

## Developing a research protocol

Research protocol requirements are often directed by the funding agency. Below is a list of common research proposal requirements – not all elements may be required; conversely additional requirements may be requested by the grant funding agency.

A Logic Model (see separate document) is an effective means to develop a basic outline for a research protocol

### Step 1: The research question

A research protocol is designed to answer a research question. In general research questions are designed to:

- Explore a problem
  - Review existing data to look for patterns or correlations
  - Survey or interview providers regarding their opinions or beliefs
  - Survey or interview patients regarding their opinions or beliefs
  - Gather new data to better understand a problem or possible solution
- Evaluate the effectiveness of an intervention
  - A patient treatment
  - A process for delivering care
  - A process to help providers adopt a new guideline (practice transformation)

The research question should drive the development of the protocol to answer a very specific question(s) which can be answered by recording specific and measurable data.

### Step 2: Elements of the research protocol

Background/Significance – this section is designed to establish background and the clinical significance of the research question and to establish the specific aims of the proposal. Elements include:

- Review of existing practice data/observations/previous pilot data
- Literature review
  - Literature which establishes the importance of the research
  - Literature which establishes that the proposed research has NOT been undertaken before (Also establishes INNOVATION)
- Specific aims for the proposed research
  - What is the proposed goal (i.e., to determine, evaluate, establish)
  - What is the proposed process (i.e., compare two methods, review existing data)
  - What is the proposed method (i.e., comparison to a control, survey, focus group)
  - Who are the study/control subjects (patients, providers)

Methods – this section is designed to describe the details of how the proposal will be carried out. Elements include:

- Method: Survey, focus group, review of existing data, cohort study, comparative (to previous research or to control)
- Study populations
  - Specific characteristic of the study/control populations –inclusion/exclusion criteria
    - Providers maybe study populations

- Patients maybe study population
      - Priority populations – minorities, underserved
  - Setting: Clinic, hospital; Rural, urban
  - Study measures survey results, focus group responses, clinical measures
  - Proposed statistical analysis
  - Human subjects protections
    - IRB review
    - Consents
    - Participant recruitment plan
  - Proposal timeline (Gantt chart)
  - Dissemination plan – publication, presentation

### **Step 3: Budget**

The budget should consist of a spreadsheet summarizing project costs and a budget justification describing details of the budget. Elements of the budget should include:

- Key personnel needed to carry out the proposal and their salary requirements
- Facilities
- Equipment
- Travel
- Supplies
- Contract work
- IRB costs
- Indirect costs

Elements of the budget justification include:

- Brief description of the qualifications of key personnel and their salary requirements
- Associated facility costs
- Justification to purchase/lease equipment for study
- Need for travel and basis for calculating cost (i.e., milage)
- Contract costs
- Basis for indirect costs