



System Patient Care Services

POLICY/GUIDELINE TITLE: Nursing Research and Evidence Based Practice	SYSTEM POLICY AND PROCEDURE MANUAL
POLICY #: PCS.1629	CATEGORY SECTION:
System Approval Date: ❖6/17/20	Effective Date: 5/18/18
Site Implementation Date: ❖6/17/20	Last Reviewed/Approved: 5/18/18
Prepared by: Lily Thomas Ph.D., RN, Myrta Rabinowitz, Ph.D, RN, System Nursing Research and Evidence Based Practice (EBP) Council	Notation(s): N/A

GENERAL STATEMENT of PURPOSE

The purpose of this policy is to define the process for conducting or participating in nursing research and evidence based practice projects at Northwell Health. Conducting Research generates new knowledge and Evidence Based Practice projects integrate knowledge into practice.

POLICY

It is the policy of Northwell Health for System Patient Care Services to properly conduct nursing research to develop new knowledge and to conduct evidence based practice projects in order to test knowledge for practice. Refer to the procedures and guidelines described below to achieve these goals. All applicable Northwell Health policies, such as research policies, must be adhered to.

SCOPE

This policy applies to all Northwell Health employees, as well as medical staff, volunteers, students, trainees, physician office staff, contractors, trustees and other persons performing work for or at Northwell Health; faculty and students of the Donald and Barbara Zucker School of Medicine at Hofstra/Northwell or the Hofstra Northwell School of Graduate Nursing and Physician Assistant Studies conducting research on behalf of the Zucker School of Medicine on or at any Northwell Health facility.

DEFINITIONS

- **Evidence-Based Practice (EBP):** Evidence-based Practice (projects) is the integration of best research evidence, clinical expertise, and patient values into the decision making process for patient care (Sackett D, et.al, 2000).

- **Human Subject:** An individual about whom an investigator conducting research obtains data or material through intervention or interaction with the individual or identifiable private information.
 - **Intervention** – includes both physical procedures by which data are gathered and manipulations of the subject or the subject's environment that are performed for research purposes.
 - **Interaction** – includes communication or interpersonal contact between investigator 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). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order to obtain the information to constitute research involving human subjects.
 - **Human subject** means an individual who is or becomes a subject in research, either as a recipient of the test article or as a control. A subject might be either a healthy individual or a patient. For research involving medical devices, a human subject is also an individual on whose specimen an investigational device is used.

When medical device research involves in vitro diagnostics and unidentified tissue specimens, the FDA defines the unidentified tissue specimens as human subjects.

- **Northwell Health Institutional Approval:** Northwell Health has determined that an investigator can conduct clinical research under its auspices. It is separate from IRB review and approval and is a signed contract. It means that the study has been evaluated and that as an organization, Northwell Health has decided to engage in the conduct of the study.
- **Institutional Review Board (IRB):** A committee constituted in compliance with the Department of Health and Human Services (DHHS) regulations at 45CFR46 and FDA regulations at 21CFR50 that has been formally designated by an institution to review and monitor biomedical and behavioral research involving human subjects. In accordance with regulations, an IRB has the authority to approve, require modifications in, or disapprove research. The purpose of IRB review is to ensure, both in advance and by periodic continuing review, that appropriate steps are taken to protect the rights and welfare of humans participating as subjects in the research. To accomplish this purpose, IRBs use a group process to review research protocols and related materials (e.g., informed consent documents and investigator brochures) to ensure the protection of the rights and welfare of human subjects of research.
- **Northwell Health Institutional Approval:** Northwell Health has determined that an investigator can conduct clinical research under its auspices. It is separate from IRB review and approval and is a signed contract. It means that the study has been evaluated and that as an organization, Northwell Health has decided to engage in the conduct of the study.
- **Nursing Research:** Systematic inquiry in the field of nursing to provide a scientific basis for the practice of the profession. 'Nursing research encompasses a broad scope of scientific inquiry including clinical research, health systems' and nursing education research' (AACN,

2006).

