Ochsner Health System

GUIDE TO NURSING RESEARCH PROPOSAL AND EBP PROJECT APPROVAL AT OCHSNER HEALTH SYSTEM

FOR EMPLOYEES AND ACADEMIC PARTNERS

CENTER FOR EBP & NURSING RESEARCH

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INTRODUCTION

The Center for Evidence Based Practice (EBP) and Nursing Research at the Ochsner Health System is committed to facilitating the conduct of cutting-edge research and innovative evidence-based practice projects. Our goal is to ignite a spirit of scientific inquiry in nurses at all levels to change practice and change lives. The System Nursing Research Council provides research/EBP consultative and mentored services to both Ochsner and non- Ochsner staff that are pursuing academic degrees.

To help nursing students navigate Ochsner's policies and available resources, we've developed a Guide to Academic Project Approval that includes an Academic Toolkit. The Academic Toolkit components include:

- The Iowa Model of Evidence-Based Practice to Promote Quality Care
- Nursing Academic Project Approval Flowchart
- Protocol Template
- Feasibility Checklist
- PowerPoint templates for Verbal Presentation of Research Projects and Scholarly Projects (EBP or Quality Improvement) to the System Nursing Research Council.

In addition to providing critical information to navigate project approval, this guide also includes important contact information in acquiring clinical affiliation agreements and accessing human subject education modules (CITI modules) required by the Ochsner Institutional Review Board.

Please take the time to become familiar with the steps outlined in this guide and the components of the Academic Toolkit. Hyperlinks are located throughout this document – indicated in blue.

For students: we strongly recommend reaching out to the System Nursing Research Council (SNRC) co-chairs, nursing.research@ochsner.org, **as early as possible but at the latest in the semester prior to your planned implementation** to allow sufficient time for permissions and approvals.

Important Contacts

The Center for Evidence- Based Practice and Nursing Research:

- Internal (Ochsner) Site
- External Site

nursing.research@ochsner.org

Academics Department to facilitate clinical affiliation agreement & requirements:

clinicaleducation@ochsner.org

or, for North Louisiana students

OLHS.students@ochsnerlsuhs.org

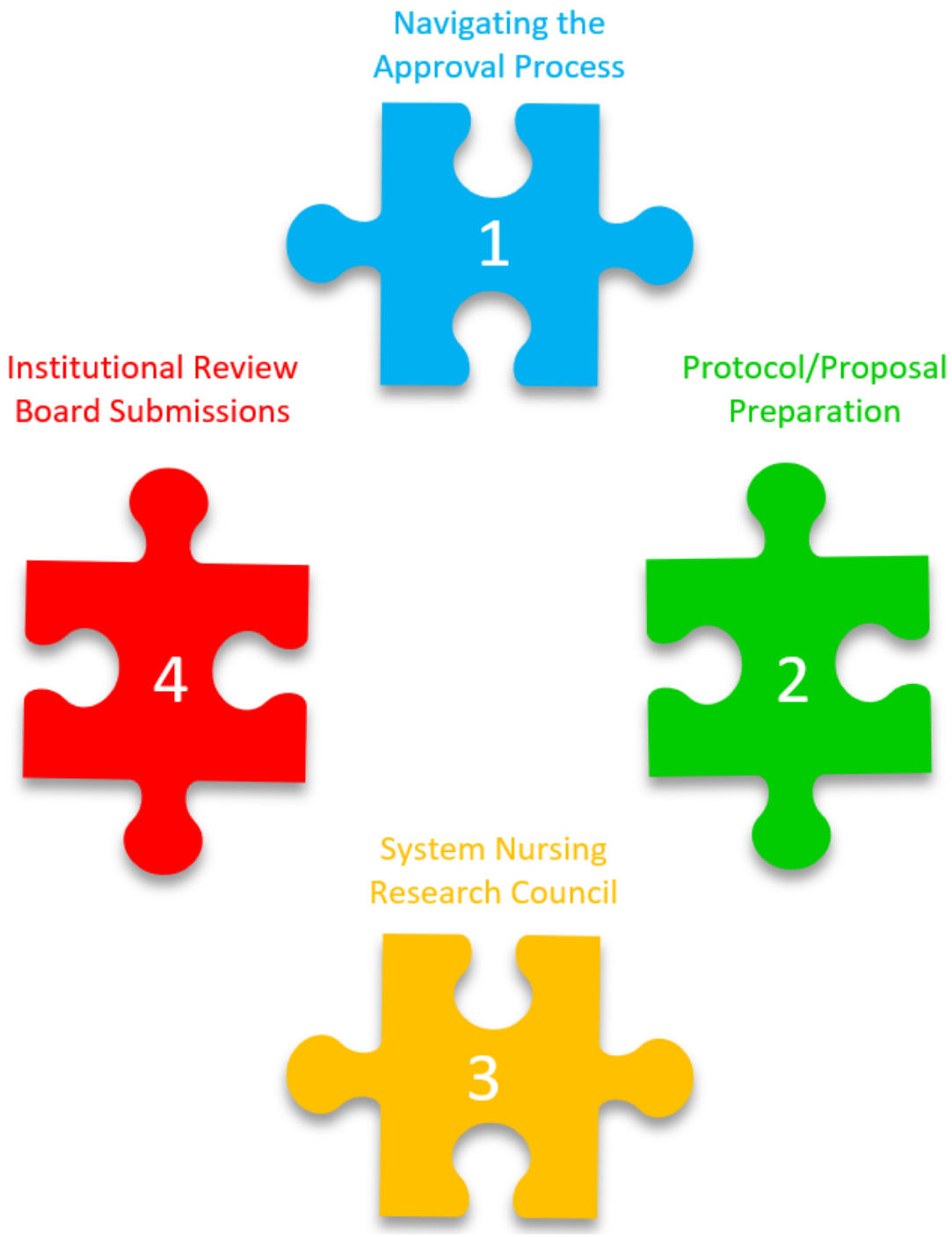
Ochsner Clinic Foundation Institutional Review Board:

