MANUAL FOR CLINICAL PRACTICE GUIDELINE DEVELOPMENT (CPGD)
Doctor of Nursing Practice (DNP) Scholarly Project
CONTENTS

DNP Scholarly Project—Clinical Practice Guidelines Development ........................................... 3
  Definition of a Clinical Practice Guideline ........................................................................... 3
  Purpose of Clinical Practice Guideline ................................................................................ 4

Resources ................................................................................................................................. 12
  References ............................................................................................................................... Error! Bookmark not defined.

Appendix A: Site approval documentation for CPGD Doctoral Project ..................................... 14

Appendix B: Disclosure to Expert Panelist Form for Anonymous Questionnaires ...................... 15
  Disclosure to Expert Panelist ............................................................................................... 15
  Questionnaire Procedures ................................................................................................... 15
  Voluntary Nature of the Project .......................................................................................... 15
  Risks and Benefits of Being in the Project .......................................................................... 15
  Privacy ................................................................................................................................. 16
  Contacts and Questions: ....................................................................................................... 16
DNP SCHOLARLY PROJECT—CLINICAL PRACTICE GUIDELINES DEVELOPMENT

Prior to beginning the work of any DNP scholarly project, Walden students will complete the steps of prospectus development and approval. Once the prospectus is approved, the committee will be formed, proposal developed, and oral proposal defense completed per the DNP Project Process Guide. The ethics approval process begins during proposal development but can only be finalized after the proposal defense is entered into MyDR.

The DNP nurse is often involved in the development of clinical practice guidelines within a nursing specialty. Practice guidelines within a healthcare organization or system provide a method to translate evidence into practice and improve outcomes. Assessment of patient needs or scientific advances may generate the development of practice guidelines that are informed by a systematic process of review of evidence. In situations where the demand for practice change is quicker than the pace of national guideline development, the dissonance may result in a need to develop guidelines at the local healthcare organization (White, Dudley-Brown, and Terhaar, 2016). The DNP nurse may be the impetus for change and lead the professional team in the process of evaluating the evidence for the development of clinical practice guidelines to meet organizational and patient needs.

It is important to understand what is meant by a Clinical Practice Guideline and the expectations for developing a Clinical Practice Guideline in the context of the DNP scholarly project. Development of Clinical Guidelines is aligned with the DNP Essentials and within the scope of practice for the Doctor of Nursing Practice (DNP).

Definition of a Clinical Practice Guideline

Clinical practice guidelines were first defined as “systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances” (Field and Lohr, 1990, p. 38). The Institute of Medicine (IOM) noted the need to incorporate new evidence and best practices into the healthcare setting in a timely and efficient manner. The IOM defines clinical practice guidelines as “statements that include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options” (Institute Of Medicine, 2011).
Purpose of Clinical Practice Guideline

Guidelines are developed within a healthcare organization to provide care providers with the evidence and knowledge needed to deliver safe, effective care to specific populations. The eight defining principles of clinical practice guidelines include the following:

1. Describing appropriate care based on the best available scientific evidence;
2. Reducing preventable variations in practice;
3. Providing a rational basis for referral;
4. Providing focus for continuing education;
5. Promoting efficient use of resources;
6. Providing a focus for quality control, including audit;
7. Highlighting gaps in the existing literature; and
8. Suggesting appropriate areas for future research (http://www.openclinical.org/guidelines.html#gandp).

Clinical Guideline Development Using AGREE II

Clinical Practice Guideline Development requires a systematic method with inclusion and exclusion criteria to search the literature, and grade the strength of evidence (Moran, Burson, and Conrad, 2017). The Appraisal of Guidelines Research and Evaluation (AGREE) II provides the framework that the DNP can use to guide the development of Clinical Practice Guidelines and to assess the quality of the guideline developed.

The AGREE II is both valid and reliable and consists of 23 key items organized within six domains (http://www.agreetrust.org). The six domains include:

Domain 1: Scope and purpose
Description: The Scope and Purpose domain is concerned with the overall aim of the guideline, the specific health questions and the target population.
Items:
1. The overall objective(s) of the guideline is (are) specifically described.
2. The health question(s) covered by the guideline is (are) specifically described.
3. The population (patients, public, etc.) to whom the guideline is meant to apply is specifically described.