- **Principal Investigator (PI):** The individual responsible for the administrative, programmatic, and fiscal aspects of a program or project. The PI must have the technical competence and substantive capabilities (i.e. scientific expertise) to conduct the program or project. Types of programs or projects include funded (through internal and/or external funds) and non-funded research, sponsored projects, and service delivery activities. Every program or project which uses Northwell Health resources must have a designated Northwell Health/Zucker School of Medicine PI.
- **Research:** A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration, quality improvement, and service programs may include research activities. Research means any experiment that involves a test article and one or more human subjects, and that either must meet the requirements for prior submission to the Food and Drug Administration under section 505 (i) or 520 (g) of the Federal Food, Drug, and Cosmetic Act, or need not meet the requirements for prior submission to the Food and Drug Administration under these sections of the Federal Food, Drug and Cosmetic Act, but the results of which are intended to be later submitted to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit. The terms research, clinical research, clinical study, study, and clinical investigation are synonymous for purposes of FDA regulations. [21 CFR 50.3(c), 21 CFR 56.102(c)]

I. Nursing Research and Evidence Based Practice Guidelines:

A. Students:

1. School **must** have an Educational Affiliation Agreement to conduct research or EBP projects with Northwell Health.
2. **Northwell Health has the sole authority to determine whether a project constitutes research or EBP.**
3. Performance of quality improvement projects will not be permitted.
4. The research or EBP project needs to be approved by:
 - a. The Chief Nurse Officer/Executive of the hospital
 - b. The Northwell Health Institute for Nursing's (IFN) System Nursing Scientific Review Committee (**Research studies**) or the System Nursing EBP Review Committee (**EBP Projects**).

B. Student Research Studies:

1. Qualified Students who meet the requirements for conducting research at Northwell Health as a requirement for completion of their academic degree must be receiving guidance from their academic advisor and follow the Northwell Health policy for Institutional approval.
2. School Committee Chairs must attest to having an affiliation agreement with Northwell Health for specific programs of study allowing students to conduct research.
3. Students cannot conduct a research study at Northwell Health until an affiliation agreement to conduct research is obtained.

4. The Student's Committee chairperson must review and approve (signature) the students **FINAL** proposal being submitted to the Northwell Health System Nursing Scientific Review Committee for its approval (see **APPENDIX B**: Request for Scientific Review Form).
5. For Student led studies University IRB approval must be obtained prior to Northwell's IRB approval and the approval letter attached to the application (May be waived in extenuating circumstances).

C. Student EBP Projects:

1. All Students (including Northwell employees) planning to conduct an EBP project at Northwell Health as a requirement for completion of their academic degree must receive guidance from their academic institution.
2. Students must follow the Northwell Health Policy for approval described below:
 - a. School Committee Chair must attest to having an affiliation agreement with Northwell Health for specific programs of study allowing students to conduct an EBP project.
 - b. Students cannot conduct an EBP project at Northwell Health until an affiliation agreement to conduct the project is obtained.
 - c. The Student's Committee chairperson must review and approve (signature) the student's **FINAL** proposal being submitted to the Northwell Health Institute for Nursing's System Nursing EBP Review Committee for its approval (see **APPENDIX F**: Request for EBP Review Form).
3. All EBP proposed projects must be submitted to the System Nursing EBP Review Committee and receive approval prior to initiating the project.
4. The EBP project lead may work collaboratively with the site research & EBP council members on developing the project summary prior to submission to the system review committee.
5. An IRB determination letter **may be necessary** if human subjects are involved with the proposed project.
6. Northwell Health will utilize the STEVEN'S STAR Model for Knowledge Transformation as a framework for operationalizing evidence-based practice processes. (See APPENDIX C)
7. Students completing an EBP project for completion of a degree may use an appropriate foundational Model
8. If the student is planning to implement the project, the methods of implementation should be detailed including resources, education/training, steps involved in changing the practice and outcome measures.

