

FACILITATOR/MENTOR GUIDE



Developing a Protocol

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Introduction

LEARNING OBJECTIVES

1. At the end of the training, participants will be able to:
 - a. Write a proposal that includes the following.
 - Background
 - Justification for the study
 - Research question or hypothesis
 - Objectives of a study
 - Proposed methods
 - Expected benefit
 - b. Assess the quality of a sample protocol.
 - c. List the information to include in a protocol for a noncommunicable disease (NCD) study you are proposing.
2. When participants return to their jobs, they will be able to develop all sections of a protocol for an NCD study.

ESTIMATED COMPLETION TIME

The workbook should take approximately 10 ½ hours to complete.

TARGET AUDIENCE

The workbook is designed for Field Epidemiology Training Program (FETP) residents who specialize in noncommunicable diseases (NCDs). However, you can also complete the module if you are tasked to develop a protocol or proposal to address other types of diseases.

PRE-WORK AND PREREQUISITES

Before participating in this training module, participants must complete the pre-work assignment. The activities for the assignment include:

- Identifying an NCD health problem for which to conduct a study
- Searching the literature for information about the problem you are researching

- Determining whether others are currently engaged in similar or related research
- Identifying critical areas for research
- Identifying the incidence or prevalence of the problem, when and where it is occurring, who is affected by the problem and possible reasons for the problem

In addition, participants should have completed training on the following topics:

- Data collection methods
- Study design
- Data analysis and interpretation

Two to three weeks prior to the training, send out correspondence to participants explaining the pre-work and prerequisites.

MATERIALS

For the Facilitator or Mentor:

- Facilitator / Mentor Guide

For the Participant:

- Participant Workbook
- Activity Workbook

OPTIONS FOR FACILITATING THIS TRAINING

There are two options for facilitating this training:

1. Individual facilitator-directed: A facilitator helps the participant complete the training. The facilitator's main responsibility will be to review the participant's work and provide feedback.

A facilitator will meet with the participant a minimum of two times. At the first meeting, the facilitator should orient the participant to the training, provide examples and direction indicated, answer questions, and set future modes of contact and meeting time(s). Very small groups (less than 5 individuals) may choose to work on the training together and find individual or collective facilitator(s).

2. Classroom: There are two options for classroom training. For option a, participants read the training material *prior* to attending class and then review what they read in class. For option b, participants read the training material *during* class.

- a. **Participants read training material *prior* to attending class.**
At the start of each module section, the facilitator reviews key points. The facilitator may prepare PowerPoint slides for a brief presentation of key points, lead an informal discussion about the reading, or ask participants to answer questions individually or in small groups about what they read. After each review, participants will complete practice exercises and skill assessments as directed.
- b. **Participants read training material *during* class:** The facilitator directs students to read the training material and complete the exercises as indicated in the workbook. The facilitator leads group discussions to review what participants have read and reviews participants' answers to the exercises and skill assessments.

ICON GLOSSARY

The following icons are used in this guide:

Image Type	Image Meaning
 Book Icon	Read a section in the participant workbook
 Activity Icon	Activity, exercise, assessment or case study that participants complete
 Group Icon	Group discussion that you will lead, either to review key points or answers to an activity

ACKNOWLEDGEMENTS

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Many thanks to the authors who have shared their protocols which have been used as examples in this module.

- *“Assessing Risk Factors for Chronic Disease – Jordan, 2004”* MMWR, June 16, 2006. Vol 55/No. 23: 653-655 (A. Belbeisi, M Zindah, Jordan MOH; H Walke, B Jarrar, AH Mokdad, CDC).
- *“Study of prevalence and factors associated with tobacco consumption among adolescent students from middle level schools in Antigua Guatemala, Sacatepéquez, Guatemala, 2012”* (Seventh cohort of the Masters Degree students at the Field Epidemiology Training Program, University of the Valley in Guatemala). Provided by Dr. Victor Caceres, Centers for Global Health.

How to Facilitate This Module

FACILITATOR RESPONSIBILITIES

This training module