

Pharmacy Research Committee and Oversight Plan
Department of Pharmacy
Duke University Hospital
Approved by Vice Dean for Clinical Research, 12/16/2014

Purpose

The Pharmacy Research Committee is a scientific advisory committee designed to enhance pharmacy staff, resident and student knowledge and participation in research.

Committee Function

The scope of the committee responsibilities shall include:

- **Oversee, guide and facilitate research activities to include:**
 - study feasibility assessment
 - compliance with Investigational Review Board requirements
 - adherence to data security requirements via review of the Research Data Security Plan
 - compliance with institutional training requirements

- **Identify and arrange extra-departmental research support resources which may include:**
 - statistical consulting services
 - Clinical Research Unit /Institutional Review Board protocol review
 - Duke Office of Clinical Research (DOCR) review

- **Issue a call for research project ideas on an annual basis and maintain a directory of interested research preceptors and their areas of research interests**
- **Establish guidelines/timelines for research projects**
- **Provide assistance to preceptors in developing suitable research projects**
- **Review and provide feedback to study investigators on Research Project Outlines and Research Protocols (including evaluation of scientific merit, design, feasibility, relevance to internal/external audiences, resources and regulatory compliance)**
- **Make recommendations to the Pharmacy Senior Management Group (SMG) regarding approval of projects**
- **Review and provide feedback on abstracts and presentations. Specific feedback shall be provided to pharmacy residents in preparation for the University Healthsystem Consortium (UHC) meeting and Southeastern Residency Conference (SERC)**

- Review and provide feedback on final research report in manuscript format prior to publication
- Perform an annual assessment of the effectiveness of the resident research process
- Assess pharmacy staff and residents' learning needs regarding necessary research skills and facilitate the scheduling of research training sessions to meet these needs and those required by the institution
- Ensure that investigators maintain a regulatory file, which may be held electronically. Recommended contents of the files could include documents such as a project staff list and training updates, all IRB communications, a copy of the protocol and if applicable, consent templates.
- Other activities, as needed, to support staff and resident research

Operating Procedures

The Committee will be directed by an appointed Chair.

Research Budget

The committee Chair will submit a budget to Pharmacy SMG annually for pharmacy research-related expenses, to include (but not limited to) statistical consulting services, CRU/IRB review, and other extra-departmental resources needed to support pharmacy staff participation in research. The budget must be approved by SMG.

Approval of Pharmacy Residency Research

Pharmacy resident research projects will be approved by Pharmacy SMG (upon recommendation from the committee).

Pharmacy Staff Research

Upon request, the committee will help facilitate research and mentor Pharmacy staff interested in conducting research. Pharmacy staff projects requiring CRU/IRB review will be approved by the Pharmacy SMG (upon recommendation from the committee)

Pharmacy Student Research

Pharmacy student projects requiring CRU/IRB review will be approved by the Pharmacy SMG (upon recommendation from the committee).

Monitoring of Pharmacy Residency, Pharmacy Staff and Student Research

To ensure that research activities are being conducted in accordance with submitted proposals to the IRB, the Pharmacy Research Committee Chair and Study Coordinator

will review study regulatory files every six months, at a minimum, while the study remains active.

Authorization

Authorized by the Pharmacy Senior Management Group; September 2011

Membership

This is a voluntary committee of pharmacists with research experience and expertise. The Chief Pharmacy Office shall appoint the Chair of the committee. The Chair shall then appoint committee members. Term of membership is at least one fiscal year (July 1 through June 30). Members who no longer wish to continue to serve on the committee following the end of their term must notify the Chair prior to the start of the next term (by May 1). In the event that a committee member cannot be present at a meeting, he/she should send his/her contribution to the Chair in advance of the meeting.

Frequency of Meetings

The committee will meet as needed to carry out committee business, approximately monthly, and more often during the period of review of residents' research proposals and protocols.

Reporting Channels

The committee shall report its proceedings to the Pharmacy SMG via meeting minutes and other communications from the Chair, as needed

Committee Minutes

Written reports of recommendations, actions taken, and the results of actions will be recorded in the minutes. The minutes shall be reviewed by the Pharmacy SMG.