Initial Application (Version 1.0)

1.0 General Information

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

Sample Retrospective Study IRB Application

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

IRB Application
* 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** - OUWB Student
○	**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:

PI Name (typically this is the mentor)

3.2 If applicable, please select the Research Staff personnel:

A) Additional Investigators

Medical Student Name
Co-Investigator

B) Research Support Staff

Jankowski, Michelle
Biostatistician
Karabon, Patrick Joseph
Biostatistician
Wunderlich, Tracy
Other role - not employed by the Research Institute

3.3 *Please add a Study Contact:

Medical Student Name

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

4.1 Form being completed by:

Name:

Student Name

Title:

Medical Student

Department:

OUWB

Phone number:

123-456-7890

Email address:

student@oakland.edu

4.2 Describe the purpose of this application:

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

4.3 If an external IRB is being requested select which IRB below:

4.4 Is this Nursing Research (e.g., a nurse is the PI of the study)?

All nursing research must be approved by the Corporate Nursing Administration 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

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
- ( ) Humanitarian Use Device
- ( ) Beaumont Research Coordinating Center - To be selected only by BRCC staff.
- ( ) Administrative Pre-Grant Acknowledgment

6.0 Identification of Students, Residents and Fellows

6.1 Complete the Educational Requirement Table below:

If Yes, complete table below:

Student/Trainee Name	Program	University (enter N/A for residents & fellows)	If student, describe the activities the student will be participating in
Medical Student Name	( ) Residency ( ) Fellowship (•) Medical Student ( ) Anesthesia ( ) Nursing ( ) Pharmacy ( ) PT/OT/Rehab ( ) Health Administration ( ) Other	OUWB	Study design, data collection/cleaning, and manuscript preparation.

6.2 Is this an Embark/Capstone project for the Oakland University William Beaumont School of Medicine? If yes, please include Tracy Wunderlich, Michelle Jankowski and Patrick Karabon as Key Personnel for the study (see Section 3).

(•) Yes ( ) No

If Yes, you will be required to submit Embark/Capstone specific forms at the end of the application, just prior to submission.

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

(•) Yes ( ) No

If Yes, who is the mentor?
Mentor must be included as key personnel.

PI Name

7.0 Project Identification

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

(•) N/A

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

7.2 Did a Beaumont Investigator write or develop the protocol?

- ◉ Yes
- ○ No

If Sponsor, provide name:
Only provide Sponsor name if they are overseeing the entire project. List a company's name in the Funding section if they are only providing financial resources.

Provide the Protocol number:

7.3 Location of Study
Check all that apply.

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

If Physician Offices provide name and address where research will be performed:

- ☐ Other

Provide name and address of Other non-Beaumont hospital local facilities where research will be performed:

8.0 Determining Human Participant Research

8.1 If you do NOT have experience with research or know if your project meets the regulatory determination of human participant research and require assistance, select Yes.
If either situation applies, please check "Yes".

- ◉ Yes ○ No

9.0 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" <u>and</u> "human participants" constitute human participant research and require IRB approval and oversight.

9.1 <u>45 CFR 46.102(f):</u>

Human subject - a *living individual* about whom an investigator (whether faculty, student, or staff) conducting research obtains: (1) data through *intervention or interaction* with the individual or (2) *identifiable private information*.

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:

9.2 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

If no, explain why the proposed activities do not involve a systematic approach:

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

(•) Yes ( ) No

If No, explain the intent of proposed activities and explain how the proposed activities are not intended to contribute to generalizable knowledge:

10.0 Determination of Human Subject

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

(•) Yes ( ) No

If Yes, do the activities involve intervention or interaction with the individuals (i.e., prospective collection of data/specimens)?

( ) Yes (•) No

10.2 Do the activities involve obtaining *individually identifiable* and *private* information about living individuals?

(•) Yes ( ) No

11.0 Yes - Human Participation Research

11.1 Based on your responses the activities constitute human participant research. Please use the Save and Continue button to complete your IRB application.

12.0 Determining Level of Review Required

12.1 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

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

(•) Yes ( ) No

12.3 Will the study be collecting/storing any identifiers (list of identifiers noted below)?

Please be reminded that if you choose "No" and will NOT keep linking identifiers you will NOT be able to go back to access/review any past data collection variables. (Example: If you were to publish and additional questions were raised you would NOT be able to go back to access/review any past data collection variables to answer or confirm the proposed question.)

(•) Yes ( ) No

- Names
- 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)
- 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"
- Telephone number
- Fax number
- E-mail address
- Social security number
- Medical record number
- Health plan beneficiary number
- Account number
- Certificate/license number
- Vehicle serial number
- Universal Resource Locators (URLs)
- Device Identifiers and serial numbers
- Internet Protocol (IP) address numbers
- Biometric indicators such as fingerprints or voiceprints
- Full-face photographic images and any comparable images
- Any other uniquely identifying number, characteristic, or code.

