellowship<br>◉ Medical Student<br>○ Anesthesia<br>○ Nursing<br>○ Pharmacy<br>○ PT/OT/Rehab<br>○ Health Administration<br>○ Other | OUWB | Data collection, analysis and manuscript development. |

**4.8** **Is this an Embark project for the Oakland University William Beaumont School of Medicine?**

◉ Yes ○ No

Please include Tracy Wunderlich-Barillas, Michelle Jankowski and Patrick Karabon as Key Personnel for the study (see Section 3). You will also be required to submit Embark specific forms at the end of the application, just prior to submission.

**4.9** **Is a student, resident or fellow taking a lead role in the research (i.e. co-investigator)?**

◉ Yes ○ No

Who is the mentor?
**Mentor must be included as key personnel.**

Wunderlich, Tracy

## 5.0 Atypical Research

**5.1** **Does this application cover one of the types of atypical projects listed below? If so, select the type.**

◉ N/A - Does not apply to study
○ Single Time Emergency Use (differs for a compassionate use because of the emergency use of the test article)
○ Compassionate use/expanded access use for a single patient, intermediate group (more than one patient) or widespread expanded access use
○ Humanitarian Use Device
○ Administrative Pre-Grant Acknowledgment

## 6.0 Project Identification

**6.1** **Phase of study: (For chart review select N/A)**

◉ N/A
○ I/Pilot

- ○ I/II
- ○ II/Feasibility
- ○ II/III
- ○ III/Pivotal
- ○ IV/Post Market

**6.2 Did a Beaumont Investigator write or develop the protocol independent of a sponsor?**

- ◉ Yes
- ○ No

**6.3 Is your study funded, in part or wholly, by the National Institute of Health (includes any of the NIH agencies or by a federal sub-contract with a university, institution or organization)?**

**If you answer yes above, this means your study is federally funded requiring the COI training. If COI training is not completed for all Key Personnel listed on the study, there will be modifications to remove the individual without the required training.**

- ○ Yes ◉ No

**6.4 Location of Study** **For chart review studies, only check the location(s) where the research team is physically located collecting data (NOT where participants are located).**

- ☑ Beaumont - Royal Oak
- ☐ Beaumont - Troy
- ☐ Beaumont - Grosse Pointe
- ☐ Beaumont – Dearborn
- ☐ Beaumont - Farmington Hills
- ☐ Beaumont – Taylor
- ☐ Beaumont – Trenton
- ☐ Beaumont – Wayne
- ☐ Physician Offices
- ☐ Other

## 7.0 Determining Human Participant Research

**7.1 If you think your project is Evidence Based/Quality or you would like help in determining whether your project meets the definition of Human Participant Research? IF YOU ANSWER "NO", THE IRB APPLICATION WILL AUTOMATICALLY BRANCH TO RESEARCH. If you do NOT have experience with research or are unsure whether your project meets the regulatory determination of human participant research, select Yes.**

- ◉ Yes ○ No

## 8.0 Human Participant Research Determination

**Federal regulations and Beaumont Hospitals (BH) policies require IRB review of research involving human participants. Activities that meet the regulatory definitions of "research" and "human participants" constitute human participant research and require IRB approval and oversight.**

**8.1 45 CFR 46.102(e): Human subject - means a living individual about whom an investigator**

**(whether professional or student) conducting research: (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between researcher and subject. Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record information). Private information must be individually identifiable. *Individually identifiable* includes where the identity of the subject is or may be ascertained by the researcher or associated with the information. Use the definitions above to answer the following questions:**

**8.2** **Do the proposed activities include scholarly and journalistic activities (e.g., meta analysis of the current literature, single case report, journal club, oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected?**

○ Yes ◉ No

**8.3** **Do the proposed activities involve public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority? *Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters.***

○ Yes ◉ No

**8.4** **Do the proposed activities involve collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes?**

○ Yes ◉ No

**8.5** **Do the proposed activities include authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions?**

○ Yes ◉ No

**8.6** **Do the proposed activities involve a *systematic approach*?**

**45 CFR 46.102(d): Research** - a systematic investigation, including research development, testing and evaluation, designed
to develop or contribute to generalizable knowledge.