Domain 2: Stakeholder involvement
Description: This domain focuses on the extent to which the overall aim of the guideline was developed by the appropriate stakeholders and represents the views of its intended users.
Items:
4. The guideline development group includes individuals from all the relevant professional groups.
5. The views and preferences of the target population (patients, public, etc.) have been sought.
6. The target users of the guideline are clearly defined.
Domain 3: Rigor of development
Description: This domain relates to the process used to gather and synthesize the evidence, the methods to formulate and update recommendations.
Items:
7. Systematic methods were used to search for evidence.
8. The criteria for selecting the evidence are clearly described.
9. The strengths and limitations of the body of evidence are clearly described.
10. The methods for formulating the recommendations are clearly described.
11. The health benefits, side effects and risks have been considered in formulating the recommendations.
12. There is an explicit link between the recommendations and the supporting evidence.
13. The guideline has been externally reviewed by experts prior to its publication.
14. A procedure for updating the guideline is provided.

Domain 4: Clarity of presentation
Description: This domain deals with the language, structure and format of the guideline.
Items:
15. The recommendations are specific and unambiguous.
16. The different options for management of the condition or health issue are clearly presented.
17. Key recommendations are easily identifiable.

Domain 5: Applicability
Description: This domain pertains to the likely barriers and facilitators to implementation, strategies to improve uptake, and cost implications of applying the guideline.
Items:
18. The guideline describes facilitators and barriers to its application.
19. The guideline provides advice and/or tools on how the recommendations can be put into practice.
20. The potential resource implications of applying the recommendations have been considered.
21. The guideline presents monitoring and/or auditing criteria.

Domain 6: Editorial independence
Description: This domain is concerned with the formation of recommendations not being unduly biased with competing interests.
Items:
22. The views of the funding body have not influenced the content of the guideline.
23. Competing interests of guideline development group members have been recorded and addressed.

For a guideline to receive high AGREE scores, there has to be a clear link between the proper collection and use of research evidence by qualified professionals and the development of trustworthy recommendations made in the guideline. The higher the AGREE scores, the more confident users can be that the guideline developers used an evidence-based approach to reach their recommendations.
Clinical Practice Guideline Process (Using the AGREE II Criteria as a Checklist in Each Step)

1. Identify a problem to be addressed with a guideline.
2. Develop a PICO (Problem Population, Intervention, Comparison, Outcome) question.
3. Develop evidence selection criteria:
   a. Describe the systems used for recording, tracking, organizing, and analyzing the evidence—including any software used for these purposes.
   b. Outline the procedures used to assure the integrity of the evidence, including approaches to managing outliers and missing information.
   c. Describe analysis procedures used in the doctoral project to address the practice-focused question(s) (e.g., coding, statistical analyses, etc.).
4. Search the literature.
5. Critically appraise the evidence from the literature using GRADE.*
6. Synthesize the evidence from the literature.
7. Develop recommendations /guideline.
8. Identify an expert panel.
9. Using the AGREE II Instrument, the expert panel reviews the guideline to validate content. The AGREE II instrument and users guide can be found here:
10. The AGREE II instrument is scored per the instructions provided by the Agree Trust, those instructions can be found at the following website:
    http://www.agreetrust.org/about-the-agree-enterprise/introduction-to-agree-ii/scoring-the-agree-ii/
11. The guideline is revised based on recommendations.
12. Identify a group of key stakeholders/end-users.
13. Present the revised guideline to end-users/key stakeholders /local experts and discuss to validate content and ensure usability.
15. Disseminate the final report to key stakeholders.

*Option to use Fineout-Overholt, Melnyk, Stillwell, and Williamson or Johns Hopkins Nursing EBP literature assessment for levels of evidence with faculty approval.
Obtaining Ethics Approval in Compliance With Institutional Review Board (IRB) Requirements

All doctoral projects are required to have ethics approval from the university’s IRB, even those that might not be considered “research.” The DNP program has set up a blanket ethics preapproval for Clinical Practice Guideline Development (CPGD) Doctoral Projects falling within the parameters described in the blue table below, as per the preapproved Site Agreement (Appendix A) and the Disclosure to Expert Panelist Form for Anonymous Questionnaires (Appendix B). Only CPGD projects involving public data, the literature, anonymous questionnaires from expert panelists, and archival data from the organization(s) are eligible for the blanket preapproval.

