1.0 General Information

1.1 *Please enter the full title of your study:

Evaluating Registered Nurses knowledge regarding Evidence Based Practice in Medical Surgical Nurses in a Community Hospital

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

Evaluating EBP

2.0 Add Department(s)

2.1 List of Departments associated with this study:

Primary Dept?	Department Name
•	**Beaumont Health System** - - Nursing

3.0 Assign key project personnel(KSP) access to the project

***The current project status does not allow for changes to the Key Study Personnel. If you wish to change the Key Study Personnel, please contact the IRB.**

3.1 *Please enter the name of the Principal Investigator (PI) for the project (a study may only have one PI):

Randy Whitney, RN, NE-BC

3.2 If applicable, please select the Research Staff personnel:

A) Additional Investigators

- ☐ Anne M Stewart
  Co-Investigator

B) Research Support Staff

3.3 *Please add a Project Contact:

01. Anne M Stewart

11. Randy Whitney, RN, NE-BC

The Project 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:

Randy Whitney

Title:

Director of Professional Practice & Magnet Program Director

Department:

Nursing Education and Research

Phone number:

313-473-2087

Email address:

randy.whitney@beaumont.org

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 Project Identification

6.1 Phase of study:

- ● 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?

- ● 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:

6.3 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:

7.0 Determining Human Participant Research

7.1 Do you require assistance determining if your project is Human Participant Research or do you believe your project does not meet the criteria for Human Participant Research? If either situation applies, please check "Yes".

○ Yes • No

8.0 Determining Level of Review Required

8.1 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

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

• Yes ○ No

8.3 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.

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

□ Existing Data (Retrospective)
□ Prospective Collection of Data from Chart Review or Research Activities
■ Prospective Questionnaire or Survey

9.0 Exempt - Request for Exemption Status

9.1 Category 1: Will the research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

○ Yes • No

9.2 Category 2: Will the research involve the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, where information obtained is recorded in such a manner that human subjects cannot be identified, directly or through identifiers linked to the subjects AND disclosure will not be damaging to subject (place subject at risk of criminal or civil liability, damage financial standing, reputation, etc).

NOTE: If children are participants in the research and there is to be interaction with them, a research exemption will NOT apply.

• Yes ○ No

9.3 Category 3: Will the research involve the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under item (2) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter?

○ Yes • No

9.4 Category 4: Will the research involve the collection or study of existing data, documents,

records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects?

○ Yes ● No

9.5 Category 5: Will the research and demonstration projects be conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs;(iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs?

○ Yes ● No

9.6 Category 6: Will the research 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 be approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture?

○ Yes ● No

10.0 Exempt - Study Description

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

105

10.2 Date of expected study completion:

November 15, 2016

10.3 State study objectives and/or endpoints:

Evaluating Registered Nurses knowledge regarding Evidence Based Practice.

10.4 Describe study methodology:

This is a descriptive, explorative survey in which medical surgical nurses will be asked to complete the 29 question 2005 Nursing Evidence-Based Practice Survey as well as some non identifying demographic information. The survey's will be a hard copy and distributed by hand, by the secretary in the nursing business office. The packet will include a cover letter, a information sheet , the demographic sheet and the survey. Each packet will have a self address envelope address to Randy Whitney so they may be returned anonymous. This is a one time study at this point. It may be completed 3 - 5 years after Grosse Pointe Hospital Receives Magnet. Randy Whitney or Anne Stewart have no direct report staff that will be

completing the survey. The survey and information sheet will be give to all nurse on 2 South, 3 South and 3 West during during the study period. A receipt of information sheet will be reviewed and completed on all RNs who will be given the Survey.

10.5 Describe study population and state sample size:

The study will be conducted on 3 medical surgical units at Beaumont Hospital-Grosse Pointe. The units are 2 South, 3 South and 3 west. The suvey will be distributed to about 105 registered nurses.

10.6 Does research involve interaction with participants?

• Yes ○ No

11.0 Exempt - Participant Interaction & Verbal Consent

11.1 Explain how you will describe the research to participants (i.e. verbal consent):

A cover letter will explain the study and each participant will be given an information sheet. The information sheet will have the IRB number, the title of the research study, introduction, study procedure, risks, benefits, cost, compensation, confidentiality, voluntary participation/withdrawal, participation and a way to contact the PI and IRB.

11.2 List the name & credentials of key personnel involved in participant interaction (i.e. who will obtain verbal consent):

N/A

12.0 Exempt - Data Collection

12.1 Will you initially be using medical records, computer databases, other recorded information sources to identify participants, or extract de-identified data?

○ Yes • No

12.2 Describe Data source: (e.g. chart review; anonymous survey; use of existing* data, films, "waste" blood, urine or tissue samples). **Existing at time of submission*

Anonymous survey

12.3 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

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.

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

On a desktop PC?
○ Yes • No

On a network server?
○ Yes • No

On an encrypted laptop (must be encrypted)?
○ Yes • No

On Beaumont IronKey encrypted flash drive?
• Yes ○ No

Beaumont Property Tag Number

464343

Beaumont SharePointe site?
Upon IRB approval, contact Erin Kozlowskiat (248) 551-8252 to request a SharePoint folder for your study
• Yes ○ No

Other electronic storage?
○ Yes • No

If Other, provide details:

12.4 Will you be sharing data with external collaborators?

○ Yes • No

You will be required to attach the Data Collection Tool/Form at the end of the application, just prior to submission.

13.0 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.

13.1 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)

13.2 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

14.0 Research Waiver of Authorization

14.1 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.

14.2 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
□ SharePointe
□ Other- Describe:

14.3 Who will have access to patient identifiers?

Check all that apply:

■ N/A Exempt study no identifiers
□ Key Personnel listed on study roster
□ Sponsor
□ Federal Agencies
□ Other

14.4 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
- □ Deletion of electronic data

14.5 The list of identifiers will be destroyed:

Check all that apply:

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