THE CHAMBERLAIN IRB

The Chamberlain College of Nursing Institutional Review Board (IRB) is accountable for ensuring that human subjects are protected during research/projects conducted under its jurisdiction. The Chamberlain IRB’s primary responsibility is to enforce the rules of the US Department of Health and Human Services and all relevant laws and regulations in order to protect the rights and welfare of human subjects recruited for, or participating in, research/projects conducted by Chamberlain faculty, staff or students.

The rules for IRBs evolved from landmark ethical standards including the Nuremberg Code, the Declaration of Helsinki and the Belmont Report. The Chamberlain IRB is committed to the objective that research at Chamberlain College of Nursing must meet the highest standards of ethical conduct as defined by these and other documents.

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Comprehensive consumer information is available at chamberlain.edu/studentconsumerinfo.
THE ROLE OF THE INSTITUTIONAL REVIEW BOARD (IRB)

The framework for the Chamberlain IRB structure and function is derived from the Department of Health and Human Services (DHHS) Regulations, Title 45 of the Code of Federal Regulations part 46. These regulations (often referred to as “The Common Rule” because they were adopted by 16 different federal departments and agencies) address minimum levels of human subjects protection in research. In addition, the IRB closely follows policies and guidance provided by the Office for Human Research Protections (OHRP) in the United States Department of Health and Human Services, the federal agency charged with ensuring compliance with the regulations.

The IRB strives to create a supportive, collaborative environment for members of the Chamberlain community so that the design and implementation of research studies take place in a culture of ethical conduct. Nonetheless, the responsibility of the IRB is limited to review of research/project proposals for compliance with ethical standards, federal rules and other applicable laws. **The IRB does not provide advisement or mentoring on study design nor does it assist students or faculty in creating required documents.** Specific areas of emphasis for the IRB include:

- Protecting the privacy of participants and confidentiality of their data or records
- Respecting the autonomy and dignity of participants
- Ensuring that decisions concerning participation are voluntary
- Minimizing risks while maximizing benefits to participants
- Ensuring participants have adequate information to make informed decisions
- Ensuring that the benefits and risks of research are equally distributed
- Protecting vulnerable populations

Chamberlain’s IRB applies the policies and guidance in this handbook for all research/projects involving human subjects that:

- Is conducted by or at the direction of the administration of Chamberlain College of Nursing
- Is conducted by any faculty member of Chamberlain College of Nursing (of any rank or track) in connection with his or her institutional responsibilities
- Is conducted by any staff member of Chamberlain College of Nursing
- Is conducted by any student enrolled in Chamberlain College of Nursing
- Is conducted using any property or facility of Chamberlain College of Nursing

REQUIRED COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI) FOR ALL RESEARCHERS

The Chamberlain IRB requires that all persons submitting proposals to the IRB first complete the assigned training modules provided by the CITI located at [https://www.citiprogram.org/](https://www.citiprogram.org/). These modules present foundational information on the ethical and legal implications of human subjects research.

The CITI website will prompt you through registration. You will be asked to designate Chamberlain as your affiliated institution. Depending upon your role, you should register for either the “Faculty or Staff Researchers”; the “Student Researchers”; or the “IRB Member” curriculum. Each category includes a different set of modules to complete. Faculty, staff and students should anticipate spending between three-to-five hours completing all the required modules; IRB committee members should expect to spend about eight hours to complete the modules. After finishing the CITI program, you may request a completion report which serves as verification of successful completion. This form must accompany the other documents submitted with your IRB proposal.

CITI program certification expires after five years. If your certification is still current, you need not retake the CITI program; however, you must submit a copy of your completion report with each IRB submission.

NOTE: Some research/projects involve specialized populations or include unique elements. The IRB may require completion of additional modules if appropriate.
FREQUENTLY ASKED QUESTIONS (FAQS)

What is research?

Department of Health and Human Services (DHHS) defines research as “a systematic investigation designed to develop or contribute to generalizable knowledge.” DHHS further defines “human subject” as “a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual or identifiable private information.” DHHS does not define what constitutes generalizable knowledge or a contribution to generalizable knowledge. The lack of clarity on generalizable knowledge has forced IRBs to interpret the definition of research in light of dynamic scientific, academic, business and healthcare environments.

Newer forms of scholarly activity are becoming increasingly important and commonplace in healthcare, including quality improvement (QI) and evidence-based practice (EBP) change activities. Using various methods, QI activities apply existing knowledge to improve existing practice, whereas EBP change activities translate existing knowledge into practice settings to change existing practice. Both types of activities aim to improve selected system or client outcomes that are setting specific. The setting specific emphasis of QI and EBP change activities typically does not generate generalizable knowledge and, therefore, would not be considered human subjects research.

When dissemination of information generated from QI and EBP change projects goes beyond the project setting, some have assumed that the information becomes a contribution to generalizable knowledge. DHHS has further clarified that such dissemination does not, in and of itself, make QI “research”. Presentation or publication of findings from non-research activities serves non-generalizable purposes, including strengthening the evidence base for a particular intervention or sharing process and implementation information in order to facilitate other QI, EBP change and research projects.

Based on a synthesis of the literature and definitions used by multiple academic IRBs, the Chamberlain IRB defines generalizable knowledge as information that would be applicable to populations outside the study population in order to draw conclusions, expand theory or the knowledge base of a particular field of study, or inform policy beyond the study setting. Projects that do not involve human subjects nor develop or contribute to generalizable knowledge do not need IRB review.

The Chamberlain IRB, however, will consider a project to be research if:

- The aim of the project is to test a theoretical model or assess its applicability to a specific setting
- The project implements an intervention that is untested or deviates substantively from the evidence base
- The aim of the project is to replicate or extend a previous research study

The following cases are provided as examples.

Example 1: A student implements and evaluates a program of follow-up telephone calls to clients of a wound care clinic in order to catch possible wound infections earlier in the treatment course. This program has been used effectively in other ambulatory clinics. (Not research, application of existing evidence. No IRB review required.)

Example 2: A student implements and evaluates the introduction of group appointments for Hispanic and Caucasian clients. (Research, intervention untested in this unique population. IRB review required.)

Example 3: An instructor explores whether or not self-efficacy is influenced by level of acculturation in Haitian students. (Research, theory testing/expansion. IRB review required.)

Example 4: Congruent with the “flipped classroom” model, an instructor introduces lectures that students access from home accompanied by devoted in-class case studies in a section of NR-340 and monitors student outcomes. (Not research, application of current evidence in a limited setting. No IRB review required.)

Example 5: An instructor integrates components from two, well-tested remediation models into one comprehensive model that is then piloted the next semester. (Research, substantive deviation from the evidence base. IRB review required.)

If a project does not meet the criteria for research, the project is not required to have an IRB review. The project, however, may still be subject to reviews by other Chamberlain bodies. A decision tree to assist investigators in determining whether or not a project should be reviewed by the IRB is provided on the following page. If an investigator is not clear whether a specific project constitutes research, the investigator should contact the IRB at irb@chamberlain.edu.

