Version 15 December 2015

Faculty Research Education Workgroup

Curriculum for Investigator Training Program (ITP)

First session, Thursday, 21 January 2016 8am – 12: 00 noon (NP 2532)

Co-chairs – Penny Jester, Mansoor Saleh

Title: **Clinical Research: A Practical and Pragmatic Approach For investigators**

Session Objectives:

- Describe the steps and requirements from receipt of proposed clinical trial/study, to start of study.
- Describe the requirements and steps essential to successful conduct and completion of a clinical study.
- Define the scope and importance of principal investigator oversight.
- To provide a forum for education and an opportunity to engage in a productive dialogue.

Target Audience:

All Clinical investigators from the experienced to the novice.

Curriculum

7:30 – 8:00 **Registration**

8:00 – 8:15 **Overview** (roles and responsibilities of the investigator)

8:15 – 9:45 **Pre-Award** (Overview) (15 min)

So you want to do a study: how to start:

(10 min) CDA and Contracts: what are these? How to manage
(25 min) Study Feasibility: should you do the study (factors to consider)
(30 min) Pre-Activation starting a study
(20 min) **PANEL discussion** – Q & A

9:45 – 10:15 Break

10:15 – 11:15 **Post-Award** (after activation) (5 min)

Starting and implementing the study (and you thought pre-award was challenging)

(20 min) PI oversight overview during the study
(20 min) Subject and study management
(25 min) Data management

11:15 – 11:45 **Team work** – you are not in this alone

- Working together as a team
- GCP adherence: subject safety and clean, complete data

11:45– 12:00 **PANEL discussion** – Q & A