Doctor of Nursing Practice  
IRB Guidelines

IRB Process
It is recommended that the DNP candidate discuss the IRB process with their clinical mentor. The candidate should share a copy of the application and begin to set goals as to how the candidate and clinical mentor will collaborate. The IRB process will be completed in Practice Inquiry and IRB (NRDNP 862). If IRB is required at the clinical site and the clinical mentor does not have experience with formal research and IRB process, it is recommended that the student seek consultation from persons familiar with research design, statistical analysis, and/or IRB process. The IRB process will be written in Practice Inquiry and IRB (NRDNP 862) but cannot be submitted until the project defense has been approved and any changes are made.

IRB Approval
In accordance with the Belmont Report, all MUSC DNP candidates must adhere to ethical standards in conducting research. There are different levels of IRB approval depending upon the type of project. The three IRB review categories are exempt, expedited, and full review.

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<tr>
<th>IRB Review Categories</th>
<th>Description</th>
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<tr>
<td>Exempt</td>
<td>Means that the research is exempt from some of the federal regulations regarding human subject protections. Exempt studies still need to be reviewed by the IRB to make sure the proposed study meets the requirements for this level of review.</td>
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<tr>
<td>Expedited</td>
<td>Does not mean “fast track.” The study is less than minimal risk, thus it does not require the full board to review. While more review time is needed when compared to an exempt review, it is hoped that this process takes less time than a full board review would require, but many factors go into that, including how well prepared the application is.</td>
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<tr>
<td>Full Review</td>
<td>Full review requires most IRB forms and must be reviewed by the full IRB committee. Logically this is a lengthy process.</td>
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The student should not assume that any of these levels of review are less important. Each level is to be considered seriously and students should plan to spend a considerable amount of time in this phase following the IRB instructions explicitly. Shortcuts and assumptions add to the students overall timeline.
Many times, because IRBs are composed of a variety of individuals (including lay persons), methodological and human subject concerns may be raised that were not anticipated by the candidate or draft reviewers. Candidates should respect the need for changes in their projected timelines in order to address issues raised by the IRB.

It is important to note that **any changes to the project**, once approved by IRB, **must go back to IRB** for re-approval. Students may not begin any changes in their project without IRB approval.

**Guidance For Data Handling and Data Protection- Why and How**

The HIPAA (Health Insurance Portability and Accountability Act) Privacy Rule establishes the conditions under which protected health information (PHI) may be used or disclosed by covered entities for research purposes. Research is defined in the Privacy Rule as, “a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.”

The U.S. Department of Health and Human Services issued new regulations in 2009 requiring health care providers, health plans and other entities covered by HIPAA to notify individuals when their PHI is breached. Recently, a Connecticut State Attorney General filed an action against a HIPAA "covered entity" that was charged with a serious data breach after a computer disk drive, containing personal information of over 500 individuals, was stolen and the company failed to take appropriate actions. The company was fined $250,000 and was required to develop and implement a “corrective action plan.” This legal action sends a strong message to all users of private health information about their profound responsibilities to protect health and medical records.

Thus, it is imperative that students engaged in an MUSC online or distance education program store research data in a secure location. The best option to protect against breaches is to collect and store data that is de-identified. However, this may not always be a feasible option due to the design of the research. If the study requires the collection and storage of identifiable PHI, please note the following:

1. **The MUSC IRB prohibits the use of identifiable databases containing PHI.** Information in databases must be stored in a de-identified format.
2. **MUSC strictly prohibits the use of portable devices (e.g. thumb drives, flash drives, CDs, PDAs, laptops) for identifiable PHI.**
3. **Students can access MUSC servers from off-site locations via the MUSC virtual private network (VPN) for secure storage of PHI.**
4. **The REDCap database is an additional option for the storage of PHI on secure MUSC servers.**