Occasionally, a QI or EBP change project may produce unexpected results that investigators may want to share with the larger community as new information that contributes to the knowledge base. In this case, investigators may wish to change the aim of the project to that of a research study. At this point, investigators should halt the project and seek IRB review and approval to continue. The IRB cannot retroactively approve a study.
DECISION TREE FOR DETERMINATION OF WHETHER A PROJECT REQUIRES REVIEW FROM THE CHAMBERLAIN COLLEGE OF NURSING INSTITUTIONAL REVIEW BOARD (IRB)

Does the project involve the collection of data, information or specimens from a living individual through intervention or interaction, or does it involve the collection of identifiable personal data?

- **NO**
  - Project does not need IRB review

- **YES**
  - Will the project generate information that could be applied to populations beyond the project setting that could be used to:
    - Draw conclusions about outside populations?
    - Expand or test a theoretical model or its applicability in a given population?
    - Inform policy beyond the project setting?

  - **NO**
    - Will the project implement an intervention that is untested or deviates substantively from its documented use?
      - **NO**
        - Project does not need IRB review
      - **YES**
        - Project requires IRB review. Submit IRB application and relevant materials to irb@chamberlain.edu

  - **YES**
    - Will the project replicate or extend a previous research study?
      - **NO**
        - Project does not need IRB review
      - **YES**
        - Project requires IRB review. Submit IRB application and relevant materials to irb@chamberlain.edu
How do I know if my research involves human subjects?

Federal rules and regulations provide the following definitions to help you determine if your project will involve human subjects.

Human subjects are defined as living individuals about whom an investigator will be collecting data through direct intervention with the person, interaction with the person or from identifiable private information.

Intervention is defined as physical procedures by which data are gathered (e.g., venipuncture, blood pressure, etc.) and/or manipulations of the subject or the subject’s environment that are performed for research purposes. Interaction is defined as communication or interpersonal contact between the investigator and the subject (e.g., an interview).

Private information is defined as “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 (e.g., a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may be easily discovered by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.” (45 CFR 46.102(f))

If your research project will include intervening or interacting with individuals or with their private identifiable information, then it involves human subjects.

Only proposals meeting both definitions of research and human subjects are required to be reviewed by Chamberlain’s Institutional Review Board (IRB).

Who will review my research?

Chamberlain’s IRB has the authority to review and approve all human subjects research conducted within its jurisdiction. The members of the Chamberlain IRB must develop and demonstrate competency in the protection of human research subjects by completing required training in the online Collaborative Institutional Training Initiative (CITI).

IRB members are appointed by the College president on the recommendation of the vice president of academic affairs. Members are full-time faculty or staff with demonstrated experience and interest in the research process. In addition, the IRB must include at least one external community member. Members must be capable of determining whether proposed research complies with College commitments and regulations, applicable law, and standards of professional conduct and practice. Diversity in gender, background, race/ethnicity and areas of scientific and ethics expertise must be present among the members. Occasionally, the IRB may use consultants if members lack specific areas of expertise relevant to a given proposal.

When do I submit my research proposal for review by the IRB?

When developing your research proposal, make sure sufficient time is allotted for the IRB review. Most student and many faculty/staff research studies pose minimal or low risk of harm to human subjects. Such research can be reviewed relatively quickly, often within two weeks. Some research studies involve greater risk, involve particularly vulnerable populations, or are complex in design or content. Such research requires review by the entire IRB membership and will require more time to review. It is important to note, however, that delays might occur at any time. Submissions are often incomplete or unclear requiring back-and-forth communication between the IRB and the submitter. Even if you believe your proposed research study poses minimal risk, you should plan sufficient time for any clarification or revisions requested by the IRB. If your proposal is denied, you will have an opportunity to modify your planned research and resubmit your request. You should allow at least four-to-six weeks for any resubmission and secondary review.

NOTE: The IRB may not approve studies that have already been completed (retroactive approval). Under certain conditions, the IRB may review and approve studies that have already commenced; however, data collected from subjects prior to IRB approval may not be used if changes in current study protocols are required for IRB approval.

Where can I get assistance?

Preparing a research proposal and completing an IRB application for approval can be challenging. Students with questions about their proposals and IRB applications should work with their faculty advisors. Faculty and staff members with questions about their proposals and IRB applications should work with a mentor who has demonstrated expertise in conducting research.

What are the procedures for submitting an application to the IRB?

Researchers sometime believe the IRB application and supplemental forms will be easy and quick to complete. Unlike other applications you may have completed, the IRB forms will require additional preparation time because you may need to make revisions, seek additional input, consider new ideas or grapple with difficult ethical issues. It is often surprising to students and faculty that the preparation of an IRB submission package may take a significant amount of time and energy. IRB forms contain a series of guided questions that require you to reflect on your study design, information about how your study will be conducted and protection of human subjects and their private information.

In order to demonstrate to the IRB that your plan for protecting human subjects is adequate, your completed forms must be intelligible to the reviewer (a person who may not have expertise in your specialty area) and must demonstrate that your study meets the IRB’s criteria for approval. The reviewer will look for evidence that your decisions are based on thoughtful attention to responsible and ethical practices and a clear assessment of risk. The reviewer will determine whether or not you have adequate rationales for your recruitment strategies, informed consent processes, study procedures and data management plans.
All forms needed for submission of a research proposal may be accessed on the IRB link on the Chamberlain homepage or obtained by sending an email request to IRB@chamberlain.edu. Completed forms should be submitted electronically as email attachments to IRB@chamberlain.edu. Make sure all forms are signed (when appropriate) prior to submission.

The amount of material that must be submitted to the IRB will vary upon the type of study. All initial submissions require the following:

1. IRB Application Form
2. Investigator’s Assurance and Confidentiality Form
3. Confirmation of Completion of the (CITI) modules as required by Chamberlain College of Nursing

Other materials that may be required include:

1. Recruitment and advertisement materials
2. Study instruments (e.g., surveys, questionnaires, assessment tools, protocols, interview guides, etc.)
3. Copy of the consent form that will be signed by participants
4. Copy of the information letters and directions given to participants
5. Copy of assent forms (for minors) and parental consent forms
6. Copies of approvals from other/collaborating IRBs
7. Letters of support
8. Others (e.g., HIPAA forms, authorizations, certifications, etc.)

NOTE: Failure to complete all IRB forms and/or failure to include all relevant materials will delay the approval process and may result in the submission being returned without being reviewed.

*All surveys, questionnaires and other tools competed by study subjects that will be administered to Chamberlain students, staff or faculty must first be reviewed and approved by the Chamberlain Office of Institutional Effectiveness (OIE). This review and approval process ensures that members of the Chamberlain community are not burdened by numerous surveys in a short period of time or with redundant surveys. The OIE review and approval process is separate from, but compliments to, the IRB review process. Investigators should provide documentation with the IRB application submission that the study instrument has received OIE approval. Further information on the OIE review and approval process is available by contacting John Loafman at jloafman@chamberlain.edu. Additionally, study instruments such as surveys and questionnaires may not include the Chamberlain logo or other branding material without approval from Chamberlain Marketing.

Are there special considerations for grant-supported studies?

DHHS regulations require that the IRB review the actual application or proposal for DHHS support to ensure that all research described in the application or proposal is entirely consistent with any corresponding protocol(s) submitted to the IRB. Other funding agencies also have this same requirement. Provide the cover page and narrative section of the grant proposal (i.e., specific aims, background, preliminary studies, research design/methods and human subjects) unless otherwise requested by the Chamberlain IRB.

