GUIDE TO ACADEMIC PROJECT APPROVAL AT OCHSNER HEALTH SYSTEM

CENTER FOR NURSING RESEARCH
# Table of Contents

**INTRODUCTION**

- Important Contacts ................................................................. 3

**GETTING STARTED**

- Steps to Approval ........................................................................ 5
- Contact Center for Nursing Research ........................................... 6
- Navigating the Approval Process .................................................. 7
- System Nursing Research Council ............................................... 8
- Institutional Review Board Submissions ....................................... 9

**OCHSNER HEALTH SYSTEM CENTER FOR NURSING RESEARCH ACADEMIC TOOLKIT**

- Iowa Model of Evidence-Based Practice to Promote Quality Care ................................................................. 11
- Nursing Academic Project Approval Flowchart .......................................................... 12
- Protocol Template ........................................................................... 13
- Feasibility Checklist ........................................................................ 15
- System Nursing Research Council Template for Verbal Presentation of Research Projects .................................... 17
- System Nursing Research Council Template for Verbal Presentation of Scholarly Projects (EBP or Quality Improvement) ........................................................................... 18
INTRODUCTION

Greetings,

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

In an effort 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
- Template for Verbal Presentation of Research Projects to the System Nursing Research Council
- Template for Verbal Presentation of 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 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.

Karen Rice, DNS, APRN, ACNS-BC

Important Contacts

Karen L. Rice, DNS, APRN, ACNS-BC
Program Director for The Center for Nursing Research
krice@ochsner.org
504.842.6193

System Nursing Professional Development to facilitate clinical affiliation agreement & requirements
SNPD@ochsner.org

Ochsner Clinic Foundation Institutional Review Board
IRB@ochsner.org
504.842.3535
CITI Program – Human Subjects Protection
Steps to Approval

Center for Nursing Research

OHS Approval Process

Project Success

System Nursing Research Council

Institutional Review Board
Contact Center for Nursing Research

The Center for Nursing Research is responsible for facilitating the approval and conduct of academic EBP and research projects in the Ochsner Health System.

**Step 1**

**PURPOSE** is to orient the student to:

- The Academic Project Toolkit
- Resource availability
- Approval process at Ochsner Health System

**Tasks For Student to Do:**

- Contact Center for Nursing Research early, before or during your project planning course
- Contact System Nursing Professional Development to facilitate a clinical affiliation agreement, [SNPD@ochsner.org](mailto:SNPD@ochsner.org)
- Complete the [CITI Course](#)
Navigating the Approval Process

The approval process is streamlined to allow quality improvement projects to bypass the System Nursing Research Council and go directly to IRB submission. EBP/research projects must be approved by the System Nursing Research Council prior to IRB submission.

Step 2

**PURPOSE** is to:
- Facilitate efficient project approval
- Proactively identify obstacles to meeting project deadlines
- Minimize project-related anxiety

**Tasks For Student to Do:**
- Convert academic proposal into an abbreviated version
- Meet with Center for Nursing Research staff to determine project:
  - Feasibility
  - Quality Improvement vs. Research
  - IRB type of review (Exemption, Expedited, or Full Panel)
System Nursing Research Council

The System Nursing Research Council is the **authorizing body** for all EBP and research proposals. Members include representatives from each Ochsner campus and faculty from five universities.

**Step 3**

**PURPOSE** is to:

- Provide scholarly review, discussion, and approval of nursing academic proposals
- Approval generates a letter of support to proceed with IRB submission

**Tasks For Student to Do:**

- Submit faculty-approved proposal 1 week before System Nursing Research Council meeting
- **Verbally present proposal** to council using presentation template
- Address appropriate **feasibility checklist** criteria in presentation
Institutional Review Board Submissions

The IRB ensures that projects are aligned with the federal Office of Human Research Protections regulations. Ochsner’s policy requires that only the 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 academic projects

**Tasks For Student to Do:**

- Communicate your academic requirements for
  - Letter of support
  - University IRB before or after Ochsner IRB approval
Iowa Model of Evidence-Based Practice to Promote Quality Care

Problem Focused Triggers
* Risk Management Data
* Process Improvement Data
* Internal/External Benchmarking Data
* Financial Data
* Identification of Clinical Problem

Knowledge Focused Triggers
* New Research or Other Literature
* National Agencies or Organizational Standards or Guidelines
* Philosophies of Care
* Questions from Institutional Standards Committee

Find, assemble relevant research and/or literature

Consider other Triggers

Is the Topic a Priority for the Organization?