◉ Yes ○ No

**8.7** **Is the intent of the proposed activities to *develop or contribute to generalizable (scholarly) knowledge*?**

◉ Yes ○ No

**8.8 Do the activities involve obtaining information about *living individuals*?**

(●) Yes ( ) No

Do the activities involve face to face interaction with the individuals (i.e., prospective collection of data/specimens)?

( ) Yes (●) No

**8.9 Do the activities involve obtaining individually identifiable and private information about a living individual(s) or identifiable biospecimens from living individuals?**

(●) Yes ( ) No

## 9.0 Determining Level of Review Required

**9.1 Does this study involve greater than minimal risk?**

Minimal risk means the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

( ) Yes (●) No

**9.2 Does this project involve living individuals or data (e.g., surveys/questionnaires, information, data, specimens, images) from living individuals?**

(●) Yes ( ) No

**9.3 Will you be using Epic, a patient chart, patient list, another medical record or any other Protected Health Information (PHI) to identify your population? (i.e., screen for participants, identify the charts to review or data to be extracted)?**

(●) Yes ( ) No

**9.4 Indicate below which elements of PHI you will be keeping in your research data set: (PHI must include patient identifiers *and* health information. If your study does not involve patients, answer no to each element.)**

Names

(●) Yes ( ) No

Address (including all geographic subdivisions smaller than a state, including street address, city, county, precinct, zip code, and their equivalent geo-codes, except for the initial three digits of most zip codes)

( ) Yes (●) No

All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, and date of death. All ages over 89 and all elements of dates (including year) indicative of age over 89, except that ages over 89 may be aggregated into a single category of “age 90 or older”

(●) Yes ( ) No

Telephone number

( ) Yes (●) No

Fax number

○ Yes ◉ No

E-mail address

○ Yes ◉ No

Social security number

○ Yes ◉ No

Medical record number

◉ Yes ○ No

Health plan beneficiary number

○ Yes ◉ No

Account number

○ Yes ◉ No

Certificate/license number

○ Yes ◉ No

Vehicle serial number

○ Yes ◉ No

Universal Resource Locators (URLs)

○ Yes ◉ No

Device Identifiers and serial numbers

○ Yes ◉ No

Internet Protocol (IP) address numbers

○ Yes ◉ No

Biometric indicators such as fingerprints or voiceprints

○ Yes ◉ No

Full-face photographic images and any comparable images

○ Yes ◉ No

Any other uniquely identifying number, characteristic, or code

○ Yes ◉ No

**9.5 Will the research data collected and retained for this study include other identifying information? (This would include identifiable information that does not include Health Information. Examples include, but are not limited to, staff names, student education records subject to FERPA, physician NPI #'s or pager #' s, faculty email addresses).**

○ Yes ◉ No

**9.6 What type of data will be utilized in the study? Check all which apply.**

- [x] Existing Data (Retrospective)
- [ ] Prospective Collection of Data from Chart Review
- [ ] Data collected from a research intervention/manipulation of environment or other research activities
- [ ] Prospective Questionnaire or Survey
- [ ] Face to face interaction

## 10.0 Research Review Categories - Exempt

**10.1 Please answer the following questions to guide you in selecting the correct Research Review Category (select all that apply):**

**Exempt Category 1:** Will this research be conducted in established or commonly accepted educational settings that specifically involves normal educational practices? This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

○ Yes ◉ No

**Exempt Category 2:** Will this research include interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording)?

OHRP Guidance- interpretation of "public behavior" as being behavior generally open to view by any member of a community and/or which would not involve any special permission to observe (i.e., no reasonable expectation of privacy by those being observed), such as, at a park, in a mall, at a movie theater, etc. There are exceptions. Some classes might be conducted in a public space e.g. a biology class might be conducted in a public park. Or consider educational activities in public spaces such as museums or libraries. Or there may be activities in classrooms that are audio or video recorded and made available to anyone e.g. public courses. Although in each of those cases there might be some debate whether all the activities in the educational setting are public or only some subset. Participants in those examples would, I think, reasonably have different expectations of privacy than they would in a regular classroom in a school.

