To submit a new IRB application at Beaumont (expedited – chart review):

- Log on to: https://hic.beaumont.edu/
- Under "Study Assistant," click "Add a New Study"

1.0 - Enter project title and short title (required)

2.0 – You should already be assigned to a department but if you're not, you'll need to add this information here.

3.1 & 3.2 – List the PI, additional investigators and other research personnel. To do this, you'll need to click on the green + tab that says "add user." When this opens, please search in either the IRIS or LDAP databases. Check the box on the left and click "save and continue." Use this same process for all study personnel. **Please check with your mentor to determine your role (usually students are listed as Co-PI).

❖ Under "research personnel," you MUST add the following individuals as they will have access to your folder on the Sharepoint server (drop down list - "other - not Beaumont employee" and for Ms. Jankowski ("biostatistician"):

- Jean Szura
- Rose Wedemeyer
- Tracy Wunderlich
- Michelle Jankowski

3.3– Project contact – please add yourself as well as your assigned Capstone director (Tracy, Jean or Rose). If you're not sure who this individual is, please contact the course director.

4.1 - Please enter your information - title "Medical Student," department should be "OUWB School of Medicine"

4.2 – Type of application – click on "entering a new study application"

4.3 - Typically should be "none"

4.4 - Nursing research - "no"

4.5 - Part of an education requirement - "yes"

4.6 - Students or trainees working on the study "yes"

Atypical Research

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

Please answer "N/A"

6.1 - Complete the Educational Requirement Table:
First, enter a new row enter your name, Medical Student, OUWB, and activities you will be participating in, i.e., data collection, manuscript preparation, etc.

6.2 - Is this project a Capstone for OUWB? Please answer "yes"

6.3 - Is a student taking the lead? Typically is answered "yes" and then you'll need to enter your mentor's name below (it should appear in the drop-down list).

7.1 – Project identification – Phase (this refers to type of clinical trial) – answer N/A

7.2 – Study initiated by - Investigator
7.3 – Location – please select the location(s) where the research will take place.

8.1 – Assistance determining human subjects research.
Please answer "No" to this question unless instructed otherwise by your Capstone Director.

8.1 Do you need assistance to determine whether your project qualifies as Human research?	
○ Yes ○ No	

9.0 Determining Level of Risk

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 (Please answer specific to your study)	

9.3 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 - (In most cases, this will be yes)

- 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.

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

☐ (Please answer according to your study)

Existing Data (Retrospective)

☐ Prospective Collection of Data from Chart Review or Research Activities

☐ Prospective Questionnaire or Survey

9.4 – Please note that if you're conducting a chart review, you'll primarily be using retrospective data. Research involving surveys in which data has not yet been collected is considered prospective.

10.0 - Expedited Review Category – Please choose the appropriate category for your study. Chart reviews are category 5. You are required to answer yes or no to each category.

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	
10.2 Is a waiver of consent being requested? (i.e. chart review, database analysis) Refer to Policy #221 - *"Informed Consent and Authorization in Research* for additional information" http://www.beaumont.edu/research-policies-and-procedures	
○ Yes ○ No	

Unless your study is exempt, you will most likely be requesting a waiver. Please check with your Capstone Director should you have any questions.

11. 1 – Will the waiver adversely affect the patient's rights? Answer NO

11.2 – Can research be practically carried out without the waiver? Answer NO

11.3 – Will participants be provided with additional pertinent information? In most cases, this will be answered "N/A"

11.4 – Will screening of available records take place to determine study eligibility? There are a couple different ways to screen participants: 1) If you're using data from an existing database then you would not necessarily to screen for eligibility, 2) if you're searching through the EMR, you would most likely need to screen for eligibility. Please contact Tracy Wunderlich for a template if needed.

11.5 – You'll need to enter text explaining why you're requesting a waiver. For retrospective studies, you might say, " This study is retrospective and therefore, it is not practical or feasible to contact patients."

12.0 – Special Study Considerations
12.1 - How will informed consent be obtained, if required?
Please check the button next to the 4th option for "waiver of consent"

12.2 - Name and credentials of consent provider - N/A
12.3 - When asked about ICH and GCP guidelines, answer N/A
12.4 - Multi - site trial? In most cases, this will be N/A

12.5 - Will Beaumont serve as the coordinating center? In most cases, this will be answered no.
12.6 - Will the study require collection of SSN? Typically, this will be answered no
12.7 - Department of Defense Research - typically these will all be answered no.

13.0 - Study Overview/Inclusion/Exclusion Criteria

13.2 – Duration of project - typically 3 years
13.3 – Retrospective studies - please give time frame of data to be reviewed, i.e., 2/1/2013 through 12/31/2015

14.2 – Enter duration of your study – typically 3 years. If your study is a chart review, please include dates of records, i.e., 1/2009 – 6/2013. If your study is retrospective, you cannot list dates in the future.

