A Vision: Clinical Translational Research Network

January 2015
A Vision for Clinical Translational Research

A comprehensive and integrated group of experts who will provide services for all affiliated clinical research
POSSIBLE ROLES AND RESPONSIBILITIES

- Timeline creation
- Navigator to other offices
- MCA creation
- MCA liaison
- MCA revision
- Budgeting assistance
- Liaison to Contracting
- NCT registration guidance
- IND trial initiation
- IDE trial initiation
- MAC assistance
- Liaison to industry
- Master contract maintenance
- IRB assistance
POSSIBLE ROLES AND RESPONSIBILITIES

- Pool of trained Research Coordinators
- Provide guidance throughout active studies to PIs and Research Coordinators
- Assist with navigation of UM systems and offices
- Liaison for unresolved billing questions
EXPANSION OF Clinical Research Operations & Regulatory Support (CRORS)

- Create and provide training
- Assess and certify research staff
- Identify and maintain pool of mentors
- Assign certified mentors to junior staff
Operations and Regulatory Support

CRORS – FOCUS ON IND/IDE STUDIES

• Consultation regarding requirements
• Regulatory and submission support
• Risk based monitoring
• SOP guidance and assessment
EXPAND EXISTING SERVICES

• System-wide accessibility
• Placebo creation
• Packaging capability
• Consistent drug tracking for all studies
• Transfer medications to research sites
INVESTIGATOR’S LINK TO HOSPITAL SITES

• Integrate research activities into hospital practices, policies and procedures
• Facilitate growth of clinical research
• Lead projects that build toward a fully operational academic medical center
• Assist the health care staff in the requirements of biomedical research
Research at MSOM

- Discovery
- Clinical
- Translational
- Nursing
- Behavioral