Appropriate Forum – Team/Committee
Critique and Synthesize Findings

Nursing Research Council

Is there Sufficient Research Base

Yes

Are Practice Changes Required or Appropriate

No

Continue to Monitor Care and New Knowledge

Yes

Pilot the Change in Practice
* Select Outcome to be Achieved
* Collect Baseline Data
* Design EBP Guideline on Pilot Units
* Evaluate Process & Outcomes
* Modify Practice Guideline
* Identify Opportunities for New Research

No

Base Practice on Other Types of Evidence
* Case Reports
* Expert Opinion
* Scientific Principles
* Theory
* Fiscal

CONDUCT RESEARCH

Disseminate Results
Nursing Academic Project Approval Flowchart

Center for Nursing Research
Feasibility Assessment
Are all of the following project-related activities TRUE?
√ Project aligned with OHS strategic goals
√ OHS mentor and project site administrator authorize sufficient resources to support project completion
√ Faculty-approved project proposal

No

Yes

Reevaluate & Revise So All Statements Are True

Quality Improvement Determination
Are all of the following project-related activities TRUE?
Prospective Project:
√ Activities produce an improvement in safety or care that will be sustained over time
√ Activities do not involve a randomized intervention
√ Activities do not involve an intervention that poses risks greater than those presented by routine clinical care
√ Activities are not in conflict with the standard of care
√ Activities do not compete with other projects
√ Activities do not involve accessing clinical records or protected health information

Retrospective Project:
√ If project is analyzing existing data, activities are limited to analyzing existing de-identified data from a QI project previously conducted (data must exist before the project begins)

No

Yes

System Nursing Research Approval

No

Yes

IRB Determination of Exempt

No

Yes

IRB Approval

No

Yes

Letter of Support Generated

No

Yes

Address Concerns and Resubmit

Yes

No

No
# Protocol Template

NOTE: This template is a guide. Although not critical, using the protocol components as headings/subheadings along with these essential elements will facilitate a clear understanding of your proposal.

<table>
<thead>
<tr>
<th>PROTOCOL COMPONENTS</th>
<th>WHAT TO INCLUDE</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Title / Investigators</strong></td>
<td>What is the Title? Who is the Principal Investigator and who are the sub-investigators?</td>
</tr>
<tr>
<td><strong>Introduction/Background</strong></td>
<td>What is the issue or problem?</td>
</tr>
<tr>
<td></td>
<td>What is the history of the problem?</td>
</tr>
<tr>
<td></td>
<td>What is the significance of the problem?</td>
</tr>
<tr>
<td></td>
<td>Why is it important to study this problem?</td>
</tr>
<tr>
<td><strong>Literature Review</strong></td>
<td>What does the literature synthesis state about studies that have been conducted regarding this problem?</td>
</tr>
<tr>
<td></td>
<td>What questions have not been answered by these studies?</td>
</tr>
<tr>
<td><strong>Purpose and Specific Aims</strong></td>
<td>What is the purpose/objectives of the project being proposed?</td>
</tr>
<tr>
<td><strong>Research Question(s)</strong></td>
<td>What are the questions that the project will answer?</td>
</tr>
<tr>
<td><strong>Design</strong></td>
<td>What type of research or project design (i.e. quality improvement, implementation science, etc.) will you use and why this is the best design?</td>
</tr>
<tr>
<td><strong>Method</strong></td>
<td>Where will this study or project be completed?</td>
</tr>
<tr>
<td><strong>Setting</strong></td>
<td>Who will be in the study or project?</td>
</tr>
<tr>
<td><strong>Sample</strong></td>
<td>How will you decide who is/is not in the study or project?</td>
</tr>
<tr>
<td><strong>Inclusion/Exclusion Criteria</strong></td>
<td>How will you get subjects enrolled or is it chart review?</td>
</tr>
<tr>
<td><strong>Sampling Procedure</strong></td>
<td>How are variables of interest defined and measured?</td>
</tr>
<tr>
<td><strong>Measures &amp; Instrument</strong></td>
<td>What instruments are you using to measure variables or outcomes?</td>
</tr>
<tr>
<td></td>
<td>What are the estimates of reliability, validity, &amp; stability for each measurement instrument?</td>
</tr>
<tr>
<td><strong>Study Procedures</strong></td>
<td>What are the interventions or project components?</td>
</tr>
<tr>
<td><strong>Data Analysis</strong></td>
<td>What are the data collection procedures?</td>
</tr>
<tr>
<td></td>
<td>What statistical tests or data analyses procedures will you use to answer the research questions or measure project outcomes?</td>
</tr>
<tr>
<td><strong>Human Subject Protection</strong></td>
<td>What things are being done to ensure human subject protection?</td>
</tr>
</tbody>
</table>