Feel free to copy and paste items 13.3 through 13.7 directly from your proposal.
13.3 – Background - include 2-3 paragraphs that sum up your lit review.
13.4 – Briefly describe your objectives.
13.5 – Describe your study methodology here – be VERY specific. Please walk the reviewer through the entire data collection process from start to finish.
13.6 – List inclusion criteria, i.e., 18 and over, females, diagnosis of breast cancer.
13.7 – List exclusion criteria, i.e., patients under the age of 18, males, no diagnosis of breast cancer.
13.8 – Sample size calculation – not required for Capstone projects – please answer "N/A – pilot study" here.

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

Please follow up with Michelle Jankowski, biostatistician, to obtain this information.

14.1
Duration of participation for individual participant – enter either N/A or fill in text box

◯ N/A - Chart review/specimen use or data collection study Clear

14.2 How many participants/specimens/charts will be enrolled or included in the study? Please slightly overestimate this number.	
Total number at all sites:	

Total number at this site:

15.3 How many participants do you expect to consent to reach the enrollment goals (include screen failures)?

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

Clear

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

Males or Females (Check all which apply)

- Male
- Female

List the age range:

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

Yes No

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

Refer to HIC Policy #234 - *Review of Advertising and Press Releases Related to Clinical Research* for guidance.
http://www.beaumont.edu/research-policies-and-procedures

Check all which apply:

- Direct person to person solicitation

- [ ] Medical record / One Chart Review / Computer databases – this is typical for chart reviews
- [ ] Advertisement/ Notice / Flyer
- [ ] Referral from other healthcare provider or support staff (e.g., physician office, laboratory)
- [ ] Other (specify):

15.0 - 15.5– Vulnerable populations – please answer according to your particular study. Depending on which category you choose, you may be required to provide additional explanation.

15.6 - Will study participants be excluded because of gender, race, age, or ethnic background. Typically you'll answer know unless your study focuses on a particular group.

16.0 – Risks

Please indicate possible risks associated with your study. In most studies, breach of confidentiality is always possible.

16.2 – Please check "Secure Sharepoint Server" and add in other information if necessary.

17.- Data Collection & Storage
17.1 - Describe how participants will be identified - typically we use MRN and unique code
17.2 – What direct participant identifiers will be shared? Please check N/A

17.3 – When asked about who else will have access to the data - this should typically be "None."

17.4 – Typically, you'll ONLY be storing electronic data on a Beaumont Sharepointe site

17.5 – Answer – if no hard copy data, please indicate this here.

17.6 – Please answer this as "yes" as all records will be maintained after the study is closed.

17.7 – Records must be kept for 11 years. Please answer "yes" here.

18.1 – Are you using a data collection tool? In most instances, you'll answer yes here.

19.0 – Funding
19.1 - For funding questions, please click on "Add a new row." In most cases you'll enter "No funding" under funding type, "N/A" under name of funding source and "N/A" under funding status.

19.2 – In most instances, you'll answer "no" here.

20.0 – Research Waiver of Authorization
20.2 –Please check Sharepointe server" here

20.3 - Who will have access? Check "key personnel" only

20.4 – Please check appropriate box. Typically this will be "deletion of electronic data."

20.5 – Please check "upon manuscript acceptance" as well as "upon study completion"

Uploading study documents

Once you're done answering all the questions in the application, you'll need to upload all study-related documents.

In section **3.0 (Key Personnel and Delegation of Authority),** you will be prompted to upload your **COID forms** (all forms - one for each key personnel - should be alphabetized by last name and scanned into one electronic file). Conflict of interest forms can be found on hic.beaumont.edu under "study assistant" and "operating procedures" under "forms."

You will then need to upload **your CV** and a CV for anyone who has not conducted research at Beaumont in the past 3 years.

In section 4.0 - Capstone - please insert blank documents in each of the three sections so that you can advance to the next section. Once you are completely done with your application and related materials, an assurance form will be uploaded by one of the Med Ed Directors.

In section 5.0 - Data Collection Tool - please upload either a list of variables you'll be collecting (for chart review), survey template, or educational materials (whichever is appropriate for your particular study).

Section 6.0 - Other study documents - Please upload your BRI module transcript here.

Please note that if your study involves consent or information sheet, you will be prompted to upload these as well.

Submitting your application

Once you've uploaded all your documents, you'll need to route for signatures (electronically). Only the PI needs to sign off on the project as key personnel. Then on the next page, you will need to have the following individuals sign off in this exact order:

1) Principal Investigator
2) Mentor (If mentor is PI, then skip this step)
3) Barbara Higgins as Capstone Administrative Reviewer
4) Clinical Research Manager
5) Department Chair

Any names of individuals you cannot find can be located by clicking on "My Assistant" on the left side of the screen, then "Operating procedures," then click on the appropriate contact information link.

Once this is done you can submit for review.

Checking on the status of your application

To check on the status of your application, please log on and click on your study application. Once you do this, you should see a page with several links listed. Please click on "Submissions History," then under "Track Location," click on the magnifying glass to see where your study currently is in the review process.