What does the IRB consider in its review?

The IRB looks closely at the materials submitted with the application to ensure that:

1. Risks to subjects are minimized (a) by using procedures that are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (b) whenever appropriate, by using procedures already performed on the subjects for diagnostic or treatment purposes.

2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB considers only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB does not consider possible long-range effects of applying knowledge gained from the research (e.g., the possible effects of the research on public policy) as benefits that fall within the purview of its responsibility.

3. Selection of subjects is equitable. In making this assessment, the IRB takes into account the purposes of the research and the setting in which the research is conducted. The IRB is particularly cognizant of the special considerations of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally challenged persons, or economically or educationally disadvantaged persons.

4. Informed consent is sought from each prospective subject or the subject’s legally authorized representative, in accordance with, and to the extent required by 45 CFR 46.116.

5. The research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

6. There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

7. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally challenged persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.
The Chamberlain College of Nursing IRB has identified the following types of risk or discomfort as those which are most often considered during study review:

1. **Physical risks:** These risks include physical discomfort, pain, injury, illness or disease brought about by the methods and procedures of the research.

2. **Psychological risks:** Psychological risks may be experienced during participation and/or after participating in the research. These risks include anxiety, stress, fear, confusion, embarrassment, depression, guilt, shock, loss of self-esteem and/or altered behavior.

3. **Social/Economic risks:** Social risks include alterations in relationships with others that are to the disadvantage of the subject and may involve embarrassment, loss of respect of others, labeling with negative consequences or diminishing the subject’s opportunities and status in relation to others. Economic risks include payment by subjects for procedures, loss of wages or income and/or damage to employability or insurability.

4. **Legal risks:** Legal risks include risk of criminal prosecution or civil lawsuit when research methods reveal that the subject has or will engage in conduct for which the subject or others may be criminally or civilly liable.

The following are particularly important areas carefully reviewed by the IRB.

**USE OF INCENTIVES TO RECRUIT SUBJECTS**

The Federal government does not specifically regulate the use of incentives for subjects in a research study, but any incentive should not be of an amount or kind that might inhibit a potential subject’s ability to choose freely whether or not to participate. Incentives cannot be coercive and must not pose an undue amount of influence on the subject in order to encourage participation. When reviewing a proposed incentive for appropriateness, the IRB considers subject characteristics, which incentives are being offered and the conditions under which the incentive offer is made. Informed consent documents must include a detailed description of the terms of the incentive, including an account of the conditions under which a subject might not receive the full incentive.

**COMPENSATION FOR PARTICIPATION**

Compensation for participation in research might be appropriate but cannot be used as coercive persuasion. Compensation, when offered, should recognize the investment of the subjects’ time, risk, expense, loss of wages or other inconveniences. When reviewing proposed compensation, the IRB will examine the informed consent documents for a detailed account of the terms of the compensation, including a description of the conditions under which a subject might not receive the full compensation offered. Compensation may not be withheld contingent on the subject’s completion of the study.

**INFORMED CONSENT**

The Chamberlain IRB provides consent form templates online for use by researchers. These forms, with occasional minor adjustments appropriate to the individual study, demonstrate that informed consent is obtained appropriately.

If investigators decide to use any other source for a consent document (including his/her own design or another IRB’s design), the following information must be included [45 CFR 46.116(a)]:

- A description of the purpose of the research
- A description of the procedures that subjects are asked to participate in or undergo
- A description of any reasonably foreseeable risks, discomforts or inconveniences that may be associated with the research activity
- A description of any benefits (if any) subjects may reasonably expect to receive, as well as a description of the importance of the knowledge that may be gained from the research.

**NOTE:** Incentives and/or compensations to subjects (see above) are not considered benefits and should not be listed as such in the consent document.

- A description of the procedures in place to maintain confidentiality
- Names and contact information for individuals (usually the principal investigator or members of the research team) who would be knowledgeable to answer questions about the research
- A statement that subjects may contact the Chamberlain IRB with any questions about their rights as research subjects. Contact information for the Chamberlain IRB must be provided.
- A statement reminding subjects that participation is voluntary and that they have the right to withdraw at any time without penalty or loss of benefits to which subjects are otherwise entitled.

The following information must be included when appropriate:

- In those cases where the research involves more than minimal risk and research-related injury (i.e., physical, psychological, social or financial) is possible, the consent document must include a statement as to whether compensation and/or treatment are provided.
  
  Note: The consent document cannot contain exculpatory language that waives or appears to waive subjects’ rights.

- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject

- Anticipated circumstances under which the subject’s participation may be terminated by the investigator without regard to the subject’s consent

- Any additional costs to the subject that may result from participation in the research

**NOTE:** All consent forms and other informational documents provided to subjects must be clearly written, concise, free of unnecessary jargon and written at a reading level and language appropriate to the participating population. It is recommended that materials provided to the general lay public be written at about an 8th grade reading level.
SECONDARY SUBJECTS
In situations where a study subject is asked to provide information about other individuals, the other individuals may be considered secondary subjects. For example, in a study using a questionnaire sent to a daughter that contains personal questions about her father and other family members, the Institutional Review Board (IRB) will consider whether the information collected about the secondary subjects is private. The collection of sensitive information about secondary subjects without their consent may involve a breach of their privacy. With studies that involve primary and secondary subjects, the IRB requires that all subjects are afforded full levels of protections.

PRIVACY AND CONFIDENTIALITY
The IRB systematically evaluates all proposed research to ensure that there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of identifiable data. Federal guidelines differentiate between privacy and confidentiality. It is important that everyone involved in the conduct of research with human subjects understand the differences between these concepts.

Privacy relates to access to people and their control over what information (including their identities) is provided to researchers. Confidentiality relates to how data that have been collected are secured, managed or shared. Privacy may be invaded; confidentiality may be breached.

In developing strategies for protecting subjects’ privacy, consideration should be given to:
- Methods used to identify and contact potential participants
- Settings in which an individual is interacting with an investigator
- Appropriateness of all personnel present for research activities
- Methods used to obtain information about participants
- The nature of the requested information
- Information that is obtained about individuals other than the target participants, and whether such individuals meet the DHHS definition of human subject (e.g., a subject providing information about a family member for a survey)
- Protocols access only the minimum amount of information necessary to complete the study

Survey research that uses identifying information is not anonymous if subjects can be identified at any point in the study, including the recruitment of subjects or payment by check. Substituting subject identities by the researcher through the use of codes or removing personal identifying information after data have been collected does not make the study anonymous research.
When developing strategies for protecting confidentiality, consideration should be given to:

- How the consent process protects the confidentiality of the data, such as the use of coding systems and locked file cabinets
- Whether the consent process adequately and clearly describes the confidentiality risks
- Whether a long-range plan for protecting the confidentiality of research data, including a schedule for destruction of identifiers associated with the data, is developed
- Whether the consent process, including forms, discloses those parties who could potentially have access to the research data and under what circumstances data may be shared (e.g., university officials, government agencies, sponsors)

The maintenance of privacy and confidentiality helps protect subjects from a variety of potential harms, including psychological distress, loss of insurance, loss of employment, or damage to academic or social standing that could occur from an invasion of privacy or a breach of confidentiality.

