Purpose: This SOP provides guidance for oversight of human subject protection for research and translation within the College of Nursing. The Office of Research Administration is responsible for human subject oversight within the CON.

<table>
<thead>
<tr>
<th>Abbreviations</th>
<th>Current CON Personnel</th>
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<tr>
<td>PI: Principal Investigator</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 (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 must determine if their project: (See IRB attachment)
   a. Is considered research
      i. Is intended for release to the scientific community as contribution to 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
   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

2. PI must determine if there are multiple IRB sites where the project/study takes place
   a. If there are multiple sites, the PI will then fill out the Project Abstract Form to the Office of Research Services
   b. ORS with submit to UTK IRB where it will be determined if the IRB will be deferred or not
   c. Communication will take place between ORS, IRB and the PI and confirmation of deferment will indicate where PI enters study

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

3. PI enters all project-related information into iMedRIS (https://ris01.uthsc.edu/) if the study runs through UTK IRB (see IRB Manual for instructions)
Office of Research Services

SOP: IRB REVIEW PROCESS

Date Approved: May 2017

CON ORS 002

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

II. Forms Required for Approval
   • Project Abstract Form (PAF)

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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.