Purpose: This SOP provides guidance for oversight of human subject protection for research and translation within the College of Nursing. The Office of Research Services is responsible for helping prepare CON faculty and student IRB applications for human subjects review, if needed, and reviewing your application for scientific rigor.

<table>
<thead>
<tr>
<th>Abbreviations</th>
<th>Current CON Personnel</th>
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<tr>
<td>PI/PD: Principal Investigator/Project Director</td>
<td>Associate Dean for Research: Dr. Tami Wyatt (Department Chair)</td>
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<td>ORS: Office of Research Services</td>
<td>Director of Research Services: Nancy Taylor</td>
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<td>CON: College of Nursing</td>
<td>Research Information Specialist: Diane Carr Tolhurst (DRC)</td>
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<td>OSP: Office of Sponsored Programs</td>
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<td>SPA: Sponsored Projects Accounting</td>
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<td>ORE: Office of Research &amp; Engagement</td>
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I. IRB Review Process

1. PI/PD must determine if their project:
   a. Is considered human subjects research
      i. Is intended for release to the scientific community as contribution to new knowledge
      ii. Is portrayed by students, faculty or staff as “research” or “experimental” investigation
      iii. Is intended to fulfill requirements for a thesis, dissertation, or other research requirements at UT
   AND
   b. Is using human subjects
      i. Are you collecting data by interacting with living individuals
      ii. Are you analyzing data that others have collected from living individuals
      iii. Are you collecting or analyzing personally-identifiable information about living individuals
   OR
   C. If Human subjects determination form indicates your project needs human subjects review

2. PI/PD must determine if there are multiple IRB sites where the project/study takes place or the research/project is occurring at a site other than UTK
   a. If there are multiple institutions involved, the PI/PD will then submit the request for a Reliance Agreement Form via UTK IRB’s website
   b. UTK IRB will determine which institution will be the IRB of record
c. Communication will take place between ORS, IRB and the PI/PD and the reliance agreement will indicate the institution that will be the IRB of record

Note: Please allow for up to 2 weeks for deferral to be determined

3. PI/PD enters all project-related information into iMedRIS (https://ris01.uthsc.edu/) if UTK is the IRB of record (see IRB Manual for instructions)
   a. Departmental Approvals
      i. Faculty – Must list DRC and ADR
      ii. Student – Must list faculty advisor, DRC, and ADR
   b. All documents, including consent form, recruitment materials, data collection form(s), and other pertinent research material (e.g., letters of support), must be included in the iMedRIS submission

4. The IRB application is routed to the DRC and Department Chair once all other study personnel sign off. DRC and Department Chair review the IRB document, informed consent (if applicable), and all supporting documents, e.g., recruitment material, data collection form(s), letter(s) of support.
   a. Review is completed with comments and recommendations within 7 business days of receiving the application in iMedRIS
   b. Summary of comments and suggestions are returned to the PI for revision
   c. Final ORS approval is done by the Department Chair once revisions are submitted and reviewed in iMedRIS

5. PI/PD is notified of the ORS approval via electronic communication (iMedRIS) and project information will be routed to the IRB

II. Scholarship Projects

1. PD must determine if their project is considered research by completing the Human Subjects Determination (HSD) worksheet

2. If the project is considered research, PD must follow steps in section I (IRB Review Process)

3. If the project is not considered research, PD submits the HSD worksheet to UTK IRB. A copy of the HSD worksheet along with the Letter of Support is submitted to ORS

4. The PD will receive a letter of determination from UTK IRB

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1 Faculty advisors must approve student projects prior to being routed to the Office of Research Administration
2 If the review process takes more than 2 editing cycles (PI and ORS), a face-to-face meeting will be scheduled for expedience.
College of Nursing Process for Studies and Projects

Is there another institution engaged in the research?
- Yes
  - Submit the Reliance Agreement Consultation Form on IRB's website
  - Submit an IRB application in iMedRIS

- No
  - Complete the Human Subjects Determination (HSD) Worksheet

Are you conducting research?
- Yes
  - Did the worksheet indicate Human Subjects Review?
    - Yes
      - Submit the Reliance Agreement Consultation Form on IRB's website
    - No
      - Is there another institution engaged in the project?
        - Yes
          - Do you need a formal letter of determination from the IRB?
            - Yes
              - Submit the HSD Worksheet, Letter of Support, and Project Abstract Form to the Office of Research Services
            - No
              - Submit HSD Worksheet to the Office of Research Services
        - No
          - Submit an IRB application in iMedRIS
            - Once reliance agreement is executed, submit to Office of Research Services
  - Unsure

- No
  - Submit an IRB application at relying institution, submit Copy of IRB application and approval to the Office of Research Services

Was it determined UTK will be the IRB of Record?
- Yes
  - Submit an IRB application in iMedRIS
  - Complete IRB application at relying institution, submit Copy of IRB application and approval to the Office of Research Services

- No
  - Submit HSD Worksheet to the Office of Research Services
  - Submit the HSD Worksheet, Letter of Support, and Project Abstract Form to the Office of Research Services

Once reliance agreement is executed, submit to Office of Research Services

Once outcome letter is provided by IRB, you may begin your project

You may begin your project

Revised 9/8/2020