Clinical Skills, Training and the Unlicensed Study Coordinator

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Study Coordinators

• Backbone of most research teams
• Primary responsibility for carrying out the study
• *Very* broad job description
• Duties can include
  — Project Coordination
  — Financial/Grants Coordination
  — Data Coordination
  — Data Collection – **Seeing Participants**
Study Coordinators and Participants

- Recruiting
- Consenting
- Data collection
  - Surveys
  - Case report forms
  - Clinical measures
- Participate in interventions

CLINICAL TASKS/SKILLS
Survey of Study Coordinators

• Autumn, 2013
• Survey sent to all non-PI, non-Co-I study team members on active protocols in eIRB (just SOM)
• 1,003 responses
• 406 indicated they were study coordinators without a license
  —E.g., MD, RN, LPN, CNA, CMA, PA-C
• 192 of those indicated that they perform some type of clinical tasks
Types of Clinical Tasks Performed

- Processing Specimens
- Collecting Height/Weight
- Collecting Vital Signs
- Collecting Urine
- Collecting Blood (Phlebotomy)
- Collecting Other Biological Samples
- Other Clinical Measures
Growing Recognition of Study Coordinators

• Understanding that unlicensed Study Coordinators are functioning in the clinical environment
  — That can be okay!
  — There are other unlicensed positions within the health system that have clinical functions

• Understanding that Study Coordinators can HAVE AN IMPACT on the clinical environment (i.e., Joint Commission accreditation)
  — Need to define acceptable parameters for clinical practice
  — Need to better define training requirements for clinical skills
New Training Initiative

• Begins this month (February, 2015)
• Training required of **ALL STUDY TEAM MEMBERS**
  — PIs
  — Co-Is
  — Data Managers
  — Everyone
• Training is a **TEN MINUTE** slide presentation in myLearning, including review questions
• Everyone has one year to complete the training
“Training for Clinical Research”

• **A RESTATEMENT OF EXISTING INSTITUTIONAL POLICY**
  —Nothing new here.

• PI is ultimately responsible for all aspects of the conduct of a clinical research study

• PI can delegate responsibilities to other study team members, consistent with their education, training and licensing
• Some clinical skills can be delegated to unlicensed study personnel, with appropriate training
  —Examples include:
    ▪ Vital Signs
    ▪ Height/Weight
    ▪ Collection of some specimens
    ▪ Phlebotomy
    ▪ Some clinical measures
• Some clinical tasks **MAY NOT** be delegated to unlicensed study personnel at any time
  — Dispensing or administering medication
  — Performing invasive procedures (beyond venipuncture)

• Unlicensed staff should not perform any procedure that is deemed to be more than minimal risk to the participant
“Training for Clinical Research”

• Research personnel should adhere to clinic standards for:
  — Conduct
  — Appearance
  — Demeanor

• As well as other clinic-specific policies and procedures
“Training for Clinical Research”

• PI is responsible for making sure everyone on the study team is:
  — Qualified to perform their delegated roles and
  — Receives appropriate training

• Training can be delegated to appropriate designees

• TRAINING MUST BE DOCUMENTED TO BE VALID
Documentation of Training

• Documentation of training must include
  — The content of the training
  — Who performed the training and when it took place
  — Documentation of the skill being adequately performed by the trainee

• Documentation should be maintained by the study team and be ready and accessible for audits (both research and clinical)
Everyone’s Responsibility

- Both the PI and the study staff should take ownership of making sure they do not perform delegated tasks unless they are appropriate (e.g., minimal risk for an unlicensed study coordinator) and they have been appropriately trained.
The ICTR Can Help

• Beginning in late February/early March
  — ICTR Website will have training resources
    ▪ Competency checklists for clinical skills
    ▪ Links to training resources
    ▪ Frequently asked questions
  — ICTR Clinical Research Units will be offering skills training
    ▪ See the ICTR website for instructions
Questions?