Duke University School of Nursing  
Center for Nursing Research  

Proposal for Research Oversight  
November 9, 2015  

Summary of the School of Nursing  
A diverse community of scholars and clinicians, Duke University School of Nursing (DUSON) is educating the next generation of research leaders in nursing. In 2015, *U.S. News and World Report* ranked Duke among the top six graduate schools of nursing in the nation. DUSON also ranks tenth in National Institutes of Health awards among U.S. schools of nursing. Faculty researchers are on the cutting edge of technology utilizing mHealth applications, virtual environments to explore chronic disease management and education for in-patients and outpatients, and visualization techniques to analyze large and complex data sets.

With direct access to in-patient and out-patient populations through collaboration with Duke University Health System, as well as working with community and global partners such as the Durham VA Center and Shandong University in Jinan China, the School conducts research both inside the clinical setting and in the community. The School is home to the National Institute of Health/National Institute of Nursing Research P30 Center of Excellence for Adaptive Leadership for Cognitive/Affective Symptom Science (ADAPT). The Center for Nursing covers all of the School of Nursing community including DUHS nurses involved in research. The Clinical Research Unit (CRU) for the School of Nursing is organized within the Center for Nursing Research. The mission of the Center is to foster development of independent researchers who have great potential for external funding to support a program of research. To accomplish this a major focus of education is on research grant development and once funded, study implementation and management. With proposed recommendations in DHHS regulations, 45 CFR 46, often called the “Common Rule” it will be extremely important for the DUSON CRU to be actively engaged in research faculty mentoring and development.

A research oversight plan is required to ensure the integrity, financial accountability, regulatory compliance and quality of clinical research in the School of Nursing. What follows outlines the structure of the DUSCN CRU.

School of Nursing Research Oversight Personnel  

**Key Personnel**

Associate Dean for Research- Marilyn Hockenberry PhD, RN, PPCNP-BC, FAAN  
Director- Research Practice- Phyllis Kennel, MS, RD, LDN  
Director-Financial Practice- Robbin Thomas  

Research Review Committee  
Consists of School of Nursing Faculty, and DUHS nurses – These individuals are appointed for a two- year term by the Associate Dean for Research in collaboration with the individual responsible for nursing research within DUHS. Research Review Committee members review new protocols as assigned by the Director – Research Practice prior to IRB submission to ensure that new studies have sufficient scientific merit, appropriate research design, sufficient budget consideration, and adequate resources for successful implementation. Once committee
members complete their review, the proposal is reviewed and signed-off by the Associate Dean for Research before IRB submission. This is documented in the eIRB.

Each Research Review Committee member also serves on one of the IRB Review Board Committees as part of the two-year term. New members are oriented to the role by the CRU Director for Research Practice and Associate Dean for Research. The Associate Dean for Research conducts IRB board member orientation in collaboration with the IRB Specialist responsible for new IRB board member training.

**Research Oversight Governance**

Research within DUSON is distinctly different than the focus for research within the School of Medicine; this Charter specifically addresses an oversight approach that meets the needs for nursing research. Oversight of research activities within the School of Nursing is the responsibility of the Associate Dean for Research who is directly accountable to the Dean of the School of Nursing. The DUSON CRU will adhere to all institution-wide policies established by the Duke University Health System, Duke Office of Clinical Research (DOCR) and other governing Duke departments (e.g. IRB, ISO, OCRC) regarding the conduct of clinical research; however, due to the nature of the research conducted by the DUSON faculty there will only be five reviews conducted under the Quality Assurance Monitoring Review Standards. Compliance with these policies as well as all applicable regulatory requirements will be audited as appropriate by the Human Subject Research Compliance staff of the Duke University Office of Audit, Risk and Compliance. DUSON CRU staff will provide an annual report to the CRU Compliance Quality Assurance Committee.

**Research Monitoring and Oversight Responsibilities**

The complexity of needs for faculty, students and DUHS nurse researchers require numerous opportunities for support along the continuum of the research process. This oversight is required to ensure the integrity, financial accountability and transparency, regulatory compliance, and quality of work. This work is done in collaboration with the Facility Science Core and the Research Design and Statistics Core within the Center for Nursing Research. These activities are integrated with the DUSON CRU and include:

**Oversight**

- Activities that involve human subjects and/or access to private information or private health information (PHI)
- Grant/contract proposal submissions for all sponsored projects (federal/non-federal, research/education)
- Budget and submission development for all grant/contract research proposals and internal small grant program proposals (includes discussion around resources, budgeting, IRB)
- Award activation for financial oversight and compliance monitoring of all research proposals
- Coordination of contract negotiations, data use and material transfer agreements, Institutional Authorization Agreements and other Research agreements
- IRB user assistance for internal and external regulatory submissions
- Data collection; integrity, security, transfer and receipt of data and retention (Research Data Security Plan (RDSP) completion and review)
- Monitoring visits and appropriate correction action, as needed
- Study coordination and allocation of resources, and the flow of funds associated with individual studies
• Study-specific expense and revenue tracking, billing compliance activities, sponsor invoicing, and proper effort tracking of personnel
• Compliance with protocol registration and results entry for Federal requirements as required by ClinicalTrials.gov

**Research Staff Support**
The CRU Director – Research Practice within DUSON will have direct supervisory responsibilities for all research staff within the School of Nursing. These responsibilities include:

- Direct oversight of all performance expectations and education requirements for individual research staff members based on study role and the six core functions (R06)
- Preparation and review of employee annual performance appraisals with final approval by the Associate Dean for Research
- Facilitation of good clinical practice by study staff (including IRB submissions and renewals; protocol initiation; patient and subject recruitment, screening, consent and enrollment; drug and device accountability; safety reporting; and study close out)
- Enforcement of minimum qualifications and experience for the CRC and other research staff roles dependent on research study needs outlined by DOCR
- Coordination of staff meetings (monthly) to review new research compliance updates, policies and procedures and DUSON issues as well as quarterly meetings with the Associate Dean of Research

**Research Study Support**
The CRU within DUSON will be responsible for educating and training staff and faculty who are new to research and will provide current staff and faculty with essential skills necessary to meet the requirements of an ever-changing research environment. The CRU will provide:

- Monitoring of CITI completion by faculty, staff and students involved in research
- Facilitation of the Duke Human Subjects Research training through DOCR
- Assistance with Maestro Care training and access coordinated through DOCR
- Coordination of new study start-up including education on subject screening and recruitment, consenting, data collection, subject tracking and follow-up and data entry, data storage; for retrospective chart reviews education on chart abstractions and data entry
- Ongoing support during study implementation phase
- Assistance with study completion and study close out requirements
- Assurance that IRB/Regulatory submissions are completed within required deadlines

**Interface with other CRUs and DOCR**
The CRU within DUSON will stay connected to other CRUs and DOCR by participating in the following:

- Bi-Monthly Research Practice Manager (RPM) meetings
- Bi-Monthly Financial Practice Manager (FPM) meetings
- Quarterly CRU Advisory Council meetings attended by the Associate Dean for Research, Director- Research Practice and Director Financial Practice.

The Associate Dean for Research within DUSON will continue to work closely with key personnel within DOCR and the School of Medicine to make sure that the clinical research needs of DUSON faculty are met.

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**Research Oversight Metrics**

Specific metrics will be established to assure that the CRU within the Center for Nursing Research provides the resources and support necessary to comply with all requirements applicable to research involving human subjects. Assurance that human subjects research will be ethically conducted is a major focus of the Center. Expectations that staff engaged in the conduct or oversight of human subject research will participate in ongoing education activities are paramount for successful implementation of research within the School of Nursing.

The following key metrics will be evaluated on the DUSON CRU Scorecard:

- **Personnel Training involved in Human Subjects Research**: Compliance with DHRT Training
- **IRB**: Deferrals, Scientific checklists from Research Review Committee uploaded in eIRB. Continuing renewals submitted before expiration date; number of expedited and full IRB committee review protocols submitted
- **Quality Control**: Five studies will be randomly selected from the following categories for review each year: more than minimal risk category requiring full IRB Committee review, data transfer studies, or software and mobile technology evaluation protocols. These five studies will be formally evaluated by the CRU.

In addition to key metrics evaluating the regulatory components for human subjects research described above, a comprehensive annual report summarizing all research activities supported by the Center for Nursing Research will be prepared and submitted annually to DOCR and the Deans of the School of Nursing and School of Medicine. If requested a verbal report the Associate Dean for Research will be prepare a formal presentation.

The annual report will include a comprehensive overview of current grant funding, number and types of grants submitted in the past year, and faculty and DUHS staff research publications and presentations. The report will include a summary of all research support activities within the Center for Nursing Research (i.e. number of brainstorming sessions, Grant Writing Club attendance, think tanks, mock reviews, educational sessions, visiting scholars sessions, ADAPT center activities, scientific writing classes, junior faculty mentoring sessions). The small pilot research grants program will be reviewed and its impact on extramural funding summarized. The report will conclude with an evaluation of how established annual goals were met and proposed goals for the next year.

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