VULNERABLE POPULATIONS

If the proposed research involves a population that may be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally challenged persons or economically or educationally disadvantaged persons, additional safeguards should be included in the study to protect the rights and welfare of these subjects. Vulnerable populations should never be used simply because they are convenient to access. Vulnerable populations may be used only if the aims of the study focus on the needs and concerns of these populations or provide equity in the risks and benefits of the specific study.

Students

Colleges and universities provide a rich source of potential research subjects. A concern with student participation in research conducted at Chamberlain is that their agreement to participate may not be truly voluntary. For example, students may volunteer to participate out of a belief that doing so places them in good favor with faculty (e.g., participation results in receiving better grades, recommendations, employment, or the like), or that failure to participate negatively affects their relationship with the investigator or faculty group in general (i.e., by seeming “uncooperative” or not part of the scientific community). When recruiting students, investigators must be aware of the possibility that students may feel pressured to participate in research and should make every effort to make clear that participation in research is voluntary and their participation decisions do not affect their academic standing or their relationships with researchers or faculty.

Confidentiality is another concern when using students as subjects. As with any research involving human subjects, the researcher must make every effort to protect the confidentiality of data related to sensitive topics such as mental health, sexual activity, breaches of academic integrity, or the use of illicit drugs or alcohol. This is especially important for research involving students since other students are often members of the research team and may be involved in data collection and/or analysis. Researchers should ensure that everyone involved in the study understands the importance of protecting confidentiality.

Persons with Cognitive Impairment or Impaired Ability to Understand a Study

Individuals with psychiatric, cognitive or developmental disorders, those who are active substance abusers, or those with limited English proficiency may be compromised in their capacity to fully understand the purpose, risks and benefits of a proposed study. Investigators must provide a rationale for involving these subjects in a study and must include additional means to protect their rights and welfare. Some individuals with psychiatric, cognitive or developmental disorders, or those who are active substance abusers may be institutionalized which may further inhibit their ability to exercise free choice. It is also important to protect the privacy of all subjects and the confidentiality of information gathered in research exploring emotionally sensitive topics, since some individuals would not want their institutionalization to be revealed to others.

NOTE: All adults, regardless of their diagnosis or condition, should be presumed competent to provide informed consent unless there is evidence of a serious condition that would impair their reasoning or judgment. Individuals who have a diagnosed mental disorder may be capable of providing informed consent. Mental disability alone should not disqualify a person from consenting to participate in research. Someone who has been determined to be incompetent by a judge will have a court-appointed guardian who must be consulted and provide consent before that individual can be enrolled in research.

Children

Federal regulations provide additional protections for children involved in research. The Institutional Review Board (IRB) may approve research involving children as subjects only if the research fits into one of four specific categories. These categories are based on the level of risk and the possibility of direct benefit to individual subjects.

Consent from the child’s parent or guardian must be provided unless the child has reached the age of consent for the procedure. Age of consent is determined by state law. When appropriate, assent from the child should be obtained. Federal code defines “assent” as a child’s affirmative agreement to participate in research. A child’s passive resignation to submit to a research procedure should not be interpreted as assent. Assent should be tailored to the comprehension level of the child. An assent form is optional and may be used for older children who can read and understand information about the study.

Discussion of applicable state law must be provided if a study will involve children. Students must work with their faculty advisor to avoid violation of federal and state restrictions on research involving children when designing a research proposal.
Pregnant Women, Fetuses and Prisoners

Federal regulations provide specific protections for pregnant women, fetuses and prisoners involved in research. These requirements are based on the level of risk and the possibility of direct benefit to individual subjects. Documentation must be provided of how specific protections will be applied for any study involving pregnant women, fetuses or prisoners. Students must work with their faculty advisor to avoid violation of federal and state restrictions on research involving prisoners when designing a research proposal.

What happens after I submit to the IRB?

Each application submitted to the IRB is briefly reviewed by the IRB coordinator within five (5) business days of receipt. You will receive an email with one of the following messages:

1. Your IRB submission packet has been received and is complete
2. Your IRB submission packet has been returned because it is missing the following documents: (a list of items that are missing will be included in the message)

Once your full submission packet has been reviewed by the IRB you will receive an email message with the IRB’s decision. If changes are required or requested, an email detailing these changes will be sent. If the research is approved, an email containing the terms of the approval will be sent. Notification of approval or need for revision is ordinarily sent within two-to-four weeks of receipt of a proposal.

CONDITIONS OF APPROVAL

• Approval of a proposal by the IRB applies only to the procedures included with the submission
• Approval is not granted until all conditions or contingencies required by the IRB have been satisfied
• Approval for any given proposal is valid only until the expiration date (usually one year) for non-exempt studies. All non-exempt studies must be reviewed again no less than annually. The IRB may require an approval period of less than one year depending on various factors including the level and degree of risk involved in the research. Exempt studies are not subject to additional reviews unless their protocols change such that they no longer meet the criteria for exemption, as described in 45 CFR Part 46. Exempt studies, nonetheless, must always be conducted ethically and congruent with Federal guidelines.
• Investigators must immediately report to the IRB any unanticipated problems involving risk or harm to subjects that arise in connection to the research

What if I need to make changes to my study after it’s been approved?

All changes that deviate from the original submission must be approved by the IRB prior to implementation, except when necessary to eliminate immediate hazards to the subjects. Investigators must submit an Amendment to Study form to the IRB. This form is available on the IRB webpage located at chamberlain.edu.

The IRB chair determines whether the requested changes must be approved by the original expedited review panel, if applicable, or by the full board. The time required to approve such changes is proportional to the relative scope and breadth of the changes requested.

Changes in exempt studies are not required to be reviewed by the IRB unless they increase the level of risk or change the procedures for recruitment, informed consent, incentive methods or payments to subjects.

What must I do when the study is completed?

When all data collection is completed prior to or at the time indicated in the proposal, the primary investigator should notify the Institutional Review Board (IRB) with the date when data collection was completed, how many subjects were recruited and a statement that all procedures described in the IRB application were followed. This information can be sent to the IRB via email.

What if my study goes beyond the approval period?

The IRB is required to determine the status of all approved proposals each year. If it is discovered that an approved study will not be complete within the approved time period, a continuing review will be conducted to ensure compliance with the original protocol or the need for a revised protocol.

The researcher must submit a Request for Continuing Review form four weeks prior to the expiration date for approval of the continuation of the study. No research may continue past its IRB approval period without a continuing review approval.
OTHER CONSIDERATIONS

Quality of materials submitted to the IRB

Materials submitted to the IRB are professional documents. They should reflect the researcher’s very best writing, preparation and attention to detail. Materials may be reviewed by auditors from government agencies or grant sponsors; therefore, submitted materials cannot be viewed only as internal documents. Researchers should consider their materials in a similar manner as grant applications, manuscripts and professional presentations.

The IRB will not disapprove a proposal based solely on the quality of the materials. The IRB, however, may request that the researcher make revisions, particularly if poorly written materials lack clarity and transparency or if materials that will be provided to the general public lack professionalism. Studies in which the lead investigator is a member of the Chamberlain community must use Chamberlain-approved templates for consent forms and recruitment flyers. These templates are available on the IRB website.

Negative reactions in subjects

Any unanticipated problem involving risks to subjects or complaints from subjects must be reported immediately to the Chamberlain IRB chair. The Chair forwards, in writing, any report of adverse events to the vice president of academic affairs, and to the relevant program dean and director or campus president.

