From Research to Practice:
Training Course in Sexual and Reproductive Health Research

Research Protocol Development

The University of Parma, Italy

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Introduction

- Research is conducted in response to a problem, such as an epidemic or an expected health outcome, or response to a need to plan or change a program or a course of action, to test a hypothesis, or to further study of recent research findings.
- Having decided to pursue a research project the researcher needs to develop a plan or protocol as a guide for study.
- A plan written to seek approval for research from a supervisor or organization is called a research proposal.

Research Proposal Components

Part I. Summary

Although the summary appears as the first section of the protocol, it is not written until all other sections are completed.

This part should be brief, **approximately 300 words.**

Part I. Abstract / Summary (continued)

The summary should answer the following questions:

- What is the problem to be studied?
- What are the research questions or hypothesis?
- What are the expected implication of the study?
- Who will conduct the study?
- When will the study be conducted?
- Where will the data collection be conducted?

Part II. General information

The following information should be presented in one page:

- Protocol title, protocol identifying number (if any), and date.
- Name and address of the sponsor/funder (if any).
- Name and title of the investigator(s) who is (are) responsible for conducting the research, and the address and telephone number(s) of the research site(s), including responsibilities of each.
- Name(s) and address(es) of the clinical laboratory(ies) and other medical and/or technical department(s) and/or institutions involved in the research.

Part III. Research Problem Identification

- State why you think the problem requires study?
- Indicate the discrepancy between the real or observed situation and the ideal, desired situation.

Part III. Research Problem Justification

- Research is often expensive and time consuming and most funding agencies are reluctant to support studies unless the results have direct program implications.
- When funds are limited it is especially important for the researcher to justify the proposed study carefully.

Part III. Problem Justifications (Continued)

In writing the justification, it is usually helpful to consider the following questions and arrange answers to these questions into a few concise paragraphs:

- Is the problem a current and timely one? or does the problem exists now?
- Does the problem have life-threatening or serious morbidity consequences?
- Does the problem affect or potentially affect a large number of people?
- Does the problem relate to on-going program activities?
- Does the problem have broad social, economic, political or health implications?
- Is the problem viewed as a concern by many different people?
- Have many studies already addressed the problem?

Part IV. Literature Search

This section depends upon information from previous research and the literature. It should therefore contain the literature review. Before writing this section you should:

- Search the literature thoroughly for information about the problem you are researching.
- Establish whether or not others are currently engaged in similar or related research.
- Classify key literature on the subject.
- Identify critical areas for research (shortcomings of previous studies or areas where no research has been or is being done).
- For more information and instruction for literature search, please consult the following lectures on core module.

Part V. Goals and Objectives

Goals are stated in terms of:

- Broad social, economic, or health concerns.
- Change in policy decisions, service delivery programs or individual health behavior.
- Populations that may be affected.

Example of ultimate goal:

- To reduce maternal morbidity in area X, by improving access to quality Antenatal Care (ANC).

Part V. Objectives

Research objectives describe what will be demonstrated, tested, evaluated, confirmed or compared. They communicate:

- What you plan to do?
- Who will do it?
- To whom it will be done?
- Where it will be done?
- What you hope to learn?

Example of Objective

MCH Department will conduct a 2-year cohort study (2008-2009) to compare the risk of complications associated with postpartum tubal sterilization and interval sterilization in 2000 women living in X area.

- What: Cohort study
- By whom: MCH Department
- To whom: 2000 women
- When: 2008-2009
- Where: Area X
- Purpose: Risk of complication of postpartum and interval sterilization

Part VI. Research Question or Hypothesis

Descriptive epidemiologic research is based on underlying questions. The research questions must be formally stated with clarity.

Ex:

What are the levels of maternal mortality in major cities of country X?

Part VI. Research Question or Hypotheses

Analytic epidemiology research is designed to make predictions about the relationship between variables and therefore test hypothesis. Hypothesis is a statement (not a question) about an expected relationship between one or more independent variables and one dependent variable.

- Ex: Children who receive sexuality education course before entering their teens are more likely to use contraceptive than children who not receive such course.

Part VII. Study design (with methods 3-5 pages)

- The proposal should first indicate whether the study is descriptive or analytic.
- A descriptive study is used when additional information is needed. It provides accurate baseline data on the occurrence of prevalence of health problem or a health issue.
- An analytic or explanatory study is used to explain the relationship between two or more variables by testing causal hypotheses that specify the relationship between variables.

Part VIII. Methodology

It should include detailed information on:

- The interventions to be made
- Procedures to be used
- Measurements to be taken
- Observations to be made
- Methods for data collection, analysis

Part VIII. Methodology (Continued)
Brief outline for the methodology:

- Define the population, including political, geographical, social, economic and demographic identifiers.
- Describe the sampling process (if applicable).
- Define the data and type of data to be collected.
- Describe the data collection instruments (questionnaire, interview, medical records, forms, etc.).
- Describe the process, control the quality data.
- Describe the methods to analyse and interpret data.

Part IX. Ethical Consideration

- The protocol should have a description of ethical considerations relating to the study. This should not be limited to providing information on how or from whom the ethics approval will be taken, but this section should document the issues that are likely to raise ethical concerns. It should also describe how the investigator(s) plan to obtain informed consent from the research participants (the informed consent process).

Part X. Expected Outcomes of the Study page

The protocol should indicate how the study will contribute to advancement of knowledge, how the results will be utilized, not only in publications but also how they will likely affect health care, health systems, or health policies.