**HOW DO I KNOW IF I AM COLLECTING “IDENTIFIABLE PHI”?**

- What is Protected health information (PHI)?
  - Individually identifiable health information
  - Transmitted or maintained in any form or medium by a Covered Entity or its Business Associate
- What is “individually identifiable health information”? 
• Health information, including demographic information
  o Relates to an individual’s physical or mental health or the provision of or payment for health care
  o Identifies the individual
• What is not PHI?
  o Employment records of Covered Entity
  o Family Educational Rights and Privacy Act (FERPA) records

De-identification of PHI
• Removal of certain identifiers so that the individual who is subject of the PHI may no longer be identified
• Application of statistical method or
• Stripping of listed identifiers such as:
  o Names
  o Geographic subdivisions < state
  o All elements of dates
  o SSNs, etc.

There are also additional standards and criteria to protect individual's privacy from re-identification. Subject identifiers must not be used as a code to link data to individual subjects. The code must be a random linking code. Any code used to replace the identifiers in datasets cannot be derived from any information related to the individual. For example, a participant’s initials cannot be used as a linking code nor can the unique code include the last four digits (in sequence) of the social security number. Additionally, the researcher must not have actual knowledge that the research subject could be re-identified from the remaining identifiers in the PHI used in the research study. In other words, the information would still be considered identifiable is there was a way to identify the individual even though all of the 18 identifiers were removed.

List of 18 Identifiers:
1. Names;
2. All geographical subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code, if according to the current publicly available data from the Bureau of the Census: (1) The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and (2) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.
3. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older;
4. Phone numbers;
5. Fax numbers;
6. Electronic mail addresses;
7. Social Security numbers;
8. Medical record numbers;
9. Health plan beneficiary numbers;
10. Account numbers;
11. Certificate/license numbers;
12. Vehicle identifiers and serial numbers, including license plate numbers;
13. Device identifiers and serial numbers;
14. Web Universal Resource Locators (URLs);
15. Internet Protocol (IP) address numbers;
16. Biometric identifiers, including finger and voice prints;
17. Full face photographic images and any comparable images; and
18. Any other unique identifying number, characteristic, or code (note this does not mean the unique code assigned by the investigator to code the data)

Minimum Human Research Protections Programs (HRPP) Standards for the Collection, Storage, and Use of Subject Identifiers for Human Subjects Research

IRB applications require investigators to address issues related to subject privacy and confidentiality, HIPAA, and information security. Before filling out IRB applications, please keep in mind the following HRPP minimum standards:

• Do not collect any subject identifiers you do not need.
• Remove/destroy subject identifiers as soon as they are no longer needed, subject to MUSC guidance on records retention. (MUSC IRB Policy 10.2: Record Retention Policy [http://research.musc.edu/ori/irb/policies.html])
• Restrict physical access (i.e. locked office, locked file cabinet) to any area or computer system that contains subject identifiers.
• Restrict electronic access (i.e. password protected) to any computer system that contains subject identifiers.
• Do not transmit PHI by email unless using Ironport.
• Subject identifiers should never be stored on laptops, PDA’s, flash drives or other portable devices.

The MUSC IRB prohibits the use of identifiable databases containing PHI. Subject identifiers must be removed from data files, and must be encrypted if stored electronically. Identifiers must be stored in a physically separate and secure location from the data files, and associated with data files through a code that is also stored in a separate and secure location. Subject identifiers and contact information may not be distributed outside of MUSC without the specific informed consent of the subjects and the approval of the IRB.

Example description of de-identified data storage & protection plan for IRB application

Data Storage & Protection Plan. The master list linking participant names to the study IDs will be maintained by the PI and kept in locked cabinets in a locked office (or on a password protected computer and/or server) that can only be accessed by the PI and approved study staff. Data entered into the study database will only identify a participant via the study ID code. All communications among study personnel relative to individual
study participants will be via the de-identified study ID. The study database will meet MUSC requirements for data security and confidentiality, including use of anti-virus software and protection against unauthorized access.