D. Northwell Employees:

1. Research Studies:
 - a. The Principal Investigator (PI) must be one of the following:
 - (1) An employee of Northwell Health
 - (2) Student at the Donald and Barbara Zucker School of Medicine at Hofstra/Northwell or the Northwell Graduate School of Nursing and Physician Assistant Studies
 - (3) Hold an Academic Appointment with Northwell Health

- b. All nurses participating in research must complete the following prior to participating in research:
 - (1) Per policy GR085 *Training Requirements for the Human Subjects Research Protection Program*, all applicable Collaborative Institutional Training Initiative (CITI) Program courses must be completed. More information can be found in GR085, on the HRPP website (www.feinsteininstitute.org/HRPP), and at [www.feinsteininstitute.org/CITI](http://www.citiprogram.org), <http://www.citiprogram.org>.
 - (2) External Interest Disclosure (COI) requirements as outlined in policy GR065 Review and Management of Institutional Financial Conflict of Interest in Research. More information can be found in GR065 and at www.feinsteininstitute.org/COI.
- 2. All nursing research studies must be submitted to the System Nursing Scientific Review Committee and receive approval before applying for IRB and Institutional approval.
- 3. All nursing research studies must be approved by the Site level Chief Nurse Executive or designee.
- 4. All studies involving multiple sites in Northwell Health must be approved by the System Chief Nurse Executive or designee.
- 5. The process for obtaining IRB & institutional approval for conducting research must be followed (**ATTACHMENT B**).
- 6. The Principal Investigator must receive both an IRB approval letter and a separate letter of Institutional Approval in order to perform research involving human subjects. Study enrollment cannot begin until the two letters are on file. Refer to Northwell Health Research Policy GR056 Research with Human Subjects; all Northwell Health policies can be found on the Intranet.
- 7. Study findings and implications for practice will be disseminated according to guidelines (**ATTACHMENT C**).
- 8. The appropriate Abstract Template (**APPENDIX D**) will be utilized for dissemination of research studies.

E. Northwell Health Employees EBP projects:

- 1. Northwell Health will utilize the STEVEN'S STAR Model for Knowledge Transformation as a framework for operationalizing evidence-based practice processes. (**APPENDIX C**)
- 2. All EBP projects should be approved by the site Chief Nurse Executive.
- 3. An IRB determination letter **may be necessary** if human subjects are involved with the proposed project.
- 4. The project lead must be one of the following:
 - a. An employee of Northwell Health
 - b. Student at the Donald and Barbara Zucker School of Medicine at Hofstra/ Northwell or the Northwell Graduate School of Nursing and Physician Assistant Studies
 - c. Hold an academic appointment with Northwell Health
- 5. The EBP Algorithm (**APPENDIX G**) will be utilized as a guide for conducting an EBP project.
- 6. The appropriate Abstract Template (**APPENDIX D**) will be utilized for dissemination of EBP projects.

CLINICAL REFERENCES /PROFESSIONAL SOCIETY GUIDELINES

1. American Association of Colleges of Nursing (2006) Position Statement on Nursing Research
2. Human Research Protection Program Policies and Procedures, Northwell Health Collaborative Institutional Training Initiative (CITI) <http://www.citiprogram.org>
3. Sackett D et al. (2000) Evidence-Based Medicine: How to Practice and Teach EBM, 2nd edition. Churchill Livingstone, Edinburgh
4. Stevens, K., (May 31, 2013) "The Impact of Evidence-Based Practice in Nursing and the Next Big Ideas" OJIN: The Online Journal of Issues in Nursing Vol. 18, No. 2, Manuscript 4

REFERENCES to REGULATIONS and/or OTHER RELATED POLICIES

GR056 Research with Human Subjects

GR065 Review and Management of Institutional Financial Conflict of Interest in Research

GR085 Training Requirements for the Human Subjects Research Protection Program

ATTACHMENTS

Attachment A – Protocol Templates

Attachment B – Process for Obtaining IRB & Institutional Approval for Conducting Research

Attachment C – Recommendations for Dissemination of Study Findings and Determining Implications for Practice

APPENDICES

APPENDIX A: General Protocol Template

APPENDIX B: Request for Scientific Review Forms (Internal and External)

APPENDIX C: Steven's Star Model/ Northwell Health Implementation Model

APPENDIX D: Abstract Template

APPENDIX E: Request for EBP Review Form

APPENDIX F: EBP Project Summary Form

APPENDIX G: Algorithm

FORMS

N/A

<u>APPROVAL:</u>	
Northwell Health Policy Committee	❖6/17/20
System PICG/Clinical Operations Committee	❖6/17/20

Standardized Versioning History:

*=Northwell Health Policy Committee Approval; ** =PICG/Clinical Operations Committee Approval
4/26/18*; 5/18/18**

❖ Expedited Approval Granted by:

Winifred Mack, SVP/Operations - Chair, Northwell Policy Committee

Morris Rabinowicz, MD - Co-Chair, System PICG/Clinical Operations Committee

Protocol Templates

IMPORTANT: These protocol templates are **required** for any new study submission using Northwell IRB. Study information should be entered directly into the appropriate template (do not cut and paste template sections into a new document). Submissions that do not use the required template will be returned without review.

