DEVELOPING A PROTOCOL
Objectives

• Describe steps in developing a protocol
• Describe components of a protocol
• Discuss when to seek for experts’ help when developing a protocol
What is a Research Protocol?

• Written detailed procedures for conducting the research study and collecting data
  [highered.mcgraw-hill.com/sites/0073049506/student_view0/glossary.html](http://highered.mcgraw-hill.com/sites/0073049506/student_view0/glossary.html)

• A document describing in detail how a research study is to be conducted in practice, including the methodology, a plan for analyzing the results, and a budget
  [www.cehjournal.org/0953-6833/20/jceh_20_61_017.html](http://www.cehjournal.org/0953-6833/20/jceh_20_61_017.html)
DEVELOPING A PROTOCOL

What Steps Should I Take To Develop A Research Protocol

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How to start developing a protocol?

• Keep a list of issues / questions
• Follow the IRB guidelines: print and read carefully
• Call your IRB rep or study mentor for clarification
• Details of methods
  • Eg, surveys go in Appendices
• Discuss with key stakeholders for buy-in
How To Be Efficient When Developing A Protocol

• Careful planning up front can help avoid possible disasters at the end - for example:
  – Insufficient sample size leads to:
    ✓ Inability to draw a conclusion for a desired patient population
    ✓ Inability to make assumptions or generalizations about findings
  – Where will you keep your study data?
    ✓ Databases: Linking data collection to data forms, to databases.
    ✓ Enlist help from experts, if necessary

• Work in one hour blocks of time
• Use an old protocol as a template
• Keep the protocol brief
• Write the first draft without a focus on grammar
To Write Efficiently, Write In The Following Order

1. Cover sheet – title, investigators, contact information
2. Background of the problem (why do it?)
3. Research questions (list specifically)
4. Methods (design, setting, sample and procedures)
5. Risks, HIPAA, Informed Consent
6. Review of the literature (write it last!!)
Protocol Development Steps

1. Know what you want to say about the study question when the study is finished

2. Write a first draft
   - Start with an outline using a completed protocol as a template
   - Do not over-write

3. Break down the protocol into components
   - Attack one component at a time
Use A Protocol Template to:

- Replicate a study
  - To evaluate the similarities and/or differences in results from the original study
    ✓ Recreate the study like the original study if the protocol is available
    OR,
    ✓ Use the manuscript to replicate the study
Use A Protocol Template to:

- Construct a new study
  - Use any existing protocol as a template
    - Replicate headings
    - Borrow wordings, construction or layout
    - Research Summary Instructions available at DUHS IRB website:
      https://eirb.mc.duke.edu/eirb/Rooms/DisplayPages/LayoutInitial?Container=com.webridge.entity.Entity%5BOID%5B2374ADAB42020F4DA3F44AD283EC1EDF%5D%5D
Tips For The First Draft Of A Protocol

• Keep It Simple
• Use A Completed Protocol as a template
  – Write all components of the protocol as section headings
• Skip difficult parts
  – Farm out the task later
    • Statistical analysis section
    • Study database
DEVELOPING A PROTOCOL

What Are Components Of A Protocol And When Should You Ask For Help?

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Components Of The Protocol Include:

- Title
- Problem/Background
- Research question/Hypothesis
- Methods
  - Design and definitions
  - Sample and setting
  - Data collection procedures
- Data analysis plan
What Is Problem and Background Information?

• The broad problem statement
  – Important for setting the stage and alerting the reader to the importance or significance of the proposed research
  – Establish the argument or need for doing the study
  • The information known about the problem is used for emphasizing the unknown
What Is Research Question Or Hypothesis?

• A succinct question or statement summarizes exactly what will be studied

• Can be a declarative statement in the form of a hypothesis when research questions:
  – Ask about relationships between two or more variables
  – Seek to compare one or more different approaches to care (interventions)
What Are The Components Of Methods Section?

• Research design:
  – **what** you intend to do

• Population and setting:
  – **who**, **when** and **where**

• Data collection process:
  – **Who** will collect and **how** it will be done
    • description of tools or instruments used for the intervention
Study Design…Methods Made Simple!