○ Yes ◉ No

**Exempt Category 3:** Does this study include only benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording with the subject's prospective agreement to the intervention and information collection?

For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

○ Yes ◉ No

**Exempt Category 4**: Does this study involve Secondary research for which consent is not required?

Secondary research is defined as using identifiable private information or identifiable biospecimens originally obtained (prospectively or retrospectively) for non-research purposes or for research other than the current proposal. **This is typically epic/chart/data review studies.**

◉ Yes ○ No

A - Are the identifiable private information or identifiable biospecimens publicly available?

○ Yes ◉ No

B - Will the Information, which may include information about biospecimens, be recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects?

(•) Yes ( ) No

C - Does the research involve only information collection and analysis involving the investigator's use of identifiable health information when the information was originally collected for ''health care operations'', ''research'' or ''public health activities and purposes'' as those terms are defined in the HIPAA regulations?

(•) Yes ( ) No

D - Is the research conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research activities, if the research generates identifiable private information that is or will be maintained on information technology subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.?

( ) Yes (•) No

**Exempt Category 5:** Is this study a research and demonstration project conducted conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs.

Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

(i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

( ) Yes (•) No

**Exempt Category 6:** Does the study involve taste and food quality evaluation and consumer acceptance studies?

(i) If wholesome foods without additives are consumed, or

(ii) If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

( ) Yes (•) No

## 11.0 Special Study Considerations

### 11.1 How will informed consent be obtained, if required?

- [ ] Full Informed Consent Document
- [ ] An Information Sheet - a Waiver of Consent Documentation is being requested (Full consent is given, but there is NO signature)
- [ ] A Survey/Questionnaire - a Waiver of Consent Documentation is being requested (Full consent, verbal or implied, is given but there is NO signature)
- [ ] A phone script - a Waiver of Consent Documentation is being requested (Verbal consent is given but there is NO signature)
- [x]

Study involves chart review or other activities that meet regulatory criteria for waiving the requirements to obtain informed consent – a Waiver of Consent is being requested

If using a consent, information sheet, telephone script, etc. you will be required to attach these forms at the end of the application, just prior to submission.

**11.3** **Does either the clinical trial agreement or protocol require full compliance with International Conference on Harmonization (ICH) Good Clinical Practices (GCP) guidance?**

**You will be required to upload a CV for each key personnel listed on the study.**

- ○ Yes
- ◉ No

**11.4** **If this study is a multi-center trial will the Beaumont PI serve as the Lead Researcher?**

***Lead or Coordinating Investigator*: A principal investigator assigned the responsibility for the coordination of investigators at different centers participating in a multicenter study [Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance (GCP E6) 1.19]. The responsibilities of the coordinating investigator(s) vary depending upon the requirements of the study. This includes all Sponsor Investigators with multi-center studies:**
***Sponsor-Investigator:* An individual (usually the study Principal Investigator) who both initiates and conducts a clinical investigation, and under whose immediate direction the investigational product is administered or dispensed. The requirements applicable to a sponsor-investigator mean that sponsor investigators must follow the regulations for both an investigator and a sponsor.**

- ○ Yes
- ◉ No

**11.5** **Is this study involved in any way with the Department of Defense (DOD)?**

**Examples could include DOD funding, use of DOD property, facilities or assets, collaborations with a component of the DOD or intentionally including military personnel?**

- ○ Yes ◉ No

## 12.0 Study Overview/Inclusion/Exclusion Criteria

**12.1** **All summaries must be written in language understandable to a non-medical person. The summary is intended for use by the IRB, lay members in particular. Avoid the use of technical language or medical terminology. If such language is required, the lay definition should immediately follow in parenthesis. Please address each of the following areas in a concise summary format. For investigator-initiated studies, the study Protocol must be a separate document. Note: *This application may be delayed or deferred if the Study Overview is incomplete, and/or the narrative description is not concise or readily understandable to the lay reader. Deferment by the IRB may cause a one-month or more delay in the review process.***

**12.2** **Describe study rationale, background and why you are conducting the study in lay terms. Include the following:**

- **Current or previously tried treatments to include rationale why this new treatment would be advantageous**
- **Background literature for treatment of this disease**
- **Include human and/or most relevant animal data**

**Do not cut and paste**

Please copy and paste background from your approved Capstone proposal. Citations should be included (bottom of the text box).

