10. REGULATORY KNOWLEDGE AND SUPPORT

### Objectives

1. Emphasize process improvement so as to decrease real and perceived regulatory burdens for investigators
2. Expand the purview of successful regulatory and clinical innovations
3. Promote the responsible conduct of research through improved education to facilitate understanding of the regulations

### Table of terms

- IAC: IRB Advisory Committee
- IRB: Institutional Review Board
- IACUC: Institutional Animal Care and Use Committee
- OHRP: Office of Human Research Protections
- RCR: Responsible Conduct of Research
- HRPP: Human Research Protection Program
- RKS: Regulatory Knowledge and Support
- CRRS: Clinical Research Regulatory Support

### Personnel

- Philip Cola, MA, (VP Research UHCMC & Adjunct Assistant Professor CWRU), Director of Core, CTSC Champion of Change
- Kathy Lawry, MSSA, CIP (Director IRB, MHS and Assistant Director, Research Admin)
- Daniel Beyer, MS, MHA, CIP (Executive Director IRB, CC)

### IND/IDE Core Process Flow

**Scope of Work (2 hours)**

**IDE application**
- Prep & Submission (2.5 hours)
- FDA Communication (1-6 hours)

**FDA approval**
- (5.5 hours)
- CRF (1 hour)
- FDA 005C (8 hours)

**IDE Sponsor Trainning**
- (2 hours)

**Site Initiation**
- (5.5 hours)

**Monitoring Plan**
- (2 hours)

**Regulatory Gender Development**
- (6 hours)

**IND/IDE**

**Protocol:** (7 hours)
- C.R.F. (6 hours)
- CRF (8 hours)
- FDA 005C (8 hours)

**Objectives:**
- Emphasize process improvement so as to decrease real and perceived regulatory burdens for investigators
- Expand the purview of successful regulatory and clinical innovations
- Promote the responsible conduct of research through improved education to facilitate understanding of the regulations

**Special Projects**

- Implemented formalized RCR curriculum for degree seeking students in the CWRU School of Medicine, “IBMS 500: On Being a Professional Scientist: The Responsible Conduct of Research”
- Implementation of a state-wide “Reliant IRB” model and expanded use of CTSC “electronic hub” (see figure above)
- Formalization of an “Investigator-initiated Research Support Core” to provide IND/IDE regulatory support for investigators across all CTSC institutions through CRRS personnel (see process flow above)
- Integration of Research Conflict of Interest (COI) procedures across all five CTSC institutions through COI Harmonization Committee.

**Notable Accomplishments**

- Paper entitled “Evaluating various areas of process improvement in an effort to improve clinical research: Discussions from the 2012 Clinical Translational Science Award (CTSA) Clinical Research Management Workshop”. Accepted for publication on February 4, 2013 in *Clinical and Translational Science*.
- Paper entitled “Ohio CTSA: Implement a Reliant IRB Model for Investigator-Initiated Multi-Center Clinical Trials.” Accepted for publication on February 22, 2013 in *Clinical and Translational Science*.
- Implementation of IND/IDE software system (Arena) (results of which will be presented nationally at Clinical Research Management Workshop in June 2013).
- Received National Award for Excellence in Human Research Protection for Best Practice from the Health Improvement Institute (HII) for Collaborative Review Structure of local IRB Consortium.