Dialysis Clinic Personnel Engagement in Research

Improving Research Readiness in Dialysis Clinics

Dialysis Research Readiness Workshop

Durham, NC

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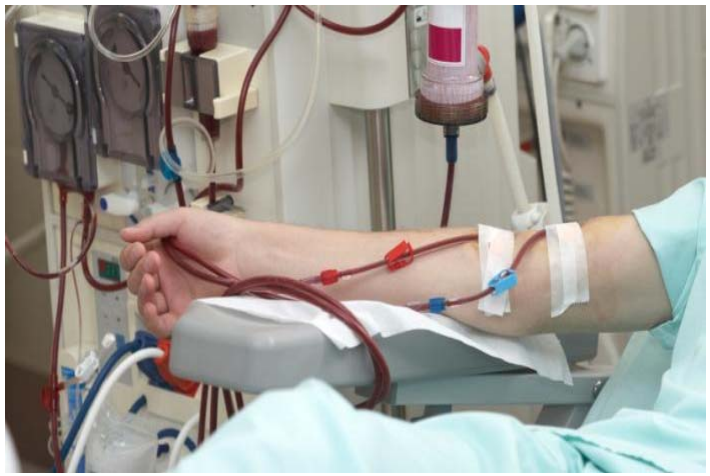
Overview

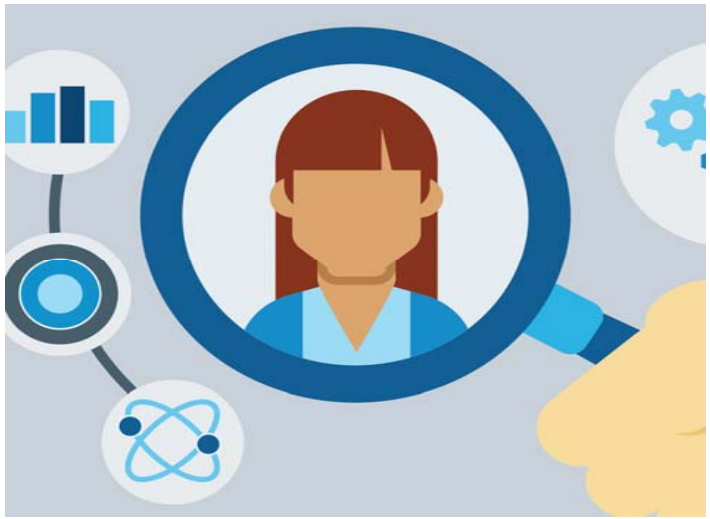
- Hannah- Regulatory Compliance issues & considerations associated with dialysis clinic personnel participating in research

- Terry- How to generate enthusiasm and build a research-ready clinic culture in this regulatory context

How research differs from job duties

- **Primary Goal/Focus**
- **Guiding Documentation**
- **Data Access**
- **Patient Interaction**
- **Equipment Interaction**
- **Certifications/Licensure**





Clinical Research vs. Medical Treatment

- **Intent**
- **Funding**
- **Consent**
- **Institutional Board Review (IRB)**
- **Timeframe**
- **Release of findings**
- **Billing**

Clinical Research vs Quality Improvement

- **Purpose**
- **Starting Point**
- **Design**
- **Benefits**
- **Risks**
- **Participant Obligation**
- **Endpoint**
- **Adoption of results**
- **Staff role**

Who is involved in review & approves research in a dialysis clinic?

1. Clinic Level

2. Organizational Level
    - Legal & Compliance
    - Regulatory
    - Patient Safety
    - Clinical Services
    - Research Experts

Organizational Research Committee & Contractual Considerations

- **Scientific**
- **Privacy & Security (HIPAA)**
- **Reimbursement Integrity**
- **Patient Safety**
- **Staff Burden**
- **Other studies ongoing in the facility**
- **Study Risk-Level**
- **Regulatory Concerns**
- **Training/Qualifications of Staff**
- **Storage of supplies/medications**
- **Processes in place to address concerns**

Aspects of research where clinic personnel usually do not participate

- Delegation of Responsibility Log- defines each study specific role
- Consent
- Recruitment
- IRB Interactions
- Research documentation
- Considerations- Federal and State Law, Contractual limitations

How can staff participate?

- Minimal time commitment or minimally invasive procedures
  - Blood draw
  - Providing access to clinical data
  - Easily coordinates with routine clinical care
- Coordinate processes with research team
- Direct research team towards the correct contact
- Would need to specify in contract what services are being provided by clinical staff

Improving Research Readiness in Dialysis Clinics

Is the Facility Research Ready?

- Facility leadership commitment to support clinical research
- Research Standard Operating Procedures (SOPs) have been developed and adopted by GB
- Basic education to staff and patients about research readiness
- Evaluation of the Facility Resources

Research Readiness through Staff Education

- All employees have an important role in research
- Start with basics on “What is Research”? Video and printed materials
- Initial and annual education on the Research Standard Operating Procedures and their location
- Existing and new employees as they are hired (per diems and travelers)
- Lunch and learns- Role of research personnel vs staff
- How can research benefit our patients?

