Dialysis Clinic Personnel Engagement in Research
Improving Research Readiness in Dialysis Clinics

Dialysis Research Readiness Workshop
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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

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