**12.3 Describe the disease process under study in lay terms. Include the following:**

- **Information on symptoms**
- **General disease progression**
- **Any severe complications from disease progression**

**For studies looking at behaviors or educational practices, describe current practice, why this study is looking at those practices.**

You can also cut and paste this information from your proposal. Include citations if appropriate.

**12.4 What is your primary research question (primary objective)? Objectives and/or Endpoints - Research objectives both general and specific (i.e., goal of study)**

1. **Primary (or general) objectives : Specify the type of knowledge the study is expected to obtain. Clearly state what is to be described, determined, identified, or compared?**
2. **Secondary (or specific) objectives : These break into component parts and flow from the primary objectives, and are an introductory view of the research design**

Please list your objectives here - fine to cut and paste from your approved Capstone proposal.

**12.5 What other questions is your research designed to answer (most relevant/important secondary objectives)?**

is this now required? ask richard

**12.6 List inclusion criteria: May be copied and pasted from the protocol**

Examples of inclusion criteria: Age range, dx info, inpatient Beaumont RO, women aged 18 and above

**12.7 List exclusion criteria: May be copied and pasted from the protocol.**

reverse of inclusion

**12.8 Describe study methodology in lay terms. If the study is analyzing two groups or populations (i.e. retrospective data collection and a second population of participants being surveyed after the research activity), describe the methodology to be used for each group or population. Do not cut and paste**

Please walk the reviewer through each step of your project here, from start to finish. It's fine to copy and paste from your approved Capstone proposal. This section should be concise and very detailed. For any chart review, you must describe how you are obtaining a list of eligible participants. Will this be taken from an existing departmental database or is this something you need help with from the Beaumont programmer. If the latter is the case, please indicate that Shirley Qu, from the Beaumont Research Institute, will be pulling a list of eligible participants.

## 13.0 Chart Review/Data Extraction

**13.1 How many participants/specimens/charts will be enrolled or included in the study?**

- (•) 1-1000
- ( ) 1001-5000
- ( ) 5001 and above

## 14.0 Research Population

**14.1 Describe your participant population by age and gender: (e.g., female over 50 years of age):**

Males or Females (Check all which apply)

- [ ] Male
- [x] Female

Age Range (Check all which apply)

- [ ] Neonates (0-30 days)
- [ ] Children <18 years of age
- [x] 18 and above
- [ ] Other specific age range - Explain below (i.e., breast cancer in pre-menopausal women in study population age 18-50)

Provide justification for age ranges selected:

Disease does not typically affect those under 18.

**14.2 Will study participants be excluded, other than minors, because of gender, race, age or ethnic background?**

- (•) Yes
- ( ) No

Provide justification:

Breast cancer typically affects females more than males.

**14.3 How will participants/specimens/charts be recruited or identified?**

- [x] Medical records
- [ ] Clinical Research Database (CRDB)
- [ ] Research Databases (other than CRDB)
- [ ] Other recorded information sources
- [ ] Direct person to person solicitation
- [ ] Advertisement/ Notice / Flyer
- [ ] Referral from other healthcare provider or support staff (e.g., physician office, laboratory)
- [ ] Other (specify):

**14.4 What methods will be utilized to ensure only the intended populations are enrolled? It is important to have a method to confirm participants meet all inclusion criteria and none of the exclusion criteria. A screening checklist is highly recommended for studies with an intervention with a participant. Verification of participant eligibility will be reviewed as part of any audit of the study. A chart review study typically selects OTHER.**

*Check all that apply*

- [ ] Screening/Eligibility Checklist
- [x] Other - Describe tool or method to assure that participants meet inclusion/exclusion criteria

If Other, explain:

Dr. Soandso has a list of patients who meet eligibility criteria. This list will be used to pull additional information from EPIC, as outlined in the variable list.

