POLICY:

The purpose of this policy is to establish a systematic process for the review and approval of any research that will be conducted in Harrison School of Pharmacy’s (HSOP) experiential education programs. This includes HSOP’s StEPS Program, Early Interprofessional Practice Experience (IPE), co-curricular activities, or other experiential education experiences that are completed by HSOP P1, P2, and P3 students.

PROCEDURES:

Faculty who are proposing research using students and/or patients who are part of HSOP’s early experiential education programs (defined as experiential education that is completed by HSOP’s P1, P2, or P3 students) will be required to submit their research proposals to the HSOP Clinical Services Advisory Committee (CSAC) committee for review and action as described in this procedure.

1) The CSAC committee will be responsible for reviewing proposed research that involves IPPE students and/or patients, and providing recommendations to the investigators and to HSOP’s executive committee on whether the research should be approved, modified, or declined based on established criteria.

2) When these research proposals are received, the proposal must be circulated to all members of CSAC for prospective review before the CSAC meeting.

3) There must be a member of each HSOP department represented during these research reviews and involved in the vote on the research proposal.

4) If the composition of the CSAC committee does not include a representative from each department, the chair of CSAC must contact the head of each department to invite a representative from Pharmacy Practice (PP), Drug Discovery and Development (DDD), and Health Outcomes Research and Policy (HORP) to participate in the review, recommendation, and vote. The chair of each department must delegate a representative to attend CSAC to complete these activities on an as-needed basis.

5) **CSAC will use the following criteria to review each proposal:**

   a) the research project has scientific merit and would be addressing a gap in scientific knowledge and the literature

   b) the research has the potential to improve the outcomes of medication use amongst the patients who are served through HSOP’s introductory pharmacy practice experience programs (improved efficacy, safety, access, etc.).
c) the patients can decline participation in the research project if patient interaction is required as part of the research design and this will not impact the patient’s relationship with the Harrison School of Pharmacy, HSOP’s Clinical Affairs and Outreach (CAO) Office of Experiential Programs, HSOP’s Clinical Health Services, Auburn University’s Pharmaceutical Care Center (AUPCC), or AU Employee Pharmacy.

d) pharmacy students are not mandated to participate in the research project, and participation is completely voluntary. Declining to participate will not impact their experiential education grades or standing within the HSOP.

e) IPPE and/or IPE mentors are not required to participate in the research project directly or indirectly (through supervision of student activities). The research must be designed so that the research investigators provide all research oversight such as student training, supervision of data collection, etc.

g) If the project is approved by CSAC, then IRB approval must be obtained before the research project can begin. The IRB approval must be filed with the CAO’s Experiential Programs Office and the AUPCC.