Edits to Appendices A and B are not permitted. If students need to customize anything about either of the two appendices or add more data points (such as observations or interviews), then the blanket approval cannot be utilized (and the students should follow the standard IRB approval steps in the DNP Project Process Guide).

Steps for ethics approval:
These steps can be completed any time after (a) the chair has uploaded the proposal into MyDR for URR review, and (b) the students have identified a partner site.

Step 1: To qualify for preapproved status, all doctoral students completing a CPGD project are responsible for completing the web-based Form A (the same form that all DNP students use to start the ethics approval process). In the first page of Form A, the students need to indicate that they will be conducting a project that falls within the preapproved parameters for CPGD and this will cause the form to skip the questions that are not applicable. The students will also need to enter the details for the partner site(s). The final page in Form A will provide instructions for next steps, based on the responses the student enters into Form A.

Step 2: For CPGD projects on the preapproved track, the instructions on the final page of Form A will indicate that the students can either upload the signed Site Agreement (Appendix A) into the form or e-mail it to IRB@mail.waldenu.edu at a later date. Note that the Disclosure Form (Appendix B) does not need to be sent to IRB because it has already been preapproved and does not need to be signed. The purpose of the Disclosure Form is to provide the expert panelist with disclosures regarding how the doctoral student will use the feedback the panelist provides. This is an important ethical step in this type of applied scholarship (similar in some ways to the “informed consent” step typically used in research studies).

Step 3: Once Form A is received by the IRB, an IRB staff member will respond within 10 business days to the students and chairs with either (a) an e-mail confirmation that the ethical standards have been met (i.e., the data collection procedures fall within the preapproved parameters), or (b) a request for more information. For certain sites (within Department of Defense, international contexts, universities, or research hospital systems), additional documentation and compliance steps may be required by the site, so the IRB
staff will work with the students to meet all of the site’s requirements. The IRB would continue to correspond with the students until all ethical issues are addressed. Once (a) occurs, the students can focus on working toward proposal approval. Doctoral students with project data falling outside the preapproved parameters in this manual will be directed to obtain IRB approval in the standard manner, which is likely to take a minimum of 4 weeks longer.

Step 4: At this point, to finalize ethics approval, students just need to have the project design approved via the proposal defense. Thus, once the students successfully defend their proposal, the MyDR system will automatically copy the IRB on the proposal approval notice and that will trigger the *IRB to reach out to the students via e-mail to confirm whether/how the data collection plan might have changed* as a result of the proposal defense. If changes to the data collection plan were made, then the IRB will need updated versions of the ethics application materials. If the students confirm no changes were made, then the IRB will e-mail the students and chairs a formal ethics approval notification which signifies that the students may begin collecting data.

Doctoral students must be actively enrolled in the doctoral study course shell to receive final IRB approval notification and must remain enrolled while collecting data. IRB approval is not valid if students are on a leave of absence or otherwise not enrolled.

**Ethical Requirements for CPGD Doctoral Projects**

Regardless of which data sources are analyzed, all DNP students completing CPGD doctoral projects are required to adhere to the following ethical requirements:

- In the doctoral project documents, the doctoral students must change the name of any partner organizations and generalize the location(s) so that the organizations are not identifiable. It is important that the doctoral students redact any information that will lead a reader to identify an organization’s identity. It is up to the organization to decide if the project should be publicized. Therefore, it is not appropriate for doctoral students to make the partner site’s name known in the doctoral project document that is published in ProQuest. The doctoral students are required to change the name of the organization in all materials (including drafts shared with peers and faculty members) to protect the organization’s identity. In some cases, it might be appropriate for the doctoral students to maintain confidentiality by removing key pieces of evidence and/or data that might give away the organization’s identity. The doctoral students should direct questions to IRB@mail.waldenu.edu when these situations arise.

- The doctoral students may not collect any type of data from patients or patients’ family members for this type of project. If, at some point, the doctoral students wish to pursue that type of data collection, they will need to follow the standard university procedures to obtain prior approval from the Walden University IRB. Collecting data from human subjects without appropriate IRB approval can result in invalidation of the data and dismissal from the program.
• The doctoral students are responsible for ensuring that no proprietary, sensitive, or confidential information is disclosed in the doctoral project document.

• The doctoral students are responsible for complying with all of the organization’s policies. This includes, but is not limited to, site IRB policies and site resource use policies (pertaining to copying/printing materials, etc.).