PROTOCOL TEMPLATE	WHEN TO USE
Clinical Trial Template	This is the NIH/FDA published protocol template that Northwell Health is adopting for all studies involving an FDA regulated product.
Protocol Plus Template	Use if your study has a protocol from a sponsor, cooperative group, coordinating center, lead PI.
Registry Studies Template	Use if your study will be a registry or repository for data and/or samples.
Research Protocol Template	Use for all other studies.

Process for Obtaining IRB & Institutional Approval for Conducting Research

Step 1: Select the appropriate Template (see ATTACHMENT A).

- All studies (including Applications for Exemption) – please complete the Research Protocol (APPENDIX A).
- Chart Review – please complete the Chart review Template (APPENDIX E)
- National Studies – please attach the protocol created by the national PI.

Step 2: Submit a request for Scientific Review

- Complete the Request for Scientific Review Form (APPENDIX B). This applies to Internal and External Requests.
- Submit the appropriate Template, APPENDIX B, Consent Form (Northwell template), recruitment materials, and data collection forms, as applicable to nursingresearch@northwell.edu.

Step 3: Submit to IRB

- After receiving Scientific Review approval, the PI will:
 1. Go to the <http://www.feinsteininstitute.org/professionals/resources-for-investigators/administrative-services/human-research-protection-program/>
 2. Follow option “Click here to access the IRB Manager for all IRB Submissions”
 3. Upload APPENDIX A, APPENDIX B, Data Collection Tools, and University Approval letter.

Recommendations for Dissemination of Study Findings and Determining Implications for Practice

1. Abstracts of completed studies must be submitted to the Vice President of the System Nursing Research or Designee; the abstract will be added to the 'completed studies' category on the Nursing Research Website and added to the agenda of the System Research and EBP Council meeting.
2. The results should be presented to the appropriate service/specialty/site/System forum.
3. If the study results have implications for practice changes, follow procedure for practice changes through the service/site/System committees.
4. Submit abstracts to the Annual Nursing Research Conference/other Northwell Health conferences/National or Regional Conferences for podium or poster presentations.
5. Consider publishing the study in peer reviewed journals.
6. Resources are available for abstract submission, publication and presentations (See APPENDIX E); contact the Institute for Nursing/System Nursing Research and EBP Council/Hospital Nursing Research and EBP Council, and the Nursing Research Website.

General Protocol Template

<http://www.feinsteininstitute.org/wp-content/uploads/2013/03/Research-Protocol-Template-Nov2016-1.docx>

Northwell Health Institute for Nursing
SYSTEM NURSING SCIENTIFIC REVIEW COMMITTEE
APPENDIX B: Request for Scientific Review Form
(Internal and External Request)

Note: This form must be typed. Please submit completed form with your protocol to NursingResearch@northwell.edu

PI Name: _____ **Email:** _____ **Phone#:** _____

Facility: _____ **Department: Nursing** ☐ **Yes** ☐ **No** _____

(If No, Please Specify)

Study Title: _____

Date of Submission: _____

Submission Type:

New Proposal ☐ **Resubmission** ☐ **Date originally submitted/reviewed by**
SNSRC _____

I am respectfully requesting a review of the attached proposal.

The following are additional considerations regarding the proposal for the Nursing Scientific Review Committee:

Signature of Principal Investigator: _____ **Date:** _____

Students only:

(1) Does your school have an affiliation agreement with Northwell Health for your specific program of study allowing you to conduct research? ☐ **Yes** ☐ **No*** (Please consult with your advisor)

*If no, please note that you cannot conduct a research study with Northwell Health until an affiliation agreement is obtained.

Committee Chairperson:

(1) I attest to the above student's program of study having an affiliation agreement with Northwell Health allowing the student to conduct research.

(2) I have reviewed and approved the attached final proposal being submitted to Northwell Health's **System Nursing Scientific Review Committee** for its approval.

