#### **WVU**Medicine**Children's**.

#### Children's Hospital Research Consortium (CHRC)





### What is the CHRC?



- Group of experts who provide <u>coordinated</u> support and navigation for QI and clinical research including:
  - Project coordination
  - IRB/Regulatory support
  - Data entry
  - Quality assurance
  - Biostatistical support
  - Writing







# **What Services Are Provided?**



### **Project Development**

- Writing draft reviews and comments
- Select writing support
- Study design consultation and summary
- Sample size calculation and summary
- Statistical analyses consultation and summary
- QI vs IRB discussion and planning
- Study planning activities (e.g., Slicer Dicer) review
- Partner/ Team building activities and support

#### Project Start-Up & Implementation: Quality Improvement

- Review invitation to participate and short summary of project
- Discuss whether WVU site is able to participate (# patients, process in place, etc.)
- If budget is associated with study, need to work with Will Bailey to establish grant proposal within KC system for OSP review of budget
- Sign interest agreement (if applicable) if OSP review is required
- Request protocol
- Interest in publishing or presenting?
- Discuss IRB types
- Complete trainings
- Develop protocol in system
- Data Use Agreement
- Submit information to coordinating center



### Project Start-Up & Implementation: Research

- Discuss study and complete feasibility discussion; obtain dept. approval as needed
- Develop protocol and other attachments; finalize IRB approach
- Review and obtain approval for budgetary needs
- Obtain appropriate approvals
- Assess support for implementation
- Access to a data safety monitoring board
- Ongoing study monitoring and regulatory reporting

### Project Start-Up & Implementation: Clinical Trial

- Discuss study and complete feasibility; obtain dept. approval
- Obtain or develop complete protocol for trial
- Navigate protocol through review and approval system (OSP, IRB, safety monitoring)
- Establish regulatory documents, study binder
- Train coordinators on protocol
- Establish on-line coordination systems
- Access to a data safety monitoring board
- Ongoing study monitoring and regulatory reporting



# **Project Closure and Write-Up**

- Analysis and write up
- Additional partner development
- Dissemination of findings discussions and planning
- Subsequent grant development and planning
- Study closure with IRB and other entities





# Which Projects Must Come Through CHRC?





#### Who is Eligible to Receive CHRC Services?

 Anyone in the institution who is conducting a QI or research project that is based on pediatric populations and/or pediatric data.







# When Should I Reach Out to CHRC?

• As early as possible.





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