Please note that Walden University does not accept responsibility or liability for research activities conducted without the IRB’s ethics approval, and the university will not accept or grant credit for student work that fails to comply with the policies and procedures related to ethical standards in research.

Other student obligations will be outlined in the final page of Form A. Faculty supervision requirements for CPGD projects include the following:

• The supervising faculty member will ensure that the students properly request any project design changes by e-mailing ethicsDNP@mail.waldenu.edu.

• The supervising faculty member will ensure that the students promptly report any unexpected or otherwise significant adverse events and general problems within 1 week by e-mailing ethicsDNP@mail.waldenu.edu.

• The supervising faculty member will report any possible noncompliance on the part of the students by e-mailing ethicsDNP@mail.waldenu.edu.

• The supervising faculty member’s supervision role continues as long as the students remain enrolled in the present course with the faculty member.

### Data Sources That Have Been Preapproved by IRB for Clinical Practice Guideline Development Doctoral Projects

<table>
<thead>
<tr>
<th>Data Sources</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Public Data: Reports, Websites</strong></td>
<td>Media coverage, publically disseminated reports, public websites, and any information that is available to the public</td>
</tr>
<tr>
<td><strong>Literature as Data</strong></td>
<td>Books, peer-reviewed articles, and other bodies of written knowledge that communicate theories and findings about practices that are relevant to the student’s doctoral project</td>
</tr>
<tr>
<td><strong>Anonymous Questionnaires from Expert Panelists</strong></td>
<td>Using the preapproved Disclosure to Expert Panelist Form in Appendix B, students may conduct paper or online surveys of expert (staff) panelists as long as they are anonymous.</td>
</tr>
</tbody>
</table>
Partner Organization’s Internal Data*: Operational Records and Other Artifacts

Partner organization’s deidentified records* including: aggregate** patient records, operational records pertaining to staff training and delivery of care, meeting minutes, digital/audio/video recordings created by site, training materials, protocols, manuals, reports, agreements, questionnaires that were administered under auspices of site as part of quality improvement (QI) operations, and other internal documents that the site has released to the student for use in the doctoral project.

*As the partner organization’s leadership deems fit to share with student (as per confidentiality terms in this guide)

**Students are only preapproved to analyze patient records that have been aggregated via asking a site contact for high level summary data (without the student actually looking at patient records). Examples:

- Citing rates of certain diagnoses: “Before the new protocol was implemented, 20% of asthma cases were readmitted within 30 days. After the protocol was implemented, re-admissions went down to 10%.”
- Citing patterns among patients: “At this facility, males are twice as likely to be admitted for [X diagnosis] than females.”
- Press Ganey scores can be analyzed.
- Patient satisfaction reports can be analyzed.

The table below includes those data tools that do NOT fall under the IRB’s preapproval. Any students wishing to analyze one of the data sources below must go through the standard IRB process to gain formal IRB approval independently.

<table>
<thead>
<tr>
<th>Data Sources That are NOT Preapproved by IRB for Clinical Practice Guideline Development Doctoral Projects</th>
</tr>
</thead>
<tbody>
<tr>
<td>(These all require the student to obtain IRB review/approval independently via the standard process.)</td>
</tr>
<tr>
<td><strong>Patient Records With Identifiers</strong></td>
</tr>
<tr>
<td>While students may in some cases access patient records during the practicum in support of patient care, the IRB preapproval does not cover students accessing patient records for the purpose of the doctoral project analysis.</td>
</tr>
<tr>
<td><strong>Interviews or Focus Groups</strong></td>
</tr>
<tr>
<td>The preapproval does not cover interviews or focus groups.</td>
</tr>
<tr>
<td><strong>Data Collection From Patients</strong></td>
</tr>
<tr>
<td>The preapproval does not cover posing questions to patients via any method (questionnaires, interviews, focus groups).</td>
</tr>
<tr>
<td>Video as Data</td>
</tr>
<tr>
<td>---------------------</td>
</tr>
<tr>
<td>Observations of Specific Individuals</td>
</tr>
</tbody>
</table>

This manual and its appendices may not be modified without prior approval from the IRB. Please submit proposed revisions to IRB@mail.waldenu.edu.
RESOURCES

AGREE II Resources
- Available resources include free downloadable copies of the AGREE II and links to the online training tool.