12.4 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 or Research Activities
- [ ] Prospective Questionnaire or Survey

13.0 Expedited Review Category

13.1 Answer the following questions on Expedited Research categories:

Category 1: Does the study involve the use of drug(s) and/or medical device(s) that do not involve an IND or IDE and are minimal risk?

○ Yes ◉ No

Category 2: Does the study involve the collection of blood samples by finger stick, heel stick, ear stick, or venipuncture from 1) healthy, non-pregnant adults. May not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or 2) other adults and children the amount drawn may not exceed the lesser of 50mL or 3mL per kg in an 8-week period and collection may not occur more frequently than 2 times per week?

○ Yes ◉ No

Category 3: Does the study involve prospective collection of biological specimens for research purposes by non-invasive means?

○ Yes ◉ No

Category 4: Does the study involve the collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves?

○ Yes ◉ No

Category 5: Does the study involve materials (data, documents, records, or specimens) which have been collected or will be collected solely for non-research purposes?

◉ Yes ○ No

Category 6: Does the study involve the collection of data from voice, video, digital, or image recordings made for research purposes?

○ Yes ◉ No

Category 7: Does the study involve research on an individual or group characteristics or behavior or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies?

○ Yes ◉ No

13.2 Is a waiver of consent being requested? This is required if you are accessing medical records for screening or if you do NOT plan to obtain consent from each individual (i.e. chart review, database analysis).

◉ Yes ○ No

14.0 Expedited Review- Waiver of Consent

If your project is a chart review or large data base, a waiver of consent is typically requested. A verbal consent using an Informaiton Sheet does NOT apply

14.1 Will the waiver "adversely affect the rights and welfare (impossible to maintain confidentiality)" of the research participants?

○ Yes ◉ No

14.2 Can the research be practicably carried out without the waiver?

○ Yes ◉ No

14.3 Will the participants be provided with additional pertinent information after participation?

○ Yes
○ No
◉ N/A - Does not apply to study

14.4 Will screening of available records take place to determine initial eligibility of a patient?

◉ Yes ○ No

If No, explain:

14.5 Provide protocol-specific justification for requesting a waiver of consent.

As this study is retrospective, it would not be feasible or practical to contact participants.

15.0 Special Study Considerations

15.1 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 - 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)
☑ 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.

15.2 Please list the study verbal or written consent providers name & credentials below (enter N/A if not applicable to study):

N/A

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

○ Yes
○ No

◉ N/A - Does not have a clinical trial agreement or protocol

15.4 If this study is a multi-center trial will the Beaumont PI serve as the Lead Researcher? (If this is a multi-cenered trial, the PI developed the protocol or holds the IND or is managing the multi-site activities, answer "Yes")

○ Yes
○ No
◉ N/A - not a multi-center trial

15.5 Will Beaumont serve as the coordinating center for this study?

The Beaumont Research Coordinating Center will submit an application separately for approval of their participation.

○ Yes ◉ No

15.6 Will the study require collection of Social Security Numbers?

○ Yes ◉ No

15.7 Department of Defense Research

Is the research funded by a component of the DoD (e.g. a grant from the Office of Naval Research)?

○ Yes ◉ No

Does the research involve cooperation, collaboration, or other type of agreement with a component of the DoD (e.g., an Army Medical Laboratory will conduct malaria antigen detection tests for study)?

○ Yes ◉ No

Does the research use property, facilities, or assets of a component of the DoD?

○ Yes ◉ No

Does the participant population intentionally include personnel (military and/or civilian) from a component of the DoD?

○ Yes ◉ No

16.0 Study Overview/Inclusion/Exclusion Criteria

16.1 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.*

16.2 How long do you estimate the study will take you to conduct the research activity? (number of days / weeks / months / years):

3 years

For retrospective data collection (collecting data which exist today, e.g. chart review), provide the timeframe of the data to be reviewed; for strictly prospective data collection (looking at future data) indicate **N/A**.

01/01/2014 - 12/31/2017

16.3 Describe study rationale or background in lay terms:
Do not cut and paste

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

- Information on symptoms
- General disease progression
- Standard of care treatment
- Any severe complications from disease progression for this study
- Current or previously tried treatments to include rationale why this new treatment would be advantageous
- Background literature for treatment of this disease

This section can be copied from your proposal. It should be approximately 2 - 3 paragraphs and citations are not necessary.

16.4 Describe study objectives and/or endpoints:

This information may be copied and pasted from the protocol. List all primary objectives and only the most relevant/important secondary objectives (< 10):

This information can be copied directly from your proposal and should state the aims of your study - approximate 2/3 is usually recommended.