Part XI. Plan to report and disseminate research findings

The proposal should indicate what reports and other means of disseminating research findings are planned. Any or all of the following are appropriate for disseminating the results of the study:

- Progress report
- Final report
- Publication
- Seminars, workshops and conference
- Discussion with policymakers and program managers

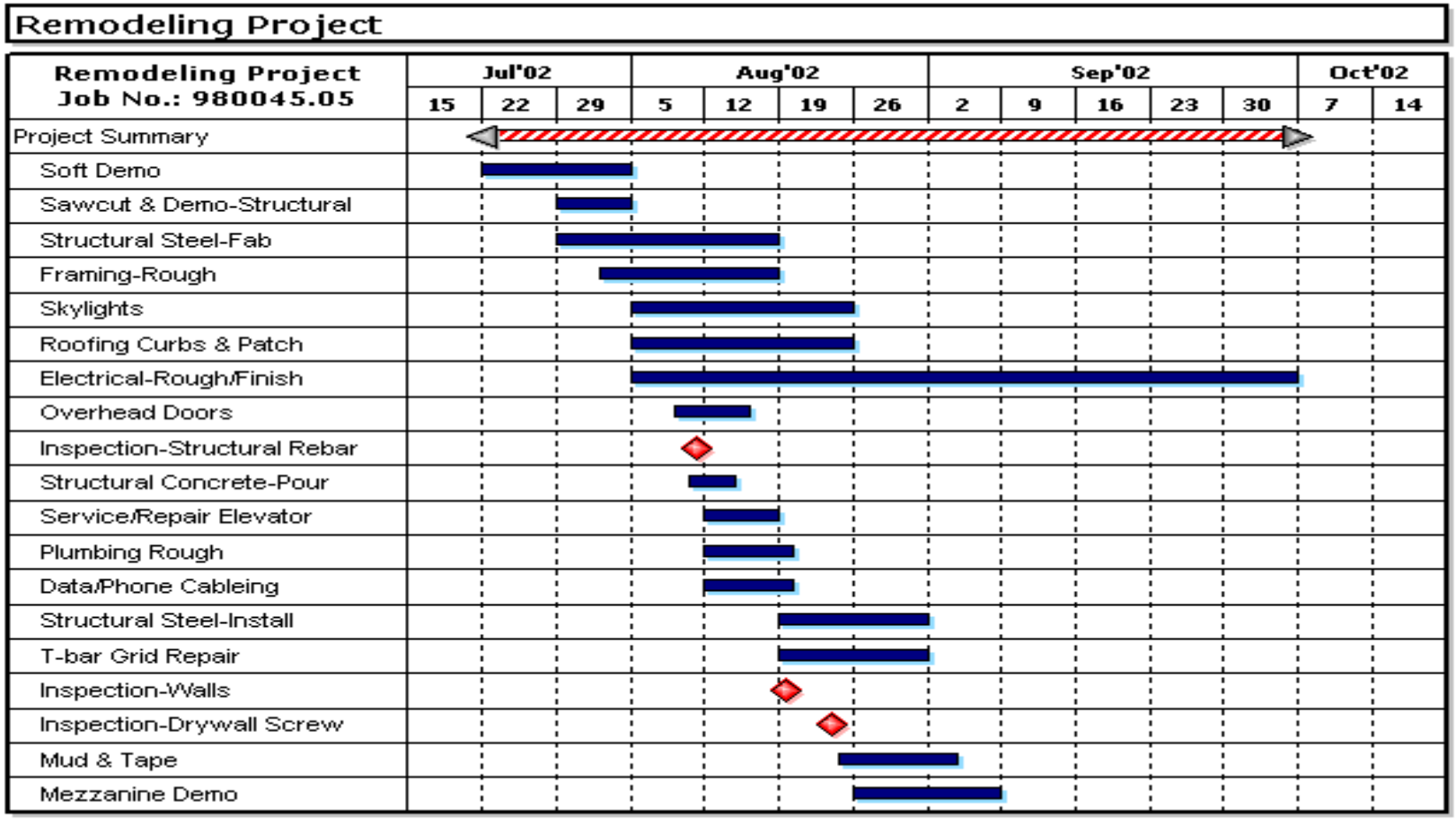
Part XII: Logistics

The logistics are the resources, personnel, facilities and budget required for the study. The proposal should indicate the anticipated cost of the study, how the funds will be allocated.

Part XIII. Work Schedule or Timeline

The steps and their sequence in the entire research process should be outlined. A corresponding calendar should indicate the amount of time each step will require.

Example of Timeline



Part XIV. Bibliography & Reference

The proposal must include a bibliography that contains all the sources cited in the text of the proposal (theses citations will be found primarily in literature review).

Part XV. Appendices to the proposal

The documents that may be annexed to proposal:

- Curriculum vitae of principle investigator.
- Information on institutional affiliation of researchers.
- Sample of data collection instrument(s).
- Informed consent form.
- Letters of endorsement for the study.
- Other information related to the study.

Useful links:

- Literature search:
  - http://www.gfmer.ch/SRH-Course-2011/research-methodology/Searching_Pubmed.htm
  - http://www.gfmer.ch/SRH-Course-2011/presentations/WHO-Library-Allen-2011.htm
- Research proposal:
  - http://www.gfmer.ch/SRH-Course-2011/presentations/Research-protocol-for-WHO-Thapa-2011.htm
  - http://www.gfmer.ch/SRH-Course-2010/Research-methodology.htm