Research Protocol Outline

How to write a research protocol for IRB

In order for the IRB to have sufficient information to properly evaluate a research proposal, a properly written research protocol should include **all** of the following information.

1. TITLE OF STUDY

- Your title should give a clear indication of your proposed research approach or key question

2. PRINCIPLE INVESTIGATOR

3. LIST OF CO-INVESTIGATORS, RESEARCH ASSISTANTS AND OTHER KEY PERSONNEL

- List by position

3. SPONSORSHIP OR FUNDING SUPPORT

- Name of Sponsor or Grant Support
- Costs to be borne by the participants
- Costs to be borne by Navicent Health

4. ABSTRACT/ INTRODUCTION/BACKGROUND AND RATIONALE

You should include:

- The background and issues of your proposed research. Give a brief overview of the pertinent literature and explain the significance of your research. Be sure to include clinical relevance and scientific merit of the project.
- Include a brief summary of the expected results and implications of findings.
- If you have done preliminary research pertinent to this project, briefly summarize pervious work.
- a summary of key debates and developments in the field

5. PROBLEM STATEMENT/HYPOTHESIS / PURPOSE OF THE STUDY

- State the major question and/or hypothesis of the research
- Explain the primary and any secondary objectives of the investigation.

6. STUDY DESIGN & METHODOLOGY

You should Include the following information:

- Type of study
    - Drug, Device
    - Clinical Trial Phase: Phase II, Phase III, Phase IV (post marketing surveillance), Observational, Descriptive
    - Prospective, Retrospective
    - (case-control), cohort), Cross-sectional (surveys), Chart Review
- Description of Study Population
    - Sample Size - Estimated # of subjects to be enrolled and how you determined this number
    - Inpatients, outpatients, staff/employees, students
    - Age Group - Adults (≥ 18yrs), Children (<18yrs)
    - Only members of a specific racial/ethnic group
    - Mentally challenged/incompetent participants
    - Males / Females

    - Pregnant Females
    - Patients with a specific health need, characteristic, diagnosis
    - Will non-english speaking participants be eligible
- Description of how recruiting & selecting participants will occur
    - Must include copies of any flyers or Advertisements to be used
    - Description of how you will obtain informed consent
- Methodology for conducting project
    - Retrospective vs Prospective review
        - How do you plan to obtain data
        - Where will you be accessing the data (e.g. electronic health record, clinic notes, lab reports, etc.)
    - Randomization method – How will you allocate subjects to different groups (if applicable)
    - Describe any and all experimental manipulations or interventions
        - An experimental manipulation or intervention is an activity you perform on participants designed to change a state or condition, such as teaching new knowledge or skills.
        - Collecting data is NOT considered an intervention
    - Projected study duration
    - Risks/Benefits
        - Include any risks to subjects including breach of confidentiality
        - Describe benefits, either direct or indirect, if any
- Explain whether participants will receive any reimbursement or incentive for participating in the project
- Feasibility of Project
    - Time Frame
    - Available population

7. DATA COLLECTION & ANALYSIS PROCEDURES

- List every type of data you intend to collect and how they are to be measured
    - Outcome variables
    - Independent variables
    - Potential confounding variables
    - Description of data collection tools or interview guides (include copies)
    - Location(s) of data collection sites
- Statistical Procedures for Analysis and Sample Size
    - Sample Size and how that was determined
    - Statistical power, alpha level, and difference to be detected
    - If this is a pilot study, how was the sample size determined and how will data be used?
    - What statistical procedures will be used for data analysis

8. PLAN OF WORK & TIME SCHEDULE

You should include an outline of the various stages and corresponding time lines for developing and implementing the research, including writing up your thesis.

9. BIBLIOGRAPHY

You should include:

- a list of references to key articles and texts discussed within your research proposal