

# **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

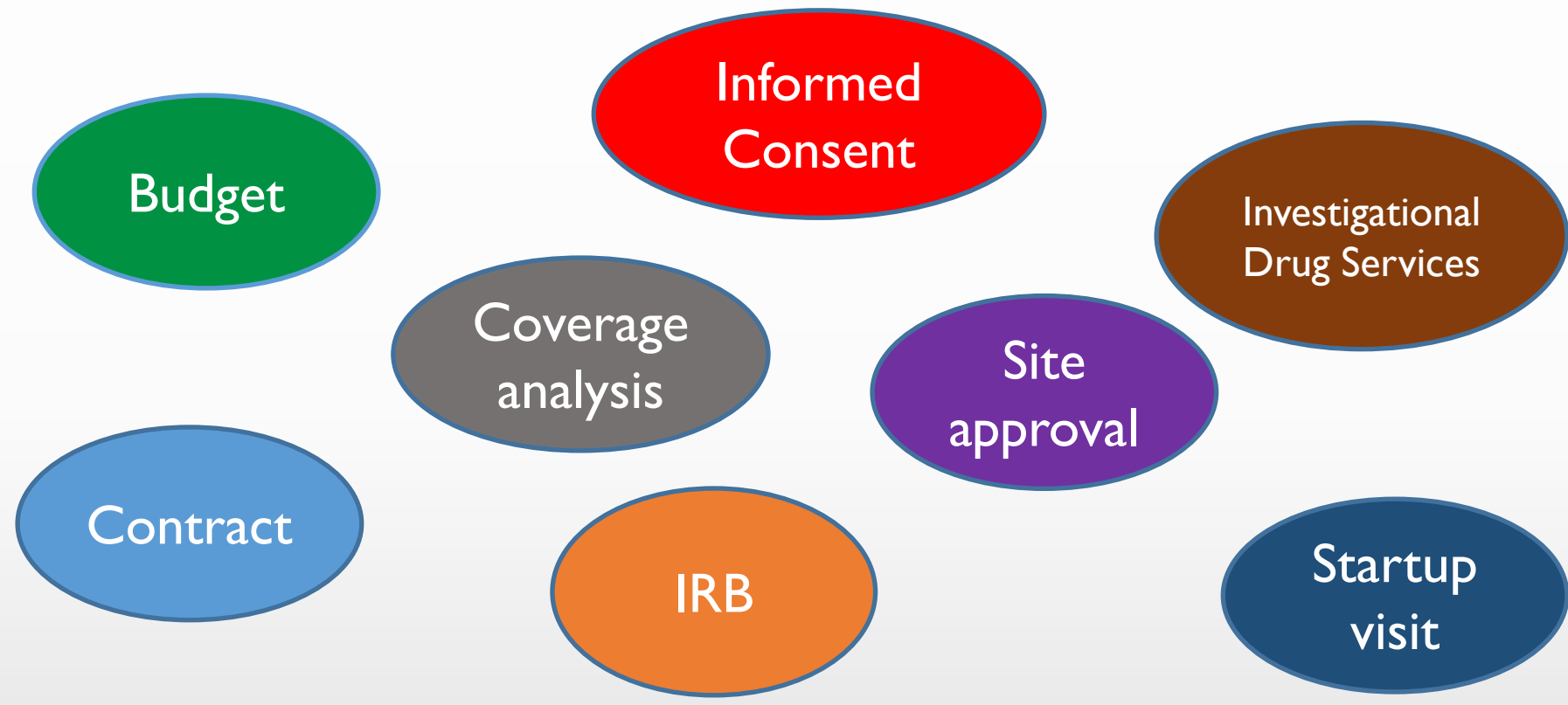
# Clinical Trials: What Do I Need?

- **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



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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