16.5 Describe study methodology in lay terms. Describe your study design including population, data collection screening, what happens at study visits. If this is a chart review describe where you will get your data and if the data is standard of care data collection-meaning no research manipulation will happen to gather the data i.e. CXR in 6 months whihc is Standard of Care.
Do not cut and paste

In this section, you will want to walk the reviewer through your project step-by-step. Here's an example for a retrospective chart review:

This project will be a retrospective chohort study utilizing medical data from the Beaumont electronic medical record system (EPIC). Patients who have undergone x surgery between January 1, 2014 and 12 /31/2017 will be included in this study. A list of medical record numbers for all individuals meeting the inclusion criteria will be generated with the assitance of a programmer (or in some cases, there is already an existing departmental database that contains this information). The name of this individual is Suzie Spade. After the list of medical record numbers is generated, medical charts for all eligible participants will be accessed and will involve the collection of the following variables: age, sex, race, date of surgery, etc. All data will be entered into a database and stored securely on Sharepoint.

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

Individuals who are 18 and over, male or female and have undergone x surgery at Beaumont Health within 1/1/2014 and 12/31/2017.

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

Individuals under the age of 18 who have not had x surgery at Beaumont.

16.8 What method of screening will be utilized to protect the rights and welfare of the research participants 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. Verification of participant eligibility will be reviewed as part of any audit of the study.

Check all that apply

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

If Other, explain:

Example: All eligible individuals will be identified with the assistance of a programmer.

16.9 Statistical Data Analysis:
If Investigator-Initiated Research: Research Institute Biostatisticians are available for all projects (Expedited or Full Board) to assist with the statistical analysis and sample size calculation if requested. Investigator-initiated projects with greater than minimal risk are encouraged to contact biostatistics (email to biostat@beaumont.org) for a statistical review before submission; other investigator-initiated projects are also welcome to request a review before submission through an e-mail to biostat@beaumont.org. A job-request form is available on the Research Institute webpage.

Provide a detailed description of the sample size calculation, including assumptions and the citations for any prior data used as basis of calculation:

Please meet with the biostatisticians for this information.

Provide data analysis plan, including how you will address your primary objective:

Please meet with the biostatisticians for this information.

17.0 Research Participant Enrollment and Participation

17.1 Duration of participation for individual participant (number of hours / days / weeks / months / years):
Indicate N/A for chart review, specimen use or data collection studies.

- (•) N/A - Chart review/specimen use or data collection study

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

Total number at all sites:

500.00

Total number at this site:

500

17.3 How many participants do you expect to consent to reach the enrollment goals (include screen failures)? Allow for participants who will NOT meet the final inclusion/exclusion criteria.

- (•) N/A - Chart review/specimen use or data collection study

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

Males or Females (Check all which apply)

- [x] Male
- [x] Female

List the age range:

18 and over

17.5 Will screening for potential study participants include the use of medical records, computer databases or other recorded information sources?

- (•) Yes
- ( ) No

17.6 How will participants/specimens/charts be recruited or identified?

Check all which apply:

- [ ] Direct person to person solicitation
- [x] Medical record / One Chart Review / Computer databases
- [ ] Advertisement/ Notice / Flyer
- [ ] Referral from other healthcare provider or support staff (e.g., physician office, laboratory)
- [ ] Other (specify):

18.0 Vulnerable Participant Populations

18.1 Will Children (< 18 years of age) be included/eligible to participate?

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

If excluded from study, provide the rationale:

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

18.2 Will Pregnant Women, Fetuses & Neonates be included/eligible to participate?

- ( ) Excluded from study
- (•) May be incidentally included

- ○ Targeted Population

If excluded from study, provide the rationale:

- ○ The effect of the study drug/device on pregnant women, fetuses and neonates is unknown at this time.
- ○ Other-Explain below

18.3 Will Economically or Educationally Disadvantaged individuals be included/eligible to participate?

- ○ Excluded from study
- ◉ May be incidentally included
- ○ Targeted Population

If may be incidentally included and/or targeted population, describe *additional* measures which will be taken to minimize risks which may uniquely affect the Economically /Educationally Disadvantaged (vulnerable participants) being included/recruited:

- ○ Any incentives offered for study participation will be within the guidelines set forth by the HIC.
- ◉ Other - Explain:

This is a chart review with incidental inclusion of this population.

If excluded from study, provide the rationale:
Examples of rationale for exclusion:
The study is NOT collecting data on the economic or educatinal status of the participants. OR
This is a chart review with incidental incusion of this population.

