Starting University Clinical Careers Efficiently, Scholarly, and Successfully

Getting Involved in Patient Oriented Research

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Why Get Involved in Patient Oriented Research?

• Improve patient care
  • Offer patients therapies not currently available
  • Patients in clinical trials do better, in part due to closer medical attention

• Generate new knowledge--if you are a believer in evidence-based medicine, why not help to contribute new evidence?

• Diversify your workday/work-life
• Travel/network
• Need academic productivity to get promoted!
Types of Patient-Oriented Research

- Case report
- Case series (retrospective)
- Retrospective observational study
  - Cross sectional
  - Case/control
  - Retrospective cohort
- Prospective observational study
  - Registry
  - Prospective cohort study
- Clinical trial
How to Get Involved

• Ask an experienced researcher or research team if you can help with an ongoing project
  • Be BOLD and sell yourself
  • Ask for a tangible (but manageable) role in exchange for co-authorship
  • Be fully engaged—make yourself indispensable, even in a small role

• Start your own project
  • Plan/plan/plan
  • Get honest assessment of feasibility BEFORE starting, even if project is small
What do I need for observational research?

• A research hypothesis
• An appropriate data source to study the question
  • Publicly available databases (NIH, “dead” clinical trials, DHS, etc.)
  • Local databases
• A statistician (or your own quantitative skills)
  • Center for Translational Medicine (Biostatistics, Epi, Research Design)
  • Department of Population and Data Sciences
• Resources to pay for data access/statistical support
  • Department/institutional pilots, service packs
Clinical Trials: What Do I Need?

- Access to a research nurse/coordinator
  - Expensive
  - Share/Borrow/Rent models
- A trial
  - Focus on therapies that offer something enticing to patients
  - Industry MSLs good resource
- A recruitment strategy
- Feasibility assessment
- Commitment/drive to recruit and retain
Who Funds Clinical Trials

• Industry
• NIH
• CTSA consortium
• Professional Societies
• Health Systems
The moving pieces of trial startup

- Informed Consent
- IRB
- Coverage analysis
- Site approval
- Investigational Drug Services
- Startup visit
- Budget
- Contract

We ALL need professional help!
Options for Research Nurses

- Join in a shared resource in your division/department
- Ask your division/department head if they know anyone who has available personnel
- Work with the Clinical Research Unit (CRU)
  - Run by John Beaver
Challenges and Pitfalls—General

- Feasibility not fully vetted
  - Cannot answer question in a single center
  - Overestimate association/effect/ease of enrollment
- Lack of support from colleagues
- Insufficient time to devote to project
- Financial
  - Have not accounted for costs of study procedures
  - Have not considered hidden costs
Challenges and Pitfalls—Clinical Trials

• Enrollment, enrollment, enrollment
  • Use existing resources to get a sense of potential eligible patients
    • Slicer/Dicer
    • Research Participant Registry
  • Lack of support from colleagues

• Logistics of study procedures—devil is in the details

• Budget
  • Almost no one makes money doing local clinical trials
  • A clinical trial is a small business and needs to be run as such
Conclusions—Patient Oriented Research

• You don’t need to have a lot of prior research experience or protected time

• Success requires
  • Planning
  • Feasibility assessment
  • Help/teamwork—none of us can go at this alone
  • Commitment
  • Resilience (to battle through the inevitable challenges)

• Patient oriented research is worth the effort
Additional Information and Resources

1. Center for Translational Medicine (CTM) Website

2. Recruitment tools
   - Slicer/Dicer (feasibility)
   - CTM recruitment support
   - UTSW Volunteer Participant Registry (opt out)

3. Office of Clinical Research (led by Dr. Nancy Rollins)
   (https://www.utsouthwestern.net/intranet/research/ocr/ocrp/)
   has a great handbook with steps laid out
Getting Involved in Clinical Trials and Patient Oriented Research

Summary of Key Points

- Start early, anticipate delays, stay on top of details
- Clinical research is a team sport—play your role and lean on your teammates
- Don’t start a project until you have fully vetted it with experienced researchers
- Take advantage of many resources available at UTSW and in your departments
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Questions? Email me!

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