IRB@ochsner.org

Human Subjects Protection
CITI Program

GETTING STARTED

Steps to Approval



Navigating the Approval Process

The Center for EBP & Nursing Research works closely with the Academics department and the IRB to facilitate EBP and research projects in the Ochsner Health.

Step 1

Purpose is to:

- Clarify any questions about the Project Toolkit
- Explain the approval process at Ochsner Health

Tasks for students:

- University requests placement for student in InPlace (clinicaleducation@ochsner.org)
- *Ochsner LSU Health System (OLHS) students, contact olhs.students@ochsnerlsuhs.org
- Students who require Epic data must request student Epic access from clinical education (*cannot use employee Epic access as a student*).
- To align with Ochsner's strategic goals and needs, you must validate the identified gap in practice or knowledge with the leadership at your proposed implementation site.
- Designate a facility/system preceptor/mentor to be primary investigator on your project/study.
- Contact System Nursing Research Council (SNRC) **early**, before or during your project planning course, *prior to the semester of implementation*. nursing.research@ochsner.org
- Complete the required CITI Courses. Be sure to choose "Ochsner Clinic Foundation" for organizational affiliation.
- *OLHS students choose LSUHSC-S for CITI organizational affiliation.

Tasks for employees:

If you are planning a research study or EBP/QI project, **not affiliated with a graduate school requirement**:

- Contact System Nursing Research Council (SNRC) as you plan your project or research study nursing.research@ochsner.org
- Complete the required CITI Courses. Be sure to choose "Ochsner Clinic Foundation" for organizational affiliation.
- *OLHS employees choose LSUHSC-S for CITI organizational affiliation.

Evidence Based Practice/Research projects must be approved by the System Nursing Research Council (SNRC) prior to Ochsner IRB submission.

Step 2

Purpose is to:

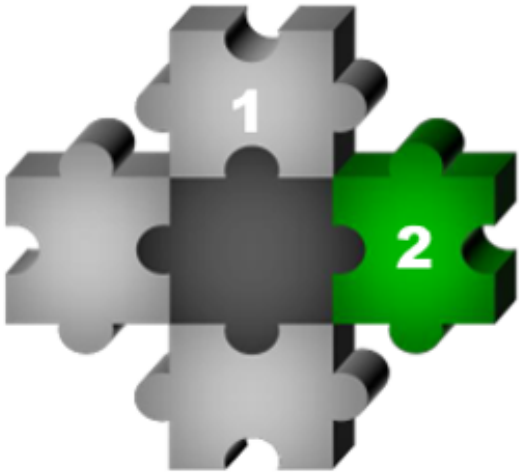
- Facilitate efficient protocol/proposal approval by the SNRC and IRB
- Proactively identify obstacles to meeting project deadlines
- Minimize project-related anxiety

Tasks for students:

- Convert academic paper into an abbreviated version (see protocol templates in the Project Toolkit)
- Meet with the chair/co-chair of the SNRC to establish initial components of the protocol and review deadlines.

Tasks for employees:

- Meet with the chair/co-chair of the SNRC to establish initial components of the protocol and review deadlines.
- Utilize protocol templates (located in Project Toolkit) to outline your project or proposal.



The SNRC is the authorizing body for all EBP and research proposals. Members include representatives from across Ochsner Health and academic partners.

Step 3

Purpose is to:

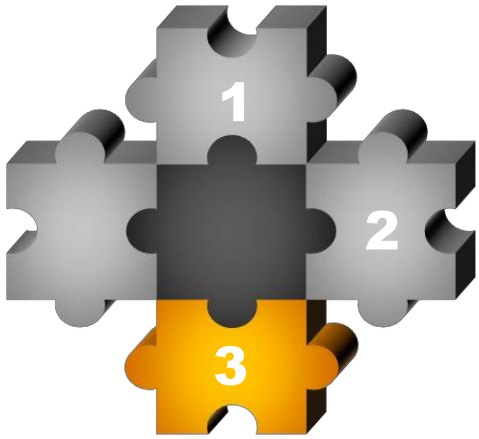
- Provide scholarly review, discussion, and approval of nursing projects or proposals.
- Approval allows the project or study to proceed to IRB submission.