Please note: University IRB approval must be obtained prior to Northwell IRB approval and the approval letter attached to the application.

 Committee Chair Signature

 Date

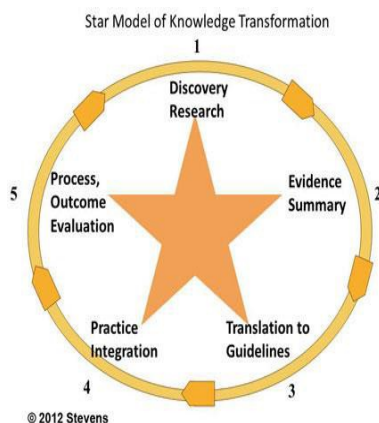
 Committee Chair Name

Version Date: 1/18/18

STEVEN'S STAR MODEL and NORTHWELL HEALTH IMPLEMENTATION GUIDELINES

Steven's Star Model

www.acestar.uthscsa.edu/acestar-model.asp



Steven's STAR MODEL

Point 1: Discovery Research:

New knowledge is discovered through traditional research.

Resources:

Bibliographic Databases such as CINAHL-provide single search reports, in most cases, multiple reports.

Point 2: Evidence Summary:

The research is synthesized into a single meaningful statement of knowledge.

Resources:

Cochrane collaboration Database of Systematic Reviews-provides reports of rigorous systematic reviews on clinical topics. See www.cochrane.org/

Point 3: Translation into Guidelines:

Research evidence is translated To develop recommendations for clinical practice

Resources:

Emergency Care Research institute (ECRI)
<http://guidelines.ecri.org/>

Northwell Health EBP Implementation Model

Formulate an answerable question (PICO)

1. Search for research studies related to topic

2. Gather Evidence:

Gather Research Evidence:

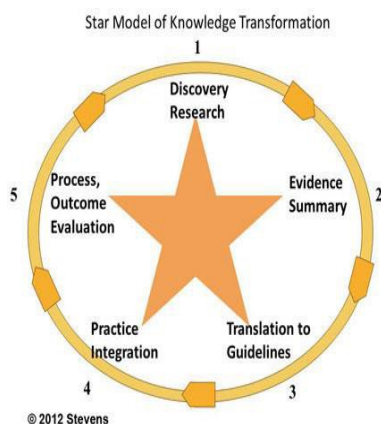
- Search for Systematic Reviews and Meta-Analysis
- Seek best practice from Northwell Health quality assurance Department (outcome data)

3. Appraise the Evidence:

- Determine **Level** and **Quality** of Evidence
- Determine **Strength** of recommendations

4. Determine validity, applicability to practice, resources, client preference, regulatory requirements

5. Develop recommendations



Point 4: Practice Integration:

Change of individual / organizational practices through formal / informal channels

Resources:

AHRQ Health Care Innovations Exchange-sponsored by AHRQ- provides profiles of Innovations, and tools for improving care processes, including adoption guidelines and information to contact the innovator. See

<http://innovations.ahrq.gov/>

Point 5: Process, Outcome Evaluation:

Evaluate outcomes: Patient health outcomes, provider and patient satisfaction, economic analysis, efficacy, efficiency, and impact on patient status.

Resources:

National Quality Measures Clearinghouse-sponsored by AHRQ- provides detailed information on quality measures and measure sets. See:

<http://qualitymeasures.ahrq.gov>

6. Design / select action plan for Pilot

7. Evaluate the outcome of the implementation

- Document evidence in data base, publish for System and external use
- Incorporate into System Policy and Procedure Manuals as appropriate

ABSTRACT TEMPLATES

Research

- Title
- Research Question/Problem
- Background Information (Literature Review and Theoretical framework)
- Significance
- Methods
- Results
- Implications for Practice
- References (2 current)

Quality Improvement/ CCC Project

- Title
- Define Problem/Significance
- Describe current process
- Strategies /Method to solve problem
- Outcomes
- Conclusions
- Recommendations / next steps
- References

Evidence Based Practice: Translating the Evidence into Practice

- ☐ Title
- ☐ Background & Significance of the Problem
- ☐ PICO(T) Question
- ☐ Evidence Synthesis
- ☐ Evidence Based Recommendations for Initiating New Practice or changing Practice (include strength and quality of evidence for each recommendation)
- ☐ Implementation Process
- ☐ Outcomes/Evaluations
- ☐ Implications for Practice
- ☐ References (2 current)