Cochrane Library
- http://www.cochrane.org

Evidence-Based Practice Research Guide at Walden University Library
- http://academicguides.waldenu.edu/healthevidence
- Guidelines Resource Center http://www.cancerview.ca/TreatmentAndSupport/GRCMain/

Joanna Briggs Institute EBP Database
- https://www.brainshark.com/wkovid/vu?pi=zHrzq3No5z2tkwz0&cmpid=Brainshark:IntroToJBIEBPDatabase

Johns Hopkins Nursing Evidence-Based Practice Model and Guidelines

Fineout-Overholt, Melnyk, Stillwell, and Williamson
- Critical appraisal of the Evidence: Part I An introduction to gathering, evaluating, and recording the evidence.
  http://download.lww.com/wolterskluwer_vitalstream_com/PermaLink/NCNJ/A/NCNJ_541_516_2011_01_13_DFGD_5161_SDC516.pdf

National Guideline Clearinghouse
- AHRQ database of clinical practice guidelines summaries and video tutorial:
  http://www.youtube.com/watch?feature=player_embedded&v=pytfoQ2K-u8
Suggested Readings


APPENDIX A: SITE APPROVAL DOCUMENTATION FOR CPGD DOCTORAL PROJECT

Partner Site
Contact Information
Date

The doctoral student, [Insert Student Name], is involved in developing updated Clinical Practice Guidelines for our organization, and is therefore approved to collect questionnaire data from expert panelists (staff members) in support of that effort, in addition to analyzing internal, de-identified site records that I deem appropriate to release for this doctoral project. This approval to use our organization’s data pertains only to this doctoral project and not to the student’s future scholarly projects or research (which would need a separate request for approval).

I understand that, as per DNP program requirements, the student will publish a scholarly report of the development of these Clinical Practice Guidelines in ProQuest as a doctoral capstone (with site and individual identifiers withheld), as per the following ethical standards:

a. In all reports (including drafts shared with peers and faculty members), the student is required to maintain confidentiality by removing names and key pieces of evidence/data that might disclose the organization’s identity or an individual’s identity or inappropriately divulge proprietary details. It is up to the organization to choose if the project should be publicized.

b. The student will be responsible for complying with our organization’s policies and requirements regarding data collection (including the need for the site IRB review/approval, if applicable).

c. Via a Disclosure to Expert Panelists Form (which is similar to a consent form but doesn’t need to be signed), the student will describe to panelists how the data will be used in the doctoral project and how the stakeholders’ integrity and privacy will be protected.

I confirm that I am authorized to approve these activities in this setting.

Signed,

Authorization Official Name
Title
APPENDIX B: DISCLOSURE TO EXPERT PANELIST FORM FOR ANONYMOUS QUESTIONNAIRES

To be given to an expert panelist prior to collecting questionnaire responses—note that obtaining a “consent signature” is not appropriate for this type of questionnaire and providing respondents with anonymity is required.

Disclosure to Expert Panelist

You are invited to take part in an expert panelist questionnaire for the doctoral project that I am conducting.

Questionnaire Procedures

If you agree to take part, I will be asking you to provide your responses anonymously, to help reduce bias and any sort of pressure to respond a certain way. Panelists’ questionnaire responses will be analyzed as part of my doctoral project, along with any archival data, reports, and documents that the organization’s leadership deems fit to share. If the revisions from the panelists’ feedback are extensive, I might repeat the anonymous questionnaire process with the panel of experts again.

Voluntary Nature of the Project

This project is voluntary. If you decide to join the project now, you can still change your mind later.

Risks and Benefits of Being in the Project

Being in this project would not pose any risks beyond those of typical daily professional activities. This project’s aim is to provide data and insights to support the organization’s success.
**Privacy**

I might know that you completed a questionnaire but I will not know who provided which responses. Any reports, presentations, or publications related to this study will share general patterns from the data, without sharing the identities of individual respondents or partner organization(s). The questionnaire data will be kept for a period of at least 5 years, as required by my university.

**Contacts and Questions:**

If you want to talk privately about your rights in relation to this project, you can call my university’s Advocate via the phone number 612-312-1210. Walden University’s ethics approval number for this study is (Student will need to complete Form A in order to obtain an ethics approval number).

Before you start the questionnaire, please share any questions or concerns you might have.