18.4 Will Students/Trainees/Staff be included/eligible to participate?

- ○ Excluded from study
- ◉ May be incidentally included
- ○ Targeted Population

If may be incidentally included and/or targeted population, describe additional measures which will be taken to minimize risks which may uniquely affect Students/Trainees/Staff (vulnerable participants) being included/recruited:

- ○ Students, trainees or staff will not be recruited or consented by a supervisor or individual who may have influence over their decision to participate.
- ◉ Other - Explain:

This study is not collecting data on students/trainees/staff or education of the participants.

If excluded from study, provide the rationale:
Acceptable answers are:
-No information regarding the students/trainees/staff or educational status will be noted.
-Any potential data from this population will be treated the same as all other patients data.
-The study is not collectiong data on students/trainees/staff or education of the participants.

18.5 Will Cognitively Impaired or Mentally Disabled individuals be included/eligible to participate?

Cognitively 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 cognitively impaired as their ability to make informed decisions may be affected. ***It is not permissible to exclude eligible participants on the basis of the cognitive abilities. The IRB may allow exclusion if there are complicated questionnaires.***

- ○ Excluded from study
- ◉ May be incidentally included
- ○ Targeted Population

If excluded from study, provide the rationale:

- ○ Study requirements (i.e., subjective questionnaires, lengthy assessments are considered beyond the scope of the participant/LAR).
- ○ Other - Explain:

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

○ Yes ◉ No

If Yes, provide justification:

19.0 Risks of Research Expedited Review

19.1 Provide the nature and degree of risk to the participant related to this research?

- ☑ Breach of confidentiality
- ☐ Other:

Explain:

19.2 In order to protect the rights and welfare of the research participants, what measures will be taken to minimize the risks listed above.

If you will require a SharePoint folder, upon IRB approval, please send Derrick Dugeon at Derrick.Dugeon@beaumont.org or Brandon Holbert at Brandon.Holbert@beaumont.org an email with the approval letter and list of the study Key Personnel who will require access to the SharePont folder. It would be helpful to have the IRB number in your email upon your request.

- ☑ Secure SharePointe site
- ☐ Password protected computer
- ☐ Encrypted flash drive
- ☐ Secured/locked department office
- ☐ Other:

20.0

Data Collection & Storage, Research Records, Confidentiality and Privacy

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

Check all which apply

- [x] Name
- [x] Medical record number
- [x] Unique code/study ID
- [ ] Patient/Participant initials
- [ ] Other - Explain below:

20.2 What direct participant identifiers will be shared with the study sponsor/outside of Beaumont?

- (•) N/A - Investigator Initiated Research with no Sponsor

20.3 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 personnel will have access to the research data?
Check all that apply

- [x] None
- [ ] Funding Agency
- [ ] National Cancer Institute (NCI)
- [ ] Cooperative Group
- [ ] External Collaborators
- [ ] Other- Explain below:

20.4 ***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, Medical Students & Fellows are required to store their data in SharePointe ONLY

On a desktop PC (Check NO if you are storing data in SharePoint)

( ) 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

On 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. Enter "11111" in the next box to proceed through the IRB application.

○ Yes ◉ No

Beaumont Property Tag Number

Beaumont SharePointe site
Upon IRB approval, contact Derrick Dugeon (248) 551-3327 or Brandon Holbert (248) 551-1480 to request a SharePoint folder for your study

◉ Yes ○ No

Other electronic storage

○ Yes ◉ No

Provide details

20.5 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:

No hard copy data will be collected.

20.6 ***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

If No, explain:

20.7 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

If No, explain:

21.0 Data Collection Tool

21.1 Are you using a collection tool (e.g. survey, RedCap, spreadsheet, word document listing variables to be collected)?

◉ Yes ○ No

If No, explain:

If Yes, you will be required to upload your survey tool or include a Word document with the variables you will be collecting at the end of the application, just prior to submission.

22.0 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.

22.1 Funding Source:

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

22.2 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

23.0 Research Waiver of Authorization

23.1 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.

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

- [ ] NA Exempt study no identifiers
- [ ] Password protected computer
- [ ] Iron Key Encrypted flash drive
- [ ] Secured/locked department office
- [x] SharePointe
- [ ] Other- Describe:

23.3 Who will have access to patient identifiers?

Check all that apply:

- [ ] N/A Exempt study no identifiers
- [x] Key Personnel listed on study roster
- [ ] Sponsor

- [ ] Federal Agencies
- [ ] Other

23.4 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 - Exempt Study No Identifiers
- [ ] Shredding of paper documents
- [x] Deletion of electronic data

23.5 The list of identifiers will be destroyed:

Check all that apply:

- [ ] NA - Exempt study no identifiers
- [x] Upon manuscript acceptance
- [x] Study completion
- [ ] At the determination of the sponsor
- [ ] At the time of consent
- [ ] When deemed ineligible
- [ ] Upon declining participation