*See MUSC IRB Policy 4.13: Privacy and Confidentiality (http://research.musc.edu/ori/irb/policies.html)*

*For an overview of Principal Investigator Responsibilities, See MUSC IRB Policies 5.1 and 5.2 (http://research.musc.edu/ori/irb/policies.html)*
Appendix A

Overview of the differences between QI and Research

Examples of implementing a practice and collecting patient or provider data for non-research clinical or administrative purposes include:

- A radiology clinic uses a database to help monitor and forecast radiation dosimetry. This practice has been demonstrated to reduce over-exposure incidents in patients having multiple procedures. Patient data are collected from medical records and entered into the database. The database is later analyzed to determine if overexposures have decreased as expected.

- A group of affiliated hospitals implements a procedure known to reduce pharmacy prescription error rates, and collects prescription information from medical charts to assess adherence to the procedure and determine whether medication error rates have decreased as expected. A clinic increasingly utilized by geriatric patients implements a widely accepted capacity assessment as part of routine standard of care in order to identify patients requiring special services and staff expertise. The clinic expects to audit patient charts in order to see if the assessments are performed with appropriate patients, and will implement additional in-service training of clinic staff regarding the use of the capacity assessment in geriatric patients if it finds that the assessments are not being administered routinely.

*If you are unsure or need clarification in making the determination of whether your project is QI or Research, please contact Katherine Bright at the IRB, 792-4843.*

<table>
<thead>
<tr>
<th>Research</th>
<th>QI</th>
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<tbody>
<tr>
<td><strong>Purpose</strong></td>
<td>To test a hypothesis OR to establish clinical practice standards where none are already accepted</td>
</tr>
<tr>
<td><strong>Benefits</strong></td>
<td>Knowledge sought may or may not benefit current subjects, but may benefit future patients</td>
</tr>
<tr>
<td><strong>Risks/Burdens</strong></td>
<td>May put subjects at risk</td>
</tr>
<tr>
<td><strong>Methods</strong></td>
<td>Systematic data collection</td>
</tr>
<tr>
<td><strong>Analysis</strong></td>
<td>Statistically prove or disprove hypothesis</td>
</tr>
<tr>
<td><strong>Result</strong></td>
<td>Answer a research question</td>
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The QI project must be submitted to the IRB if the response to any of the following is “False”:

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<tbody>
<tr>
<td>1.</td>
<td>The purpose of the project is to improve performance on a specific service or program in the institution and is part of usual care.</td>
<td>True</td>
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<tr>
<td>2.</td>
<td>The project involves implementation of established and tested quality standards and/or systematic monitoring, assessment, or evaluation of the institution to ensure existing quality standards are being met. The project does NOT develop untested methods or new untested standards.</td>
<td>True</td>
</tr>
<tr>
<td>3.</td>
<td>There is NO random assignment of participants to compare outcomes. Randomization implies an experimental approach thus projects using randomization of participants fall into the category of “research”.</td>
<td>True</td>
</tr>
<tr>
<td>4.</td>
<td>Results will NOT be used to apply knowledge to other programs outside the institution where the project occurs. Application of results to other programs outside the institution implies the intent to contribute to generalizable knowledge.</td>
<td>True</td>
</tr>
<tr>
<td>5.</td>
<td>The project is NOT subject to peer review (designed to be used outside of the institution). Application of results to other programs outside the institution implies the intent to contribute to generalizable knowledge.</td>
<td>True</td>
</tr>
<tr>
<td>6.</td>
<td>Anonymity of participants is assured. If patient data includes patient identifiers, anonymity cannot be assured. Collecting de-identified data supports anonymity of participants.</td>
<td>True</td>
</tr>
<tr>
<td>7.</td>
<td>The activities involve no more than minimal risk to participants. Minimal risk is the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.</td>
<td>True</td>
</tr>
<tr>
<td>8.</td>
<td>If there is an intent to, or possibility of publishing your work, you and your Project Advisor are comfortable with the following statement in your Methods section: “This project was conducted as a Quality Improvement initiative, and as such was not formally supervised by the Institutional Review Board per their policies.”</td>
<td>True</td>
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