Proposals that are only class assignments

A few courses at Chamberlain College of Nursing may require students to complete research proposals in order to learn how to conduct research with human participants. Although some colleges and universities require IRB review of student proposals involving the use of human participants, Chamberlain College of Nursing’s IRB does not review student proposals conducted in research methods courses if the purpose of these proposals is only to enhance learning about the research process. If the proposal will not be implemented, it is not subject to IRB review. Instructors assigning activities involving data collection with human subjects are obligated to determine whether the data collection meets the definition of reviewable research.

A proposal initially developed to learn research methods may be used for future research only if the student submits a full IRB packet and receives approval.

Non-compliance with IRB requirements

If non-compliance with federal law, state law, or any restriction, limitation or other condition imposed on a research study is suspected or alleged, the IRB chair will initiate an investigation. The researcher is informed of the allegations and given time to respond. The IRB chair then reviews the relevant information and makes a report to the College president and the appropriate academic administrators, including recommendations. Recommendations may range from dismissal of the allegations up to revocation of IRB approval of the study. The IRB exercises the right to suspend an ongoing study at any time if it believes subjects are at undue risk of harm.

IRB quality improvement

The IRB strives to improve and maintain the quality of its processes and ensure the ethical conduct of research affiliated with Chamberlain. To accomplish this, the IRB employs various strategies to assess quality and identify areas in need of improvement. One strategy includes the use of audits. The IRB routinely audits a percentage of reviewed studies to ensure that approved study protocols are followed. Investigators may be contacted by the IRB to provide information on study progress and compliance with study protocols. The audit may require the submission of study documents as allowable by law. More information will be provided to investigators at the time of the audit.
APPENDIX I: EXAMPLE OF A COMPLETED IRB FORM

**IRB APPLICATION**

**Instructions:** All applicants must submit this completed application and await disposition of the application outcome before proceeding with the proposed project or study. The content of this application as well as all supporting documents will be kept confidential within the limits of the law. Incomplete applications will not be reviewed. Do not edit or revise the application form.

### I. INVESTIGATION TITLE

Title: Analysis of Master Instruction Principles on Teaching and Student Outcomes

### II. PRINCIPAL INVESTIGATOR

<table>
<thead>
<tr>
<th>Name</th>
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<tbody>
<tr>
<td>Jane Doe</td>
<td>Master Instructor Program Director</td>
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<tr>
<td>Affiliated Program</td>
<td>Academics</td>
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<td>Mailing Address:</td>
<td>Home ☑ Work ☐</td>
</tr>
<tr>
<td>Street Address:</td>
<td>123 Main St.</td>
</tr>
<tr>
<td>City: Anywhere</td>
<td>State: Illinois Zipcode: 01101</td>
</tr>
<tr>
<td>Work Phone: 500-399-9999</td>
<td>Home Phone: n/a</td>
</tr>
<tr>
<td>E-mail Address: <a href="mailto:janedoe@chamberlain.edu">janedoe@chamberlain.edu</a></td>
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**Co-Investigators**

<table>
<thead>
<tr>
<th>Name</th>
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<tbody>
<tr>
<td>Tom Smith</td>
<td><a href="mailto:tomsmith@chamberlain.edu">tomsmith@chamberlain.edu</a></td>
</tr>
<tr>
<td>Star Professor</td>
<td><a href="mailto:starprofessor@chamberlain.edu">starprofessor@chamberlain.edu</a></td>
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### III. SUPERVISING FACULTY (if applying as a student)

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</table>
APPENDIX I: EXAMPLE OF A COMPLETED IRB FORM

IRB APPLICATION

| IV. PROJECTED DATES OF RESEARCH (Subject Recruitment, Data Collection, Data Analyses) |
| Start Date: Upon IRB Approval | End Date: June 2017 |

| V. LOCAL LAWS |
| The investigator must ensure that components of the proposed project or study comply with local state laws relating to human subject protections. If applicable, the investigator must list local state laws that apply to the study, and explain how they have been incorporated for compliance. If no state laws apply to the study, please indicate below. |

| VI. SIGNATURES |
| The undersigned acknowledge that: 1.) this application represents an accurate and complete description of the proposed research; and 2.) research will be conducted in compliance with the recommendations of and only after formal written approval has been received from the Institutional Review Board (IRB). The principal investigator is responsible for reporting any serious or unexpected adverse events or problems to the IRB that occur during the implementation of the study or project, for requesting IRB approval for modifications, for requesting continuing review and approval, and for notifying the IRB of project completion. |

A. Principal Investigator: Jane Doe |
Typed Name | March 1, 2015 |
Written or Electronic Signature | Date |

B. Supervising Faculty: (Student applications only) |
Typed Name | Date |
Written or Electronic Signature | Date |

| VII. EXISTING DATA |
| Will this study involve the use of existing data, documents, records and pathological specimens? |
No ☐ Yes ☑ If yes, include a letter of authorization to access any data that are not publicly available. |
This study will use data already collected by the Chamberlain Office of Institutional Effectiveness. |
APPENDIX I: EXAMPLE OF A COMPLETED IRB FORM

VIII. MULTI-CENTER STUDY

Will multiple institutions participate in this study? Yes ☐ No ☑

If “Yes”, which institutions will participate? ________________________________

How many subjects are anticipated at each site? ____________________________

IX. STUDY DESCRIPTION

NOTE: Use single line spacing. Type in your answers in the gray box below each section
(if you cut and paste from other documents, please make sure your formatting is consistent).

A. STUDY ABSTRACT/OVERVIEW. In 200 words or less, describe in lay language the nature, purpose, methods, risks and risk management procedures of the proposed study/project.

Master Instruction (MI) is an approach to applying learner-centered teaching principles based on the work by Ken Bain. Beginning in 2012, Chamberlain College of Nursing launched an initiative to implement MI in all its campuses and programs. A small pilot study exploring the impact of MI using faculty and student focus groups in one program suggested positive outcomes, satisfaction, and a sense of validation and transformation among faculty. The impact of MI college-wide, however, is still largely unknown. This mixed-methods study will use faculty focus groups, observations of faculty application of MI, and quantitative student outcomes data to better understand the impact of MI.

B. STUDY PURPOSE OR AIMS. In lay language, briefly describe the overall purpose or aims of the study.

The purposes of this mixed-methods study are to explore faculty perspectives and experiences in implementing MI and the relationships among MI implementation and student outcomes.
APPENDIX I: EXAMPLE OF A COMPLETED IRB FORM

C. STUDY HYPOTHESES, QUESTIONS OR OUTCOMES

1. List the study hypotheses, research questions or study outcomes.

1. How do faculty experience MI and perceive its effects on teaching and learning?
2. How completely is MI implemented by faculty in their courses?
3. Are there differences in the level of MI implementation among campuses and programs?
4. Are there differences in the scores among the six MI criteria (categories)?
5. What are the relationships between MI scores (individual MI criterion summed scores and total scores) with:
   a. Section mean course grade
   b. Section mean student satisfaction with the course
   c. Section mean student satisfaction with the instructor
   d. Section mean student engagement index
      In pre-licensure and post-licensure (online) students?