Sometimes You’re the Expert!
• Use existing study methods as a template  
  • “Tweak” design and procedures to fit your unit  
  • Do a “walk through” to identify procedure glitches

Sometimes You’re Not!
• Sample size estimation  
• Research design  
• Validity and reliability of instruments  
• Informed consent – construction and loopholes
How To Write Design Section In Methods

• Use supporting literature
  – Find a description of how the study was set up to answer the question in the “Discussion” section
    • Recommendations from authors related to design
  – Design may also be discussed under “Limitations” in the manuscript

• If design is not found in reviewed manuscripts.
  – Evaluate your own clinical setting and patient population
  – Determine what you think will be the best way to go about gathering data to answer your question
  – Call one or two authors of similar studies and discuss design
    • Ask why a particular design was selected and if the author recommends changes
When Writing Design Section In Methods

• Examine the variables and their relationships
  – *Variables:* “A variable is a characteristic measured or observed by information gathering that either varies among the persons, events, or objects which make up data or is a constant.”
    - Independent variables: represent the value being manipulated or changed
    - Dependent variables: observed result of the independent variable being manipulated
  – *Relationships* between the variables are compared, described, identified, predicted, or in some way evaluated to make a statement at the end of the study to make a statement
When Writing Design Section In Methods

• Validate design choice with an expert
  – Discuss your thoughts with a statistician or an author of a similar study to validate your choice
  • Data analysis is based on the relationships between your variables
    – It is important to design data collection to reflect the correct or desired relationship between variables
    – Enlist the same expert in the beginning that will be helping you analyze the data in the end

• Be as specific as possible
  – Include enough detail that another researcher would be able to repeat the study if desired
What Does Sample Mean?

• Description of the population and setting of the research
  – **Who**: study participants selected per study inclusion and exclusion criteria
  – **Where**: setting of the study
    • Where will you recruit study subjects?
    • Where will you follow the study subjects?
What Is An Appropriate Sample Size And How Do You Select Them?

• Appropriate number of subjects is based on
  – Type of research design
  – Statistics and significance level
  – Variables being measured
  – Anticipated effect of the study intervention on the dependent variables

• Selection of Subjects
  – List inclusion/exclusion criteria
  – How subjects will be identified?
Include Subject Recruitment And Compensation In The Methods Section

• Describe recruitment procedures
  – Who will introduce the study to potential subjects?
  – Ensure that subject selection is equitable and all relevant demographic groups have access to study participation (per 45 CFR 46.111(a))

• Define subject compensation, if there is to be any
  – Provide specific prorated amounts to include expenses such as travel and/or lost wages
  – Provide specific prorated amounts to be provided for incentive to participate
Explain How You Would Collect The Data

• Describe logistical questions
  – **What**: data to be collected
  – **When and how**: to collect data
  – **Who**:
    • Research personnel to perform intervention and data collection
    • Sample population = study participants

• Describe the exact sequence of events, time relationships and individuals involved during the data collection
What Are The Barriers To Data Collection?

• Reduce barriers to data collection – consider:
  – Feasibility to accomplish in the geographic area
  – Patient flow dynamics
  – Other realities of the clinical environment
    • Unit routines
    • Staffing patterns
    • Communication patterns
    • Unit documentation processes or standards
  – Funding resource: Is funding adequate to cover research efforts and materials needed?
What About Data Analysis?

- Include preliminary plans for data analysis
- General ideas about analysis are acceptable
  - May change with the eventual completion of the study
- Specific idea of the statistical tests that will be used
  - Helpful in considering every piece of data that will be required for the analysis
What To Consider When Designing Databases

• The less transcription of data required, the fewer opportunities for error.
  – Is this piece of information necessary to collect?
  – Is this the most direct way to get the information?
  – Is the data easily transferable to a database that is familiar to the statistician?

• Is the information necessary?
  – Is it directly related to what I need to know to answer my question?
  – Will it provide necessary supporting information for my question?
What To Consider When Designing Databases

• Is this the easiest way to get the information?

  – Use computerized data entry whenever possible?
    • Microsoft Excel©
    • Microsoft Access©
    • Web accessible databases, such as REDCap (https://vml-lin16.duhs.duke.edu/redcap/)

  – Use direct download from an electronic health record, if possible
What Is A Research Summary?

• Should be able to abstract enough information to write the summary from the research protocol
• Required by the DUHS IRB
• Research Summary Template available in DUHS eIRB website:
  – [https://eirb.mc.duke.edu/eirb](https://eirb.mc.duke.edu/eirb)
Required Research Summary Contents

1. Protocol Title
2. Purpose of the Study
3. Background & Significance
4. Design & Procedures
5. Selection of Subjects
6. Subject Recruitment & Compensation
7. Consent Process – see Section 14 of the e-IRB submission form and complete the questions in that section
8. Subject’s Capacity to Give Legally Effective Consent
9. Study Interventions
10. Risk/Benefit Assessment
11. Costs to the Subject
12. Data Analysis & Statistical Considerations
13. Data & Safety Monitoring
14. Privacy, Data Storage & Confidentiality
Enlist the Help of Expert

- DTNI: email dtni@mc.duke.edu  
  919-668-2344
- DUSON ORA:  
  919-684-5376
- DUHS Research Nurse Scientist:  
  919-613 6406