## 15.0 Vulnerable Participant Populations

### 15.1 Will Children (< 18 years of age) be enrolled/eligible to participate?

- (•) Excluded from study
- ( ) May be incidentally enrolled
- ( ) Targeted population

If excluded from study, provide the rationale:

- (•) This disease/illness does not typically affect children.
- ( ) Other

### 15.2 Will Pregnant Woman, Fetuses & Neonates be enrolled/eligible to participate?

- ( ) Excluded from study
- (•) May be incidentally enrolled
- ( ) Targeted Population
- ( ) This is a chart review/survey with incidental inclusion of this population

### 15.3 Will Economically or Educationally Disadvantaged individuals be enrolled/eligible to participate?

- ( ) Excluded from study
- ( ) May be incidentally enrolled
- ( ) Targeted Population
- ( ) This study is not collecting data on the economic or educational status of the participants
- (•) This is a chart review with incidental inclusion of this population

### 15.4 Will Students/Trainees/Staff be enrolled/eligible to participate?

- ( ) Excluded from study
- ( ) May be incidentally included
- ( ) Targeted Population
- ( ) The study is not collecting data related to students/trainees/staff or education of the participants
- (•) This is a chart review with incidental inclusion of this population

### 15.5 Will Decisionally Impaired individuals be enrolled/eligible to participate?

**Decisionally Impaired is defined as: Having a psychiatric disorder (e.g., psychosis, neurosis, personality or behavior disorder), an organic brain syndrome (e.g., stroke, dementia), a developmental disability (e.g., Down syndrome, autism), or a catastrophic event that affects cognitive functioning (e.g., traumatic brain injury, coma) to the extent capacity for judgment and reasoning is temporarily or permanently diminished. Persons under the influence or dependent on drugs or alcohol, those suffering from degenerative diseases affecting the brain, or terminally or critically ill patients, may also be defined as decisionally impaired as their ability to make informed decisions may be affected.** ***It is not permissible to exclude eligible participants on the basis of their cognitive abilities. The IRB may allow exclusion if there are complicated questionnaires.***

- ( ) Excluded from study

- ○ May be incidentally included
- ○ Targeted Population
- ○ Study not collecting information on cognitive status
- ◉ This is a chart review with incidental inclusion of this population

## 16.0 Data Collection & Storage, Research Records, Confidentiality and Privacy

**16.1 Describe how research participants/specimens/data will be identified in research documents: (e.g., case report forms, data collection forms, questionnaires, adverse event/Unanticipated Problem reports)** ***Check all which apply***

- ☐ Name
- ☑ Medical record number
- ☑ Unique code/study ID
- ☐ Patient/Participant initials
- ☑ Other - Explain below:

A linking key will be created to provide extra security.

**16.3 The Institutional Review Board, Food and Drug Administration (FDA), Office for Human Research Protections (OHRP), Office of Civil Rights (OCR) and/or the study sponsor has the authority to access study data. Who other than those listed above and study key personnel will have access to the research data?** ***Check all that apply***

- ☑ None
- ☐ Funding Agency
- ☐ External IRB
- ☐ Cooperative Group
- ☐ External Collaborators
- ☐ Other- Explain below:

**16.4** ***Confidentiality = refers to agreement between the investigator and participant in how data will be managed. Privacy = refers to persons and their interest in controlling the access of others to their information.*** **Describe how electronic data will be stored to minimize risk, preserve confidentiality of the research information collected and protect the privacy of participants:** ***Check all which apply***

**Residents, Fellows & ALL Students & are required to store their data in SharePointe ONLY**

On a password protected desktop computer

○ Yes ◉ No

On a network server (Check NO if you are storing data in SharePoint)

○ Yes ◉ No

On an encrypted laptop (Check NO if you are storing data in SharePoint)

○ Yes ◉ No

In REDCap
If your PI/department would like to use REDCap for an upcoming research project, please contact **donna.mcintyre@beaumont.org** or **brenda.stellard@beaumont.org** for the appropriate form.