2. Briefly describe how hypotheses will be tested, questions answered and/or outcomes measured.

1. Focus Groups with guided questions: face-to-face and virtual meetings with hermeneutical analysis (Diekelmann & Ironside, 1998) of transcripts for themes, patterns, and relationships.
2. Descriptive statistics of MI scores from Faculty Observation Forms
3. Descriptive statistics of MI scores from Faculty Observation Forms, ANOVA test for comparison among campuses/programs (campus/program = independent variable)
4. Descriptive statistics of MI scores from Faculty Observation Forms, ANOVA test for comparison among campuses/programs (MI criterion = independent variable)
5. Pearson’s r correlation (MI score = independent variable) with each student outcome. Outcomes will be summed into a composite score and linear regression analysis will be conducted to assess if MI total score is predictive of student outcomes and multiple regression to assess the relative predictive value of each MI criterion on student outcomes.

3. Are you using a questionnaire, survey instrument or interview as part of your procedure?

   Yes ☑ No ☐

   If yes, submit a copy of the questionnaire(s), survey(s) or interview questions.
D. SUBJECTS: Fill in as applicable if you will be recruiting human subjects

1. Subjects to be Recruited (check all that apply)
   - Adults (18-65 years) [✓]
   - Children and Minors (< 18 years) [☐]
   - Cognitively Impaired Persons [☐]
   - Prisoners [☐]
   - Elderly/Aged Persons (>65 years) [☐]
   - Minorities [☐]

2. Data will include (check all variables included)
   - Names of people [☐]
   - Income [☐]
   - Addresses [☐]
   - Social Security Number [☐]
   - Phone numbers [☐]
   - Job title [☐]
   - Age [✓]
   - Names of employers [☐]
   - Gender [☐]
   - Types of employers [☐]
   - Ethnicity [☐]
   - Marital status [☐]

3. Total number of subjects who will be contacted to participate:
   Quantitative data will be collected from all faculty observations forms completed over a 12-month period and matched with data already accessible through the Office of Institutional Effectiveness. All full-time faculty on campuses where focus groups will be held will be invited to participate. All fulltime faculty teaching in online programs will be invited to participate in virtual focus groups.

4. Total anticipated number of subjects who will participate:
   Focus groups will consist of 5 to 7 full-time faculty members. Enough focus groups will be held to establish a redundancy of themes; however, at least one focus group will be held for each online program as well as a minimum of two campus focus groups.

5. Does this study involve participants who are not fluent in English?  Yes [☐] No [✓]

6. For how long a time will each subject be involved in this study? (If you are using your subjects on more than one occasion, indicate the number of such occasions and their duration.)
   Focus groups will vary in time, but should group sessions may last approximately 45-90 minutes.
APPENDIX I: EXAMPLE OF A COMPLETED IRB FORM

7. Recruitment Source. Identify the location from which subjects will be recruited (e.g., schools, university campus, fitness facilities, hospitals, etc.).

Faculty will be recruited from Chamberlain College of Nursing.

8. Recruitment Methods. Describe how subjects will be identified and recruited. If subjects are identified from private or student records, provide documentation that authorizes your access to those records (HIPAA or FERPA forms). The official holder of the record must make initial contact of subjects identified through records to initiate involvement in the research protocol. Submit advertisements, flyers, contact letters, telephone contact protocols/scripts, website template or other recruitment materials proposed for use in subject recruitment as appendix attachments.

Campus selected for hosting focus groups will be determined based on the investigators' travel schedules and availability. Once a campus is located, full-time faculty employed at that campus will be contacted via email about the study. At least one virtual meeting will be held for each program (RN-BSN, MSN, DNP). Investigators will contact full-time faculty from those programs via email as meetings are scheduled.

9. Equity: Explain how you will achieve equitable subject representation from the subject population in the following categories. Please explain why any category will be excluded.

a. Age (e.g., minors, elderly):

b. Gender:

c. Ethnic and racial minority populations:

d. Socio-economic status:

e. Persons with limited English-language skills:

☑ No category of potential subjects will be excluded.
APPENDIX I: EXAMPLE OF A COMPLETED IRB FORM

10. Inclusion Criteria: What characteristics must subjects have to be in this study?

Criteria for participation in focus groups include:
1. Full-time faculty status at Chamberlain College of Nursing for at least 6 months prior to the focus group.
2. Completion of the Master Instruction course or workshop.

11. Exclusion Criteria: What characteristics would exclude subjects who are otherwise eligible from this study?

Inability to meet inclusion criteria.

E. INFORMED CONSENT PROCESS

Typically, signed informed consent is required for adult subjects. For non-emancipated minors, signed informed consent must be obtained by the minor’s parent or legal guardian. In addition, verbal assent from the minor must be obtained prior to participation. If the minor is capable of reading and understanding information about the study, a signed assent form should be obtained from the minor as well.

The need for signed consent and assent forms, however, may be waived by the IRB for studies examining common educational practices and tests conducted in common educational settings, for studies observing public behavior or for other situations described in Title 45 Section 46.101. Additionally, the requirement for documentation of signed informed consent form may be waived by the IRB if all apply:

a.) The study involves no more than minimal risk and consent would not be needed for the procedure/intervention if it was occurring outside a research study

OR

b) The major risk in the study is a breach in confidentiality and the consent form is the only way to link subjects to the study

In addition, the requirement for signed informed consent may be waived if it would be impractical or jeopardize the integrity of the findings, as long as the study involves only minimal risk, the lack of a signed informed consent will not jeopardize the rights and welfare of subjects, and the signed consent form would be the only document identifying the subjects.

If signed informed consent is not obtained, adult subjects should still receive written information about the study and that participation is completely voluntary.

This study will include: (check all that apply)

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<th>Form</th>
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<tbody>
<tr>
<td>Signed informed consent form</td>
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<tr>
<td>Parental/Guardian signed informed consent form</td>
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<td>Minor assent form</td>
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<td>Written information about the study (if not using consent form)</td>
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If any of these forms will be used, submit a copy with the IRB submission.

NOTE: All forms should be in a reader-friendly format and provided at a reading level appropriate to the subject population.

If none of these forms will be used, please provide an explanation.
Does this study involve:

a. Incomplete disclosure to subjects at the onset of the study? Yes ☐ No ☑
b. Deception of subjects? Yes ☐ No ☑

If “Yes” to either, explain why incomplete disclosure or deception is necessary and describe the procedure you will use to debrief you subjects. You must indicate a willingness to allow subjects to withdraw from the study after debriefing and remove from your data all records of their involvement. Please submit a copy of the debriefing script you will use.

F. STUDY LOCATION

Identify the location and describe the setting of where the subjects will participate in this research (i.e., where will the study procedures be carried out. Please submit copies of IRB approvals or letters of cooperation from non-Chamberlain research sites, if necessary as appendix attachments.

Campus-based focus groups will take place in an available room on campus. Virtual focus group meetings will occur online through Chamberlain’s conference call platform.

G. STUDY PROCEDURES

Please describe in sufficient detail and in lay language the procedures you will be doing to or with your subjects.

Quantitative Portion of the Study: Quantitative data pertinent to this study are already collected through faculty observation and institutional research procedures. Investigators will request from the Office of Institutional Effectiveness selected aggregate student outcomes data matched to course sections in which faculty observations occurred. Data will be analyzed by the OIE team using standard statistical software available at Chamberlain College of Nursing.