Tasks for students:

- Submit faculty-approved paper and the completed protocol template two (2) weeks before System Nursing Research Council meeting.
- Verbally present proposal/protocol to council using presentation template **(10 minute maximum)**.
- Address appropriate feasibility checklist criterion in the presentation

Tasks for employees:

- Submit completed protocol template two (2) weeks before System Nursing Research Council meeting.
- Verbally present proposal/protocol to council using presentation template **(10 minute maximum)**.
- Address appropriate feasibility checklist criterion in the presentation



The IRB ensures that projects are aligned with the federal Office of Human Research Protections regulations. Ochsner's stance is that only an IRB can deem a study exempt from human subject protection.

Step 4

Purpose is to:

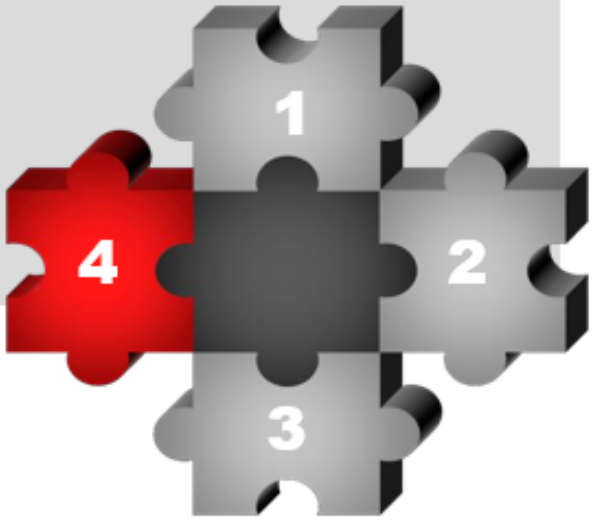
- Foster project compliance with federal regulations and Ochsner policies related to the conduct of research.

Tasks for students:

- Ochsner IRB must approve/grant determination on all projects prior to implementation, regardless of any potential University IRB determinations.
- Ensure you and any other project members have an eIRB account (particularly the Ochsner personnel designated to be the primary investigator on your project/study)
- Submit your SNRC-approved protocol and approval letter from SNRC through the Ochsner eIRB platform.
- North Louisiana students, obtain CNO approval and submit your SNRC protocol through the LSUHSC-S IRB platform "SHIeLDS"

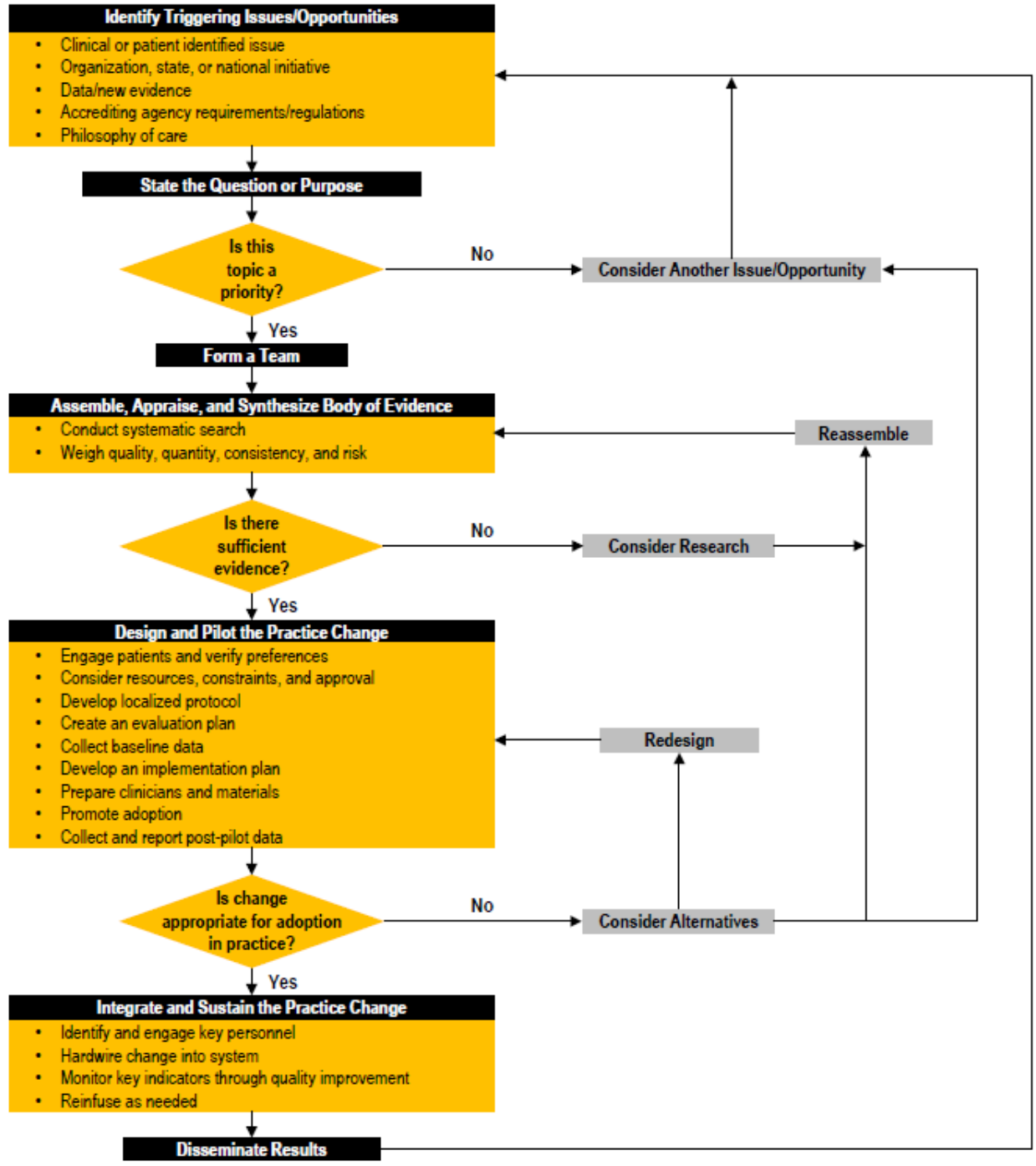
Tasks for employees:

- Ensure you and any other project members have an eIRB account.
- Submit your SNRC-approved protocol through the Ochsner eIRB platform.
- North Louisiana employees, obtain CNO approval and submit your SNRC-approved protocol through the LSUHSC-S IRB platform "SHIeLDS"



OCHSNER HEALTH SYSTEM
CENTER FOR NURSING
RESEARCH AND EBP
PROJECT TOOLKIT

The Iowa Model Revised: Evidence-Based Practice to Promote Excellence in Health Care



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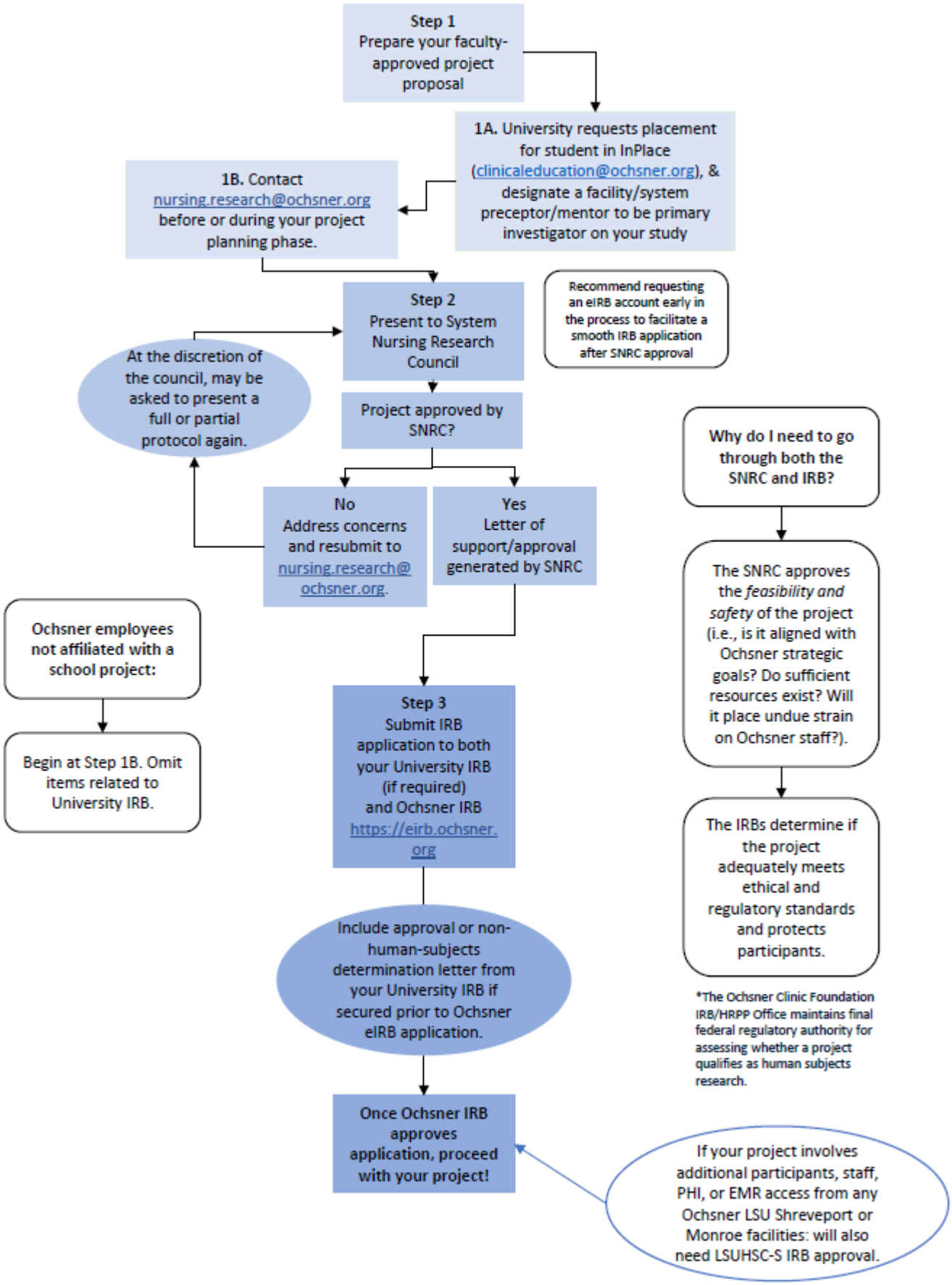
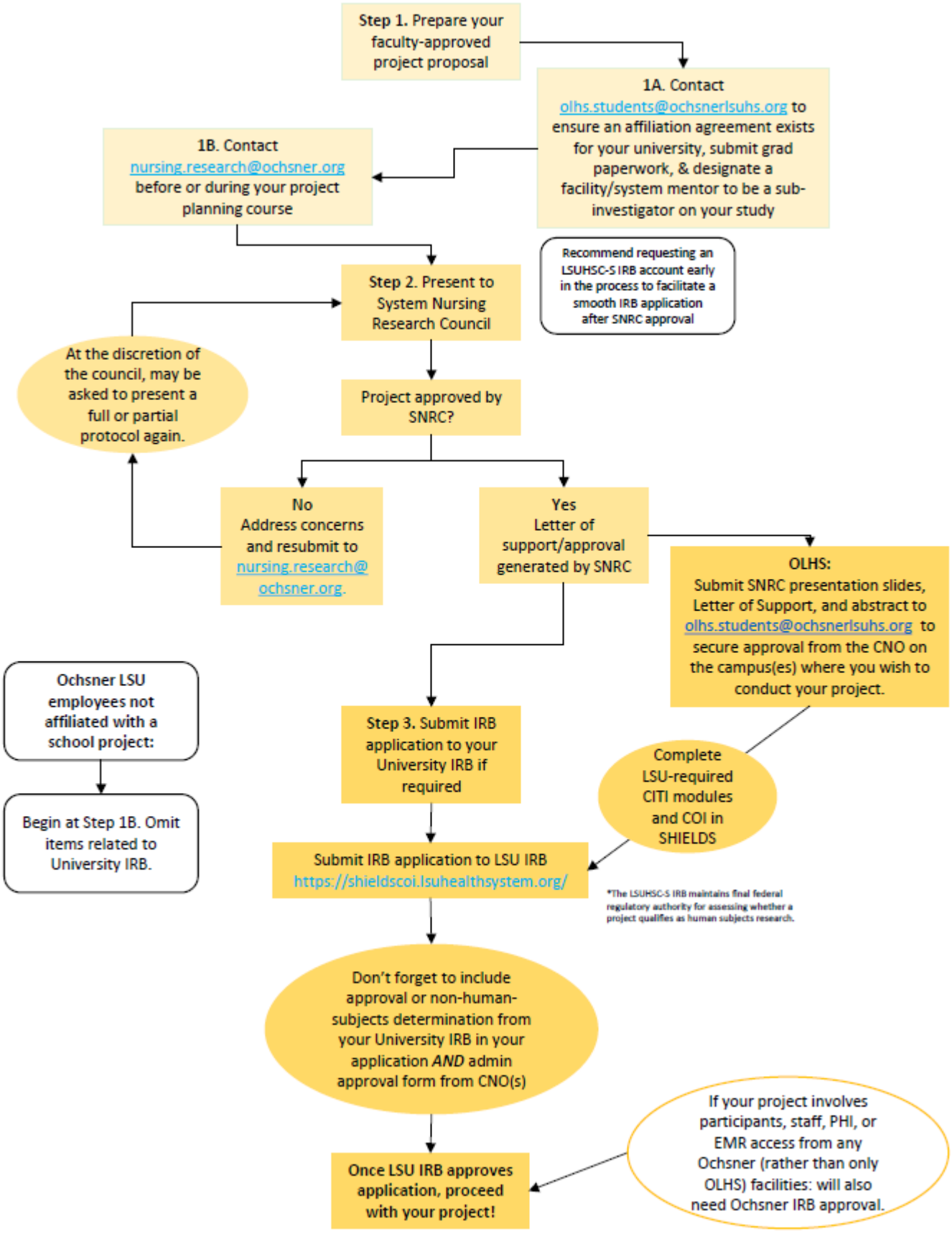
Nursing Project/Proposal Approval Flowchart – **Ochsner**



Nursing Project/Proposal Approval Flowchart – **Ochsner LSU Health**



EBP/QI Protocol Template

NOTE: This template is for reference, with prompts included. Please reach out to nursing.research@ochsner.org for a blank and editable WordDoc version. This template must be completed and submitted to nursing.research@ochsner.org two (2) weeks in advance of your presentation. Students, please additionally submit your full written faculty-approved proposal document for the council to have as a reference.