Evidence Based Practice: Generating the Evidence

- Title
- Background & Significance of the Problem
- PICO(T) Question
- Location and Appraisal of Evidence
- Evidence Synthesis
- Strength and Quality of Evidence
- Recommendations for Practice
- References (2current)

Northwell Health Institute for Nursing
System Nursing EBP Review Committee

Request for EBP Review Form - (Internal and External Request)

Students:

- (1) Does your school have an affiliation agreement with Northwell Health for your specific program of study allowing you to conduct an EBP project? ☐ Yes ☐ No* (Please consult with your advisor)

*If no, please note that you cannot conduct an EBP project with Northwell Health until an affiliation agreement is obtained.

Faculty Chairperson:

- (2) I attest to the above student's program of study having an affiliation agreement with Northwell Health allowing the student to conduct research.
- (3) I have reviewed and approved the attached final proposal being submitted to Northwell Health's **System Nursing EBP Review Committee** for its approval.

 Committee Chair Signature

 Date

- This form must be typed.
- Please submit completed form with your protocol to nursingebp@northwell.edu

Date of Submission: _____

Project Lead/student Name: _____ **Email:** _____ **Phone #:** _____

Facility: _____

Department: Nursing ☐ Yes ☐ No
 (If No, please specify department) _____

School & Program Enrolled: _____

Project Title: _____

Submission Type: ☐ New Proposal ☐ Resubmission (For resubmission, please provide date of original review) _____

This project is on: ☐ 1) Developing evidence based recommendations (with strength and quality of evidence) to answer a clinical question

☐ 2) Implementation of evidence to initiate new practice or change current practice

If "2", have you submitted a Human Subjects Research Determination Request? ☐ Yes ☐ No

If yes, what was the determination? ☐ IRB review required ☐ IRB review not required

➔ If IRB review is required, please submit a request for scientific review to nursingresearch@northwell.edu for a research study.

➔ If IRB review is not required, the Human Subjects Research Determination Document must be attached along with this form.

If no, please submit for a human subjects' research determination to IRB

I am respectfully requesting a review of the attached proposal which uses the Guideline for Preparing an EBP project.

All data collection forms that are described in the proposal are attached.

The following are additional considerations regarding the proposal for the Nursing EBP Review Committee:

I have notified the Research & EBP council chair at my site and discussed this project. ☐ Yes ☐ No

Signature of Project Leader: _____

Date: _____

**Northwell Health
Institute for Nursing
Evidence-Based Practice Project Summary Form**

EBP Project Title: _____

Site Name: _____

EBP Project Leader/student:

Name: _____

Contact Phone: _____

Contact E-mail: _____

I am a student enrolled at: _____

(Project leader is the employee who leads the project if not a student)

Guidelines for Preparing an EBP Project

- Complete the *EBP Project Summary Form*
- Complete the *Request for EBP Review*
- Submit both documents to nursingebp@northwell.edu.
- Do not delete any of the text contained within this document
- Please make sure to keep an electronic copy of this document for future modifications if needed.

1. PREVIOUS PROJECT HISTORY

Has this project ever been reviewed and not approved?

☐ No ☐ Yes – If yes, please explain: _____

2. COMPLETE THE FOLLOWING SECTIONS

Background & Significance of the Problem *(How did you select this problem and why is it important? Include implications to patient care outcomes locally, regionally, nationally or globally)*

PICO (T) Question *(Include all components of the PICO (T)-patient/population, suggested intervention, comparison/current practice, and expected outcome)*

Location and Appraisal of the Evidence (Available evidence related to your PICO (T) question- *internal evidence* -patient outcomes/quality metrics; *external evidence*-evidence from systematic reviews, meta-analysis, or clinical practice guidelines).

Evidence Synthesis (Provide summary and synthesis of available evidence specific to your PICO (T) question)

Evidence-based recommendations for initiating new practice or changing practice (Include strength and quality of evidence for each recommendation).

Plan for Implementation Process (Evaluate current practice and compare with identified evidence. Describe any identified gaps. If current practice is not based on evidence, describe the implementation plan).