Qualitative Portion of the Study: Qualitative data will be collected through focus groups comprised of full-time faculty. Face-to-face focus groups will be held on campuses selected on the basis of the investigators' availability. Focus groups with full-time online faculty will be held on the conference call platform at Chamberlain. Faculty will be invited to participate using the methods described earlier. Campus-based focus groups will occur at a time and date conducive to campus operations and faculty work schedules.

At the start of each focus group, investigators will discuss the study with the faculty and review the informed consent form. Faculty will be told that the meeting will be audiotaped. Measures to assure confidentiality will be discussed. Faculty who decline participation will be excused from the meeting. For campus-based groups, the audio recording will commence once all have submitted their signed informed consent. For online groups, faculty will receive the informed consent form prior to the meeting and be asked to email the signed consent form prior to joining the conference call. The online faculty will be told when the audio recording will commence. Select demographic data (age, gender, ethnicity, and years of teaching experience) will be collected to describe the sample.

Investigators will facilitate the focus group using an interview guide. Additional questions and follow up questions may be asked consistent with focus group methods. Faculty will be encouraged to speak freely. No names will be used during the recording. Investigators will take brief field notes to capture mood and emotions when relevant. After the meeting, the tapes will be transcribed. The investigative team will analyze the data using the techniques described by Diekelmann & Ironside (1998). Field notes will be used to inform the analysis. Findings will be shared with faculty participating in the focus groups as a member check.
APPENDIX I: EXAMPLE OF A COMPLETED IRB FORM

IRB APPLICATION

For faculty conducting research, describe the planned roles, activities and preparation for using students as research assistants. (If non-applicable, indicate N/A)

N/A

II. RISKS AND BENEFITS

1. Identification of risks. Describe nature and degree of risk of potential injury, stress, discomfort, invasion of privacy, psychological harm and other possible risks from all study procedures, drugs and devices (standard and experimental), interviews and questionnaires.

There are no risks to participating in the focus groups other than breach of confidentiality.

2. Management of risks. Explain what steps you will take to minimize risks of harm and to protect subjects’ rights and welfare.

No names will be used in the audio recordings of focus group meetings. Group members will sign a pledge imbedded within the informed consent form to keep all information shared in the meetings and identities of participants confidential. Audiotapes will be destroyed once they have been transcribed. All study documents will be stored in a password protected computer file.
### APPENDIX I: EXAMPLE OF A COMPLETED IRB FORM

**3. Identification of benefits.** Describe the anticipated direct and/or indirect benefits of this research for individual subjects.

Participants will not benefit directly; however, information obtained from the study will be used to strengthen the Master Instruction program and faculty support at Chamberlain.

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**I. COSTS, COMPENSATION AND INCENTIVES**

1. **Costs.** Describe any costs that the subject (or third-party payors) may incur as a result of participation (e.g., charges for tests, travel costs, etc.).

No costs are associated with participation in this study.

2. **Compensation and Incentives.** Will you give subjects gifts, payments, services without charge or extra course credit? **Yes ☐ No ☑**

   If "Yes", provide details of this compensation. Describe how and when compensation will be provided. Describe how compensation will be determined and provided should a subject withdraw from the study.

N/A
J. CONFIDENTIALITY OF RESEARCH DATA

1. Will you obtain from your subjects information about their private behavior, economic status, sexual activity, religious beliefs or other matters which, if made public, might impair their self-esteem or reputation, or could reasonably place the subjects at risk of criminal or civil liability or be damaging to their financial standing or employability?  Yes ☐ No ☑

If “Yes,” describe the means you will use to ensure that all your data are kept secure and confidential until they are destroyed.

N/A

2. How will you protect subjects’ confidentiality?

No names will be used in audiotapes or transcripts from focus group meetings. Quantitative data will be provided to the investigators from the Office of Institutional Effectiveness only in aggregate or de-identified formats.

3. How and to whom will data/results from this study likely be shared or disseminated?

Findings from this study will be shared with faculty and administrators at Chamberlain. Findings will also be disseminated at professional conferences and/or publications.

4. How will you destroy data and records at the end of the study? In general, it is Chamberlain IRB practice to store hard copy data for seven (7) years in a locked file or password protected device. After seven (7) years, all hard copy data should be shredded and video and/or audiotapes erased.

Study documents and raw data will be erased and/or shredded after 7 years.
APPENDIX I: EXAMPLE OF A COMPLETED IRB FORM

IRB APPLICATION

K. CONFLICT OF INTEREST
The Chamberlain IRB considers the investigator’s financial interests when evaluating the protection of human subjects. If a financial interest is reported, the Chamberlain IRB will assess the investigator’s objectivity in communicating risks, selecting subjects, promoting informed consent and gathering, analyzing and reporting data. The Chamberlain IRB may also review disclosures when a financial interest is reported.

Does any member of the research team have a financial interest in the research or its products or in the study sponsor?  
☐ Yes  ☑ No

Explain in detail any financial interest involved (i.e., a letter stating the nature of the financial interest may be requested by the IRB):

N/A

L. ADDITIONAL INFORMATION
Identify which of the following documents are provided with this submission:

☑ Documentation of completion of the Collaborative Institutional Training Initiative (CITI) modules (required)
☑ Assurance of Confidentiality Agreement (required)
☐ Full study protocol (required)
☐ Recruitment materials (list below)

Recruitment Letter

☑ Questionnaires/surveys/interview questions/tools (list below)

Faculty Observation Form, Focus Group Participation Demographic Sheet, Focus Group Interview Guide

☑ Informed consent form
☐ Parent/guardian consent form
☐ Assent form
☐ Written information provided to subjects
☐ Permissions/authorizations/approvals from IRBs from other institutions: (list below)
APPENDIX II: EXAMPLE OF AN ADULT CONSENT FORM
WRITTEN AT A 5TH GRADE READING LEVEL

ADULT CONSENT FORM

Study Title: Effectiveness of Group Appointments in Hispanic Clients with Diabetes
Investigator: Jane Doe, MSN, RN, DNP
Supported By (if applicable): General Hospital

What is the purpose of this study?
This study will see if health visits in groups will help Hispanic people who have diabetes. Group visits might be better to learn healthy behaviors and treatment. Group visits might offer support from others with diabetes.

What will I do if I choose to be in this study?
• If you join this study, you might be asked to join other patients and see the doctor together. Or you might be asked to see the doctor by yourself.
• Nothing will be different if you see the doctor alone. Your visit will be the same as your other visits.
• After you see the doctor, a nurse will ask you questions about the visit and what you learned.
• The nurse will speak Spanish if you want Spanish.
• If you see the doctor with others, the other patients will have diabetes like you.
• You will learn how to take care of your diabetes with other patients.

• You will not have to share any private information with other patients.
• If you see the doctor with other patients, you will still have some time alone with the doctor.
• Before you leave, a nurse will ask you questions about the visit and what you learned.
• The nurse will speak Spanish if you want Spanish.
• You only have to answer the questions you want.
• You can leave the group any time.
• There will be no penalty if you leave the group.

What are the possible risks or discomforts?
There should be harm from group visits. You will receive the same care by the doctor and nurses. Some people may not like group visits. You can leave the group any time I want.