PROTOCOL COMPONENTS	WHAT TO INCLUDE
Title / Investigators	What is the title? Who is the project lead?
InPlace Request ID (students only)	Students: Please provide the InPlace Scholarly Project Request ID number.
Identify the Triggering Issues/Opportunities	Please describe the current process, procedure, or program relevant to your topic. Please include a statement summarizing any relevant information that prompted this project, including any of the following if applicable: • Clinical or patient-identified issues • Organization, state, or national initiative • Data/New Evidence (i.e. concerning statistics or metrics) • Accrediting agency requirements/regulations
Purpose and Team	What is the purpose/objective(s) of the project being proposed? Is this topic a priority for staff, leadership, or the organization? Who are the team members involved in this project (for example: two departments, you and a manager, etc.)?
PICOT Question	
Review of the Evidence	What does the literature say? Describe the quality, quantity, and consistency of the evidence. Is there sufficient evidence to support a practice change*? **If not, consider research instead*** (research generates new information due to a gap in the literature).
Project Framework	What type of project will you use (i.e., quality improvement, EBP, knowledge-to-action, PDSA, etc.) ?

Practice Change Details Setting	Where will this project be completed?
Sample	Who will be directly affected by the project? How will you decide who is/is not in the project (i.e. inclusion/exclusion criteria)?
Resources	What are the resources, constraints, and approvals you have considered? What materials will need to be prepared for implementation?
Preparatory Work	How will you engage participants? What leaders or other departments need to be involved?
Procedures	How will you prepare or educate the participants? What are the interventions or project components? What are the data collection procedures? Will retrospective or baseline data be collected? Will you be doing any chart review?
Evaluation Plan	How will your outcomes be defined and measured (i.e. surveys, focused interviews, data comparison, etc.)? How will you evaluate whether the project was successful?
Sustainability	How will you promote adoption? How frequently will compliance be monitored, if at all (i.e. through quality and safety reports)? Is any ongoing education planned?
Human Subject Protection	How much risk would be involved in a practice change? What things are being done to ensure staff and patient protection? How will staff or patients indicate their voluntary agreement to participate in the project? How will data be stored and how will the confidentiality and/or integrity of the collected data be maintained?
Implications to Practice	How will this project potentially influence practice?
Plans for Dissemination	What posters, presentations, or manuscripts are you planning to disseminate the findings? Include plans to disseminate results to the staff/leaders that participated.
Project Timeline	When will the project begin and end? Include this in table or graphic format if complex timeline.
Citations / References	Please list your references in this template, in addition to citing throughout the template above. Use a consistent format throughout protocol (i.e. APA, AMA, MLA, Vancouver, etc.)

Appendices	List your appendices here in the grid. Below, include a copy of any measurement instruments, surveys, emails, flyers used to communicate about the project, any material given to participants, or other important information to support project protocol as appendices below in the APA style. Please see below for an example, and please remember to cite those appendices throughout the template above whenever mentioned (i.e. "Appendix A").

Example:

Appendix A

Survey Instrument

Please rate your level of satisfaction with this Guide to Projects by responding to the following statements:

	Strongly Disagree	Disagree	Agree	Strongly Agree
Instructions were clear.				
Font size was appropriate.				
Examples were helpful.				

[add a page break between each subsequent Appendix]

Research Proposal Template

NOTE: This template is for reference, with prompts included. **Please reach out to nursing.research@ochsner.org for a blank and editable WordDoc version. This template must be completed and submitted to nursing.research@ochsner.org two (2) weeks in advance of your presentation.** Students, please additionally submit your full written faculty-approved proposal document for the council to have as a reference.

PROPOSAL COMPONENTS	WHAT TO INCLUDE
Title / Investigators	What is the Title? Who is the Principal Investigator and who are the sub-investigators?
Introduction/Background	What is the issue or problem? What is the history of the problem? What is the significance of the problem? Why is it important to study this problem?
Literature Review	What does the literature synthesis state about studies that have been conducted regarding this problem? What questions have not been answered by these studies?
Purpose and Specific Aims	What is the purpose/objectives of the study being proposed? Most sentences start with “To characterize”, “To evaluate”, “To examine” etc. 1. 2.
Research Question(s) and/or Hypotheses	What are the questions that the study will answer?
Design	What type of research design (i.e., quasi-experimental, convergent mixed methods, correlational, etc.) will you use and why this is the best design? *for IRB submission, simply describe the design, regardless of whether you believe it to be QI, human-subjects, or non-human subjects.
Funding Source	Is this project funded internally or externally (for instance, by a grant). Could this be a source of bias?

