

## **Family Medicine and Community Health**

### **Progress Report on Science Culture & Accountability Plan**

The Department of Family Medicine and Community Health (FMCH) Clinical Research Unit (CRU) has had a Science Culture and Accountability Plan (SCAP) in place since January 2013. This plan details our commitment and responsibility for the scientific integrity, quality, academic productivity, regulatory compliance, and financial accountability of research conducted within the department.

The FMCH-CRU SCAP are updated according to the Duke Office of Scientific Integrity (DOSI) policy in order to ensure that research faculty and supporting scientific staff are aware of institutional policies and procedures and attest to the Scientific Culture & Accountability Plan.

- SCAP will be reviewed and updated annually (if applicable)
- SCAP will be reviewed by faculty and staff upon onboarding, and annual year-end performance evaluations or check-in
- SCAP is made available on a shared drive faculty and staff have access to

The key elements of the plan that have been implemented for our Clinical Research Unit (CRU) are described below:

#### **Communication, forum and meetings**

- Conduct monthly research committee meetings for FMCH faculty and staff engaged in research. These meetings are a combination of scientific presentations by departmental researchers and a forum to disseminate and discuss updates on regulatory and administrative processes.
- Hold Thursday brown bag sessions, which includes all full time researchers and clinical faculty interested in research as a vehicle for announcing and discussing important issues relevant to this work, in conjunction with scientific presentations.
- Provide and distribute monthly electronic newsletter with CRU, Duke Office of Clinical Research and Duke School of Medicine news and updates to research faculty and staff.
- Individual research groups have regularly scheduled meetings to discuss study progress and review data.
- Journal clubs, research seminars and retreats are held to encourage discussion of work conducted within the department and recent journal articles.
- The Vice Chair for Research meets regularly with individual faculty to discuss their research including any scientific or ethical concerns.
- The CRU Research Practice Manager (RPM) conducts monthly meetings for research staff to provide education and updates on research standards and to provide a forum where research staff can raise questions or concerns.

### **Trainings, clinical and data quality management plan**

- Provide onboarding for all new research faculty and staff.
- Ensure faculty and scientific staff engaged in research are in compliance with required research training.
- The CRU CQMP reviewer will conduct on-going quality assurance reviews of current research studies. Studies are selected according to the Duke School of Medicine Clinical Quality Management Plans (CQMP) policy.
- The CRU team has developed a checklist to ensure that Data Use Agreements or Material Transfer Agreements are completed through the Duke Office of Corporate Research Collaborations whenever incoming or outgoing PIs have data or materials transferred to or from Duke
- The CRU team conduct a review of data storage or disposal within the department, focusing on ensuring the Research Data Security Plans are up-to-date and that sensitive information is stored or destroyed appropriately.

### **Services and resources**

- Faculty have access to a PhD level statistician supported by the FMCH CRU to assist with study design and statistical analysis for grant applications and publications.
- All new research protocols submitted to the IRB are reviewed by a senior faculty and CRU director to insure they are scientifically feasible and investigators have appropriate expertise.
- Provide pre and post study assistance to FMCH faculty who are predominantly clinical/educator to ensure research and scholarship are completed with the necessary rigor, ethics and regulatory compliance.
- Research protocols involving primary care clinical practices are reviewed by the Primary Care Research Advisory Board for feasibility and scientific rigor. Members of this board include the FMCH CRU director, other FMCH research faculty and primary care clinicians.
- A document describing guidelines for conducting research in clinical practices or community settings has been developed and disseminated to departmental faculty. This document focuses on the need for collaborative efforts between the researcher and stakeholders in the clinical or community organization beginning with the planning of the research and continuing through the implementation of the project and dissemination of results.
- Faculty and staff are reminded regularly of the School of Medicine Integrity Line which allows for anonymous reporting of issues and concerns. Flyers and brochures from the Integrity Office are posted at faculty and staff workstations.

### **Evidence for collection of signed SOPs for wet lab research**

Not applicable. Currently there is no on-going wet lab research within the department.