*Address appropriate elements for type of proposal
<table>
<thead>
<tr>
<th>PROTOCOL COMPONENTS</th>
<th>WHAT TO INCLUDE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Will the study or project</td>
<td>Will the study or project require a written or verbal consent process? How will the confidentiality and/or integrity of the collected data be assured?</td>
</tr>
<tr>
<td>require a written or verbal consent process? How will the confidentiality and/or integrity of the collected data be assured?</td>
<td></td>
</tr>
<tr>
<td>Implications to Practice</td>
<td>How will this study or project potentially influence practice?</td>
</tr>
<tr>
<td>Plans for Dissemination</td>
<td>What posters, presentations, or manuscripts are you planning to disseminate the findings?</td>
</tr>
<tr>
<td>Study Timeline</td>
<td>What is the expected time frame to complete the project? Provide support that this timeline is adequate to address the purpose of the project.</td>
</tr>
<tr>
<td></td>
<td>Include this in table or graphic format if complex timeline</td>
</tr>
<tr>
<td>Citations / References</td>
<td>Use a consistent format throughout proposal (i.e. APA, AMA, Vancouver, etc.)</td>
</tr>
<tr>
<td>Appendices</td>
<td>Copy of any measurement instruments, emails or letters of permission to use instruments, flyers used to solicit or communicate study, any material given to subjects, or other important information to support project proposal</td>
</tr>
</tbody>
</table>
## Feasibility Checklist