Research Readiness through Patient Education

- Research Lobby Days
- Educate all patients who are cognitively able to understand what research is and how it pertains to them
- Introduce all members of the research team to the patients
- Encourage the patients to speak with their Nurses and PCTs
- Provide written material for them to take home and discuss with their caregivers/family members

Research Readiness – Prior to Start of Study

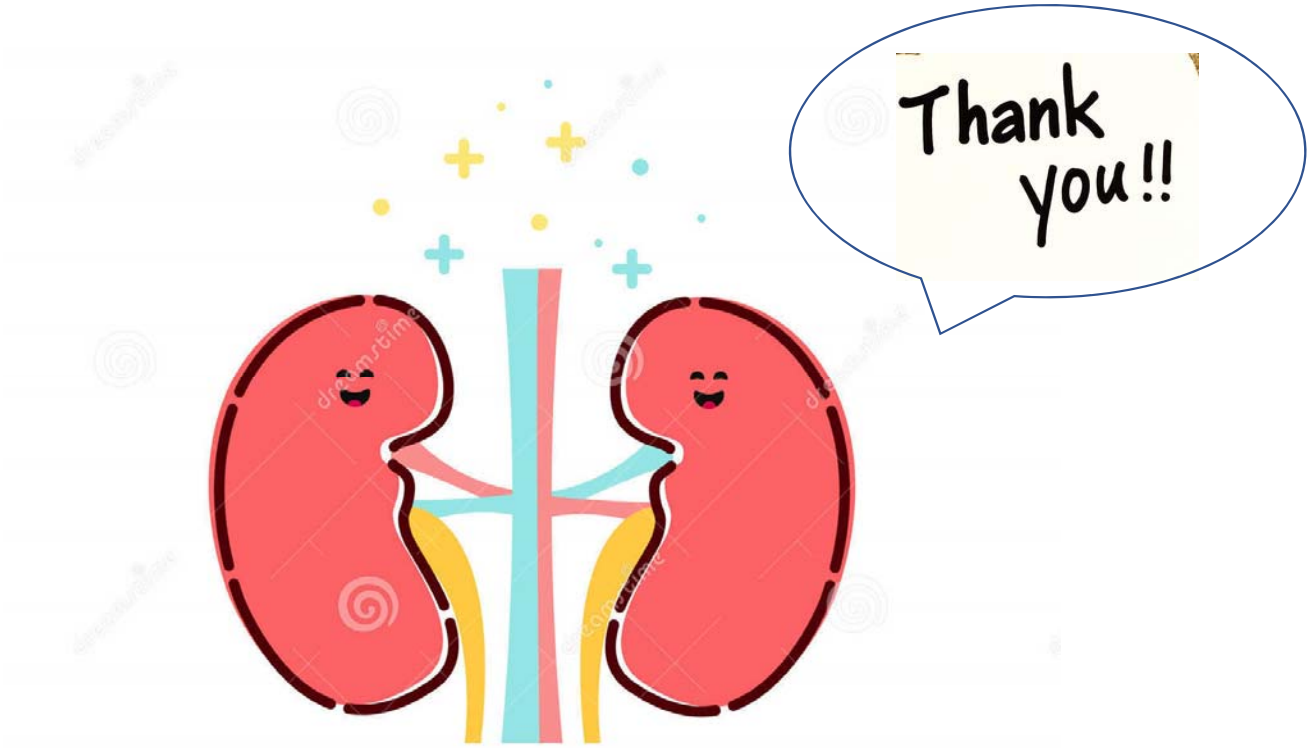
- Governing Body review and approval
- In-service required for every study
- Clear communication is key!
  - What is the study? What will it entail?
  - Who I may see in the clinic?
  - What is expected of me?
  - What is not expected of me?
  - Who should I direct patients to if they have questions?
- Executive summary saved at clinic level

Research Readiness- During an ongoing study

Encourage	**Encourage staff to ask questions! Make sure staff feel empowered to speak up if they see something that doesn't seem right**
Coordinate	**Assist with coordinating study specific procedures (should be clearly stated during in—service)**
Report	**Report any adverse events/SAEs to research staff asap**
Update	**Monthly staff meeting review of all research projects being done in the clinic (QAI/GB)**
Ongoing	**Watch for staff changes! Continuous cycle of education for clinic staff! New staff education during staff orientation**

Research Readiness- Follow Up

- The Principal Investigator should meet with the staff and discuss the results of the study
- Will there be a “Poster” of this study and at what meeting?
- Will there be a publication?
- How will the results of this study benefit their patients and many others?
- Create excitement
- Celebrate with the Staff
- Content for staff vs patients (appropriate reading level!)



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