Methods Setting	Where will this study be completed?
Sample	Who will be directly affected by the study? Please provide a power analysis or indicate why one is not appropriate.
Inclusion/Exclusion Criteria	How will you decide who is/is not in the study?
Sampling Procedure	How will you enroll subjects or is it chart review?
Measures & Instruments	How are variables of interest defined and measured? What instruments are you using to measure variables or outcomes? What are the estimates of reliability, validity, & stability for each measurement instrument?
Study Procedures	What are the interventions or study components? What are the data collection procedures?
Data Analysis	What statistical tests or data analyses procedures will you use to answer the research questions or measure project outcomes?
Human Subject Protection	What things are being done to ensure human subject protection? Will the study or project require a written or verbal consent process? Will you be applying for a waiver of consent or HIPAA waiver? Have you ensured that the voluntary nature of participating is clear to the participants? How will the confidentiality and/or integrity of the collected data be assured? Is all PHI that you will access necessary to answer your research question? What are the risks for adverse events and what steps would be taken if an adverse event were to occur?
Implications to Practice	How will this study potentially influence practice?
Plans for Dissemination	What posters, presentations, or manuscripts are you planning to disseminate the findings?

Study Timeline	When will the study period begin and end? What is the expected time frame to complete the study? Provide support that this timeline is adequate to address the purpose of the project (in table or graphic format if complex timeline).
Citations / References	Use a consistent format throughout proposal (i.e. APA, AMA, Vancouver, etc.)
Appendices	List your appendices here in the grid. Below, include a copy of any measurement instruments, surveys, emails, flyers used to communicate about the study, any material given to participants, or other important information to support study protocol as appendices below in the APA style. Please see below for an example, and please remember to cite those appendices throughout the template above whenever mentioned (i.e. "Appendix A").

Example:

Appendix A
Survey Instrument

Please rate your level of satisfaction with this Guide to Projects by responding to the following statements:

	Strongly Disagree	**Disagree**	**Agree**	**Strongly Agree**
Instructions were clear.				
Font size was appropriate.				
Examples were helpful.				

[add a page break between each subsequent Appendix]

Student/Researcher Feasibility Checklist

Title of Study:_____ Principal Investigator: _____

Issue	Yes	No
1. General		
a. Study meets mission of OCF and System Nursing Research Council?		
b. Study is congruent with SNRC strategic goals?		
c. Sufficient evidence exists to support study/project?		
d. Problem is clearly articulated as a researchable question?		
e. Inclusion/exclusion criteria for subjects realistic?		
f. Statistician input in protocol/optimal sample size?		
g. Sufficiently detailed design and procedures to understand study/project process? (i.e. appropriate design, procedures, measures / instruments, analysis plan to address the purpose and research question(s)		
h. Is projected timeline for study/project realistic?		
i. Any foreseeable IRB/Human Subjects Protection issues?		
j. Principal investigator has demonstrated expertise to execute study or appropriate mentor identified?		
k. Appropriate administrative approval?		
2. Financial Considerations		
a. Acceptable study/project budget?		
b. Funding issues?		
3. Procedures/Clinical Assessments		
a. Procedures/Assessments complex?		
b. Additional staffing/specialist involvement required?		
c. Additional FTEs needed to complete study/project t?		
4. Study Population		
a. Clearly defined recruitment plan?		
b. Recruitment plan complex?		
c. Population: Adults/Minors/Vulnerable/Employees (circle one)		

Issue	Yes	No
5. Case Report Forms/Reporting & Documentation Requirements		
a. Electronic or Paper? (circle one)		
b. Plan for data collection/forms acceptable?		
c. Plan for long-term storage (secured) of documentation?		
d. Transcription required for any component of the study/project?		
6. Other Considerations		
a. Complexity may interfere with completing the protocol/proposal?		
b. Sufficient staff/financial support to complete study/project timely?		
c. Extra storage or office space required to execute the study/project?		
d. Study/project requires departments outside of nursing?		
e. Will any study/project related procedures be completed as a part of nursing care? (i.e., increased nurses' burden)		
f. Are other hospital-based committee approvals (other than IRB) are required to complete the study/project? (i.e., SDAN, patient experience, POV, documentation council etc.).		

Note: Any gray boxes selected may require discussion or additional steps.