What are the possible benefits for me or others?
You might learn from other patients about diabetes in your group. You might enjoy talking with other patients about what it’s like having diabetes. You might make new friends, but this might not happen for everybody. Joining a group will help us learn how to better help people with diabetes.

What alternatives are available?
You may choose to not join this study. Your care will be the same.

What happens if I don’t want to participate anymore?
If you join this study, you may leave any time. There will be no penalty if you leave the study.

Will it cost me anything to participate?
It is free to join this study.
Will I get paid anything if I participate?
You will not be paid to join this study.

What are my rights?
You have the right to be treated with respect. You have the right to leave the study at any time. You have the right to answer or not answer our questions. You do not have to join this study to get care from your doctor.
If you have private questions about this study, you may email the research group (IRB) at irb@chamberlain.edu. The research group will help you privately.

What about my confidentiality and privacy rights?
You will not be asked to share private information with the other patients. Any information you give the doctor or nurse will be private. Your name will never be used in the study report.

Consent
I have read this form about the study or had it read to me. Any questions I have about this study have been answered. I understand the information about the study. I agree to join this study. I will receive a copy of this form.

Signature of Subject ____________________________ Date ____________

Signature of Witness (optional) ____________________________ Date ____________

This research study was reviewed by the Chamberlain College of Nursing Institutional Review Board (IRB). The goal is to assure that the study protects the rights and safety of the human subjects of this research.

This research study's number is ____________________________, (to be assigned by Chamberlain College of Nursing IRB.)
Study Title: Does the implementation of a formal preceptor program lead to increased nurse satisfaction and role confidence among nurse preceptors?
Investigator: Jane Doe, MSN, RN, DNP
Supported By (if applicable): General Hospital

What is the purpose of this study?
The purpose of this study is to examine the impact of formal preceptor training on nurse satisfaction and role confidence among staff nurses who serve as preceptors. You are being asked to participate because you have been identified by your organization as someone who currently serves as a preceptor, or someone who has expressed an interest in serving as a preceptor in the future.

What will I do if I choose to be in this study?
• You will be asked to participate in a preceptor training workshop in a classroom at your facility.
• The workshop will be facilitated by the chief investigator.
• Prior to the beginning of the workshop, you will be asked to voluntarily complete a survey consisting of five (5) questions.
• If you choose to not answer the pre-workshop survey, you may still participate in the preceptor training workshop.
• The preceptor training workshop will last eight (8) hours.
• During the training, you will be asked to participate by sharing your experiences as a preceptor or as someone who has an interest in becoming a preceptor in the future. Participation is voluntary and you are not required to answer any questions.
• Within 24 hours after completion of the preceptor training workshop, you will receive a post-workshop survey link via Survey Monkey.
• The post-workshop survey will consist of six (6) questions.
• You may choose to answer all or none of the questions.
• One month after completion of the preceptor training workshop, you will receive a second post-workshop survey link via Survey Monkey.
• The second post-workshop survey will consist of six (6) questions.
• You may choose to answer all or none of the questions.
• Two months after completion of the preceptor training workshop, you will receive a third post-workshop survey link via Survey Monkey.
• The third post-workshop survey will consist of six (6) questions.
• You may choose to answer all or none of the questions.
• At any time you may request to be excluded from any further surveys. If you request to be excluded from further surveys, you will not be affected in any way.

What are the possible risks or discomforts?
Your participation in this study does not involve any physical or emotional risk to you beyond that of everyday life. You may become tired during the formal preceptor training. You may take a break at any time and return to the training after a break. You may be uncomfortable with some of the survey questions. If you are uncomfortable, you are free to not answer or skip to the next question.

What are the possible benefits for me or others?
You will not benefit directly from participating in this study; however, your participation will help researchers better understand the impact of formal preceptor training on nurse satisfaction and role confidence and could minimize nurse dissatisfaction and the potential for nurse attrition.

What alternatives are available?
You may choose to not participate in this research study or to only answer some questions on the survey.
What happens if I don’t want to participate anymore?

At any time in the study, you may decide to withdraw from the study and not complete any surveys. If you withdraw, no more information will be collected from you. When you indicate that you wish to withdraw, the investigator will ask if the information/materials already collected from you can be used in the study.

Will it cost me anything to participate?

Participation in this study will involve no cost to you.

Will I get paid anything if I participate?

You will receive your regular hourly wages by your employer for the time you spend in the preceptor training workshop. You will not receive reimbursement for completing the surveys.

What are my rights?

If you choose to be in this study, you have the right to be treated with respect, including respect for your decision to continue or stop being in the study. You are free to stop being in the study at any time.

Choosing not to be in this study or to withdraw from this study will not result in any penalty to you or loss of benefits to which you are otherwise entitled. Specifically, your choice will not negatively affect your right to any present or future preceptor or other training provided by your employer, or access to web-based preceptor training.

If you want to speak with someone who is not directly involved in this research, or if you have questions about your rights as a research subject, contact the Chamberlain College of Nursing Institutional Review Board (IRB) Office. You can call the IRB Coordinator – Channan Pondexter at 630.353.7334 or send e-mail to irb@chamberlain.edu. You will be given any information that either the researcher or the IRB reasonably believes is important to my choice about whether or not to be in this research study.

What about my confidentiality and privacy rights?

The pre-workshop survey will not request any identifying information. The post-workshop surveys used for this study will be distributed via Survey Monkey and will not be identifiable. All results will be compiled into aggregate data and no names will be utilized in any part of the project or its findings.

Consent

I have read this form and the research study has been explained to me. I have been given the opportunity to ask questions and my questions have been answered. If I have additional questions, I have been told whom to contact. I agree to participate in the research study described above and will receive a copy of this consent form after I sign it.

Signature of Subject __________________________ Date ________________

Signature of Witness (optional) ______________________ Date ________________

This research study was reviewed by the Chamberlain College of Nursing Institutional Review Board (IRB). The goal is to assure that the study protects the rights and safety of the human subjects of this research.

This research study’s number is _________________________, (to be assigned by Chamberlain College of Nursing IRB.)
Accreditation and Approvals:

Chamberlain College of Nursing is accredited by The Higher Learning Commission (HLC, www.hlcommission.org). HLC is one of the eight regional agencies that accredit U.S. colleges and universities at the institutional level. The Bachelor of Science in Nursing degree program, the Master of Science in Nursing degree program and the Doctor of Nursing Practice degree program at Chamberlain College of Nursing are accredited by the Commission on Collegiate Nursing Education (CCNE, One Dupont Circle, NW, Suite 530, Washington, DC 20036; 202.887.6791). Accreditation provides assurance to the public and to prospective students that standards of quality have been met.

Chamberlain College of Nursing is certified to operate by the State Council of Higher Education for Virginia, 101 N. 14th Street, 10th floor, James Monroe Building, Richmond VA 23219, 804.225.2600. Chamberlain College of Nursing is approved to operate from the Virginia Board of Nursing Perimeter Center, 9960 Mayland Drive, Suite 300, Henrico VA 23233-1463, 804.367.4515.

Program/program option availability varies by state/location. Chamberlain reserves the right to update information as it becomes available. Information is current at the time of publication. For the most updated accreditation information, visitchamberlain.edu/accreditation. For the most updated approvals by state information, visit chamberlain.edu/stateapprovals. Comprehensive consumer information is available at chamberlain.edu/studentconsumerinfo.