

Planning Guide for Evaluation and Research in Medical Education

Phase 1 – Study Background and Contact Information

Contact Information

Project Title _____

Principal Investigator _____

Email _____ Pager _____

Department _____ Phone _____ Fax _____

Is this a Student Project? YES
 NO

Problem Statement

- Have you completed a literature review? If so, list 3 major points from the review
- What is the problem you would like to address?

Study Aims/Goals

- What are the goals of your study?
Example: To conduct an evaluation of a sports medicine clinical workshop on knee replacement.
- Who is included in your target audience?
Example: Primary care physicians practicing within 50 miles of Richmond.

Funding Source

- What is the funding source for your project?

Data Reporting and Authorship/Presentation/Poster

Please speculate on data reporting and publishable outcomes.

- Who will report the findings? For example, will the report be an internal document used for program improvement?
- What formats will be used for reporting?
- Is there an intention to publish? If so, where? What format? Which journals? Which meetings?
- Who will serve as authors?

PRELIMINARY BUDGET TABLE

- Please complete as much as possible of the Preliminary Budget Table.

Proposed Expenses

Personnel				
Name	Title of Position	Percent Effort (%)	Salary	Total
Personnel Subtotal				
Equipment (itemize)				
Equipment Subtotal				
Supplies (itemize)				
Supplies Subtotal				
Printing/Mailing/Postage				
Travel				
Other expenses (itemize)				
Other expenses Subtotal				
Patient care costs				
Fees to CPDE				
Total				

Phase 2 – Study Design and Methods

We provide consultative services on research design, program evaluation design, validity and reliability of assessment tools, and VCU IRB application materials.

Specific Research Questions

- What are the specific research questions?
Example: Are physicians able to more accurately assess range of motion after a clinical workshop than a lecture?

Methods/Materials/Procedures

- What is the sample size?
- What are their demographics?
- What are the Inclusion/Exclusion criteria? (if appropriate)
- What is the rationale for special cases of subjects (pregnant women, children, prisoners, institutionalized individuals, or others who are likely to be vulnerable)?
- What is your recruitment method?
- Are you creating recruitment materials? Describe
- Will the participants receive compensation? YES/NO Describe.
- What are the data source(s)?
- Will you be developing a survey?
- Will you need Printing/Mailing/Postage services?

Study Design

- What research design will you use to address the research questions? (Case Study, Experimental, Cohort, Case-Control, etc.)
Example: Experimental design - lecture group and control group

VCU IRB

- Which option is most appropriate for your study? (check one)
 - Full Board
 - Expedited
 - Exempt
- Have all investigators working on your study completed the VCU IRB training examination?
 - YES
 - NO

Human Subjects Protection

Is a Consent Form Needed?

- YES
- NO

Is an Assent Form Needed

- YES
- NO

Will you be requesting a Waiver of Consent (see VCU IRB application for details)?

- YES
- NO

- Who seeks consent and under what conditions (who, where)?
- Is assessment of participant comprehension needed? YES/NO Describe method.
- What is the nature of information provided to participants?
- How do you plan on documenting consent?
- List potential risks (legal, social, psychological, physical) and asses their likelihood and seriousness.
- Are there any alternative procedures (where appropriate) available?
- List procedures for protecting against or minimizing potential risks including risks to confidentiality, and assess their likely effectiveness.
- What provisions do you have in place for ensuring necessary medical or professional intervention in event of adverse events to participants
- Please describe the Risks/Benefits for this study.

Phase 3- Data Management and Data Analysis

We provide consultative services on data collection, data management, and statistical analysis.

Data Management

- Will you need to develop a database?
- Who will enter the data for you?
- How and where will data be stored?
- Who will have access to data?
- How do you plan on monitoring data for participant safety?

Data Analysis

- What methods of analysis will be required to answer your research questions? (Descriptive, Univariate, Multivariate, etc)
- What software will you need?
- Who will use the data? How will they use it?