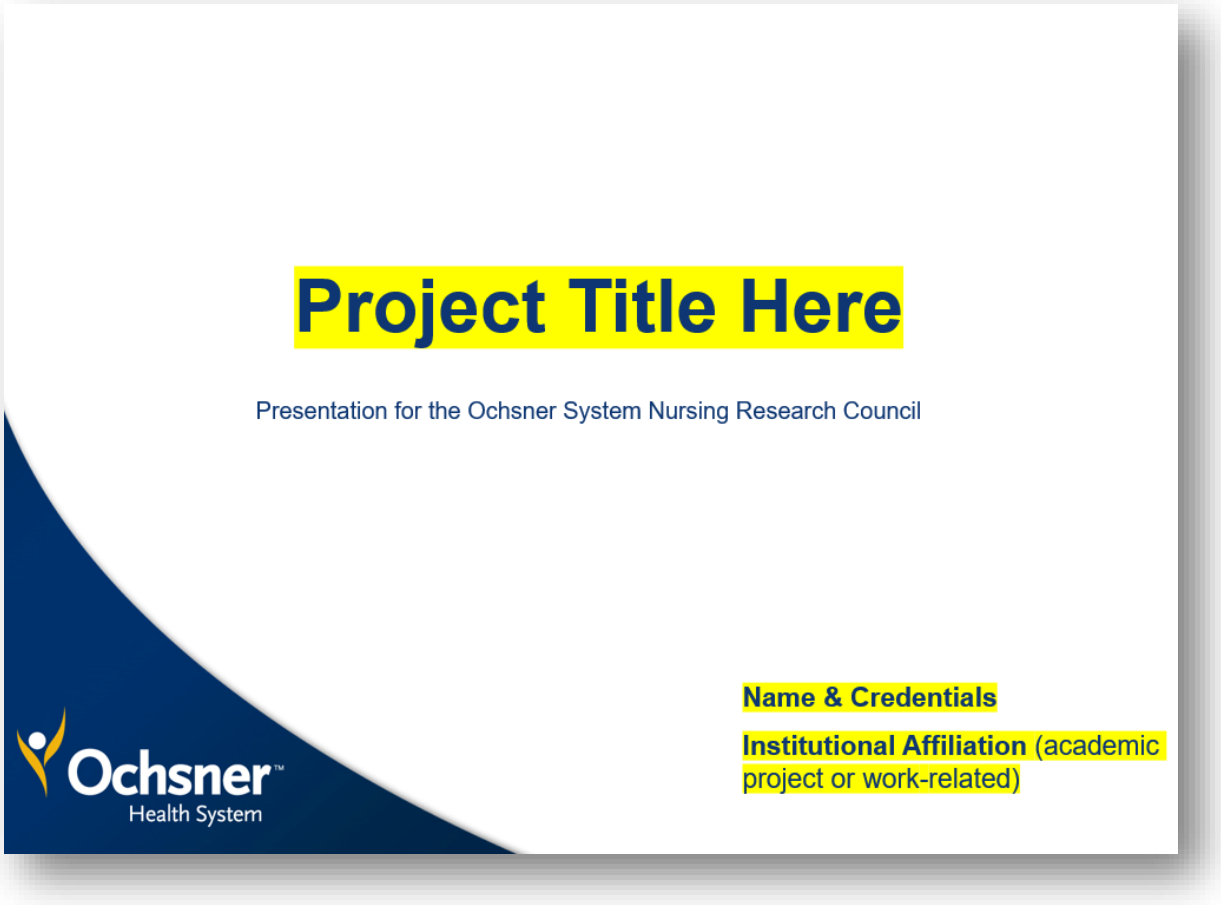
Verbal Presentation for the Council

1. Please choose the appropriate PowerPoint template ***based upon your project type:***

    - Research Proposal Template
    - EBP or QI Protocol Template

2. Once opened, please select "File" in the upper left corner and save a copy of the slides to your computer. You may enter your project-specific information into that saved copy.

Example of template:



Please remember: presentations are not to exceed 10 minutes, out of respect for the council members' time and others who may be presenting.

IRB Accounts

While you are preparing to present to the SNRC, you may be proactive and set up your IRB account to facilitate a smooth IRB submission process after SNRC approval.

Both the Ochsner and the LSUHSC-S IRBs have online portals which you will need to access to submit your project or study for IRB review. Both also require that you and any person listed on the study team are compliant with their CITI modules.

For the Ochsner Clinic Foundation IRB:

- Create an eIRB account by logging on to https://eirb.ochsner.org. In the top upper right corner, click on "login". The login page will open, however, to request a new account, click the link located at the bottom left. The required information fields will populate for completion.

- As a reminder, the preceptor or mentor in the department that the project will be conducted is the Primary Investigator and is also required to create an eIRB account if they do not already have one at https://eirb.ochsner.org. Students – we recommend checking in with your Primary Investigator and/or Mentor/Preceptor early on this matter, so that it does not come as a surprise when you are attempting to enter your project to eIRB after SNRC approval.

- Students, staff, and any primary or sub-investigators listed on the project must be compliant with CITI training under the organizational affiliation of Ochsner Clinic Foundation.

For the LSUHSC-S IRB

- Request a SHIeLDS account by emailing ShvCOI@lsuhs.edu.

- As a reminder, the preceptor or mentor in the department that the project will be conducted must be listed as a sub-investigator on the project and is required to create a SHIeLDS account if they do not already have one. Students – we recommend checking in with your Primary Investigator and/or Mentor/Preceptor early on this matter, so that it does not come as a surprise when you are attempting to enter your project to eIRB after SNRC approval.

- Students, staff, and any other sub-investigators listed on the project must be compliant with CITI training under the organizational affiliation of Louisiana State University Health Sciences Center – Shreveport.

Remember: The IRB maintains final federal regulatory authority for assessing whether a project qualifies as human subjects research. For this reason, we cannot bypass an IRB determination prior to implementation of any study or project.