○ Yes ◉ No

Beaumont SharePointe site

Upon IRB approval, contact Derrick Dugeon (248) 551-3327 or Andrea Klaver (248) 551-8252 to request a SharePoint folder for your study

(●) Yes ( ) No

Other electronic storage explain below:

( ) Yes (●) No

**16.5 Describe where hard copy data (i.e. source document, consent form, checklists, data collection forms) will be stored to minimize risk, preserve confidentiality of the research information collected and protect the privacy of participants:**

This study involves no hard copy data.

**16.6 *BH requires investigators to maintain research records, for approved human participants' protocols, in accordance with all federal and institutional requirements, including but not limited to the HIPPA Privacy Rule, the Food and Drug Act and Medicare policy. The stored data must be kept in a secure, protected manner.* After the study is closed will the hard copies of the study records be stored in an off-site storage facility as designated by Beaumont Health System?**

(●) Yes ( ) No

**16.7 Do you agree that your data will be stored at Beaumont for a minimum of 11 years per HIPAA regulations and for studies enrolling pediatric patients study records are required to be retained until the last participant turns 21 years of age? If the study is sponsored, the Sponsor's approval is required prior to destruction of the records.**

(●) Yes ( ) No

## 17.0 Funding

**Hospital policy requires all funds designated to support research utilizing Beaumont services or facilities, name or logo or includes patients identified through Beaumont, be forwarded to and disbursed by the Research Institute.**

**17.1 Funding Source:**

| Funding type | Name of funding source or N/A | Funding Status |
|---|---|---|
| Enter all sources of funding.<br>No Funding | N/A | (●) N/A - No Funding<br>( ) Approved<br>( ) Pending (study may not begin until funding is confirmed) |

**17.2 Will research participants receive any reimbursement or compensation for participating in this study (money, gifts, vouchers, etc.)? Include cost information in the Informed Consent and Authorization Document.**

( ) Yes (●) No

## 18.0 Research Waiver of Authorization

**18.1** **HIPAA Requirements to Review Patient Data without Patient Consent The Department of Health and Human Services (HHS) and the Food and Drug Administration (FDA) have made provisions to the Health Insurance Portability and Accountability Act (HIPAA) that establishes the conditions under which protected health information (PHI) may be used. This form is required to protect patient confidentiality rights when there is a need to view patient information via charts, computer databases or other recorded information sources when recruiting/screening/locating potential participants.**

**18.2** **Describe your plan to protect the identifier from improper use and disclosure:**

- [ ] NA - No identifiers
- [ ] Password protected computer/network
- [ ] REDCap Database
- [ ] Secured/locked department office
- [x] SharePointe
- [ ] Sponsor Database
- [ ] Other- Describe:

**18.3** **Who will have access to patient identifiers?**

Check all that apply:

- [ ] NA - No identifiers
- [x] Key Personnel listed on study roster
- [ ] Sponsor
- [ ] Federal Agencies
- [ ] Other

**18.4** **Describing your plan to destroy the identifier at the earliest opportunity. All lists generated with patient identifiers, (e.g. name, medical record number) used to locate potential participants, must be destroyed.**

Describe plan to destroy list with patient identifiers. Check all that apply:

- [ ] NA - No identifiers
- [ ] Shredding of paper documents
- [x] Deletion of electronic data
- [ ] N/A - Identifiers will not be destroyed as required by law (Describe law/regulation restricting destruction of identifiers in box below)
- [ ] N/A - Identifiers will not be destroyed due to health or research reasons (Describe your justification in box below)

**18.5** **The list of identifiers will be destroyed:**

Check all that apply:

- [ ] NA - No identifiers
- [x] Upon manuscript publication
- [x] Study completion
- [ ] At the determination of the sponsor/investigator
- [ ] At the time of consent
- [ ] When deemed ineligible
- [ ] Upon declining participation
- [ ] N/A - Identifiers will not be destroyed (see above justification)

**18.6**

**Could this research practicably be conducted without this waiver of authorization?**

○ Yes ◉ No

If no, why not?

As this research consists of retrospective records review, it would not be feasible nor practical to contact participants for their consent.

**18.7**

**Could this research practicably be conducted without access to and use of Protected Health Information?**

○ Yes ◉ No

If no, why not?

In order to ensure accuracy of data collected, it is necessary to retrieve name and MRN from EPIC.