**Title of Study:**

**Principal Investigator:**

<table>
<thead>
<tr>
<th>Issue</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1. General</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>a. Study meets mission of OCF and Nursing Research Council?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>b. Study is congruent with NRC strategic goals?</td>
<td></td>
<td></td>
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<tr>
<td>c. Sufficient evidence exists to support study?</td>
<td></td>
<td></td>
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<tr>
<td>d. Problem is clearly articulated as a researchable question?</td>
<td></td>
<td></td>
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<tr>
<td>e. Inclusion/exclusion criteria for subjects realistic?</td>
<td></td>
<td></td>
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<tr>
<td>f. Statistician input in protocol/optimal sample size?</td>
<td></td>
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<tr>
<td>g. Sufficiently detailed design and procedures to understand project process? (i.e. appropriate design, procedures, measures / instruments, analysis plan to address the purpose and research question(s)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>h. Is projected timeline for study realistic?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>i. Any foreseeable IRB/Human Subjects Protection issues?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>j. Principal investigator has demonstrated expertise to execute study or appropriate mentor identified?</td>
<td></td>
<td></td>
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<tr>
<td>k. Appropriate administrative approval?</td>
<td></td>
<td></td>
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<tr>
<td>l. Investigator and research assistants have completed CITI course?</td>
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<tr>
<td>m. Investigator meets academic requirements if student project (i.e. clinical affiliation, health requirements, etc.)?</td>
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</tr>
<tr>
<td><strong>2. Financial Considerations</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>a. Acceptable study budget?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>b. Funding issues?</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>3. Procedures/Clinical Assessments</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>a. Procedures/Assessments complex?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>b. Additional staffing/specialist involvement required?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>c. Additional FTEs needed to complete project?</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>4. Study Population</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>a. Clearly defined recruitment plan?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>b. Recruitment plan complex?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>c. Population: Adults/Minors/Vulnerable/Employees (circle one)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Issue</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>---------------------------------------------------------------------</td>
<td>-----</td>
<td>----</td>
</tr>
<tr>
<td>5. <strong>Case Report Forms/Reporting &amp; Documentation Requirements</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>a. Electronic or Paper? (circle one)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>b. Plan for data collection/forms acceptable?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>c. Plan for long-term storage (secured) of documentation?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>d. Transcription required for any component of the study?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. <strong>Other Considerations</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>a. Complexity may interfere with completing the protocol?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>b. Sufficient staff/financial support to complete study timely?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>c. Extra storage or office space required to execute the study?</td>
<td></td>
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</tr>
<tr>
<td>d. Study requires departments outside of nursing?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>e. Will any study related procedures be completed as a part of nursing care? (i.e. increased nurses’ burden)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>f. Other hospital based committee approvals (other than IRB) are required to complete the study? (i.e. CDAN, patient education, POV, documentation council etc).</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Note:** Any gray boxes selected are a potential for concern.
**System Nursing Research Council Template for Verbal Presentation of Research Projects**

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Title of project</td>
</tr>
<tr>
<td>2.</td>
<td>Your credentials (i.e. nurse administrator, APRN, staff nurse) and your role (academic project or work-related)</td>
</tr>
<tr>
<td>3.</td>
<td>Brief description of the problem overall and significance to the Ochsner site you will conduct study</td>
</tr>
<tr>
<td>4.</td>
<td>Evidence (i.e. published literature, national statistics) to support the researchable question(s)/hypotheses</td>
</tr>
<tr>
<td>5.</td>
<td>Specific purpose or aim of the study / Research Questions and/or Hypotheses</td>
</tr>
</tbody>
</table>
| 6. | Methodology, including:  
  a. Design  
  b. Sample (inclusion, exclusion, size)  
  c. Interventions  
  Measures & Instruments:  
  i) What measures (i.e. data, outcomes) are you using to answer each of the clinical questions or project aims?  
  ii) How will you measure project outcomes (i.e. instruments, surveys, or existing data)? |
| 7. | What resources will you need to conduct the study, including:  
  a. Staff (you and others) commitment to help (i.e. project implementation, data collection, data miners)  
  b. Purchase of equipment/supplies  
  c. Other resources |
| 8. | Human subject protection if applicable (i.e. consent, how will the data be stored securely, who has access to the data, etc.)? |

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**Page 17 of 18**  
**Back to Table of Contents**  
**May 2017**
# System Nursing Research Council Template for Verbal Presentation of Scholarly Projects (EBP or Quality Improvement)

1. **Title of project**

2. **Your credentials (i.e. nurse administrator, APRN, staff nurse) and your role (academic project or work-related)**

3. **Brief description of the problem overall and problem to the Ochsner site you will implement project**

4. **Evidence (i.e. published literature, national statistics) to support the project**

5. **Specific purpose or aim of the project**

6. **Project Description:**
   a. Who will be the focus of the project (i.e. patients, unit or facility, hospital staff)?
   b. What do you plan on doing (project details)?

7. **What resources will you need to conduct project, including:**
   a. Staff (you and others) commitment to help (i.e. project implementation, data collection, data miners)
   b. Purchase of equipment/supplies
   c. Other resources

8. **Measures & Instruments - What measures (i.e. data, outcomes) are you using to answer each of the clinical questions or project aims?**

9. **Data Analysis - How will you analyze the data (i.e. statistical tests) so that it provides answers to the clinical questions or address the project purpose?**

10. **How long will it take you to complete the project?**

11. **Human subject protection if applicable (i.e. how will the data be stored securely, who has access to the data, etc.)?**