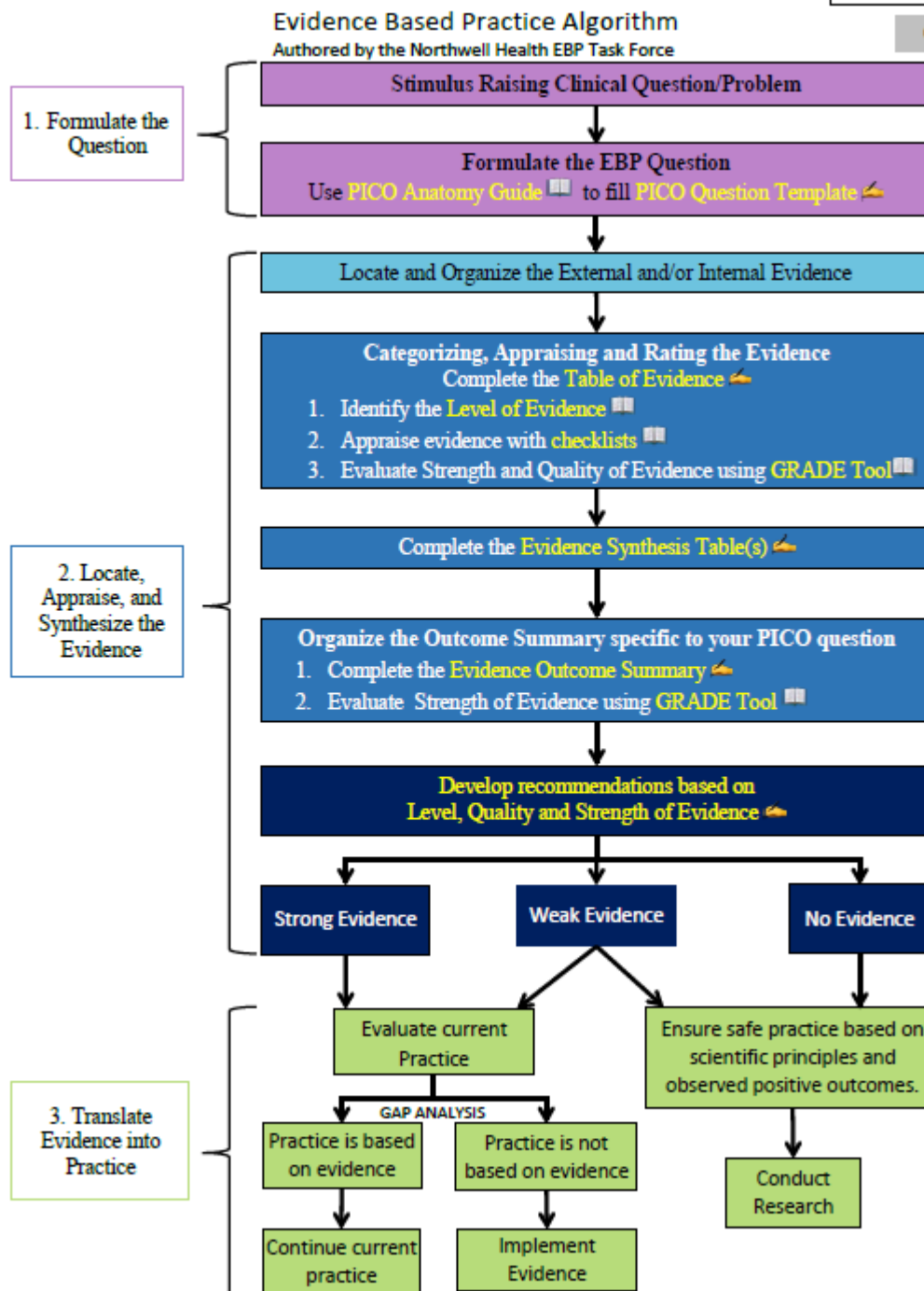
Outcomes Measurements/Results (Describe outcomes measures, specific to your PICO question. Please attach pre and post data collection tools).

Implications for Practice/Next Steps (Plan for spread & sustainability, cost/ROI etc.)

3. PROJECT TIMELINE (Describe the estimated timeline of your project; Be specific)

4. REFERENCES (Provide relevant list of references).

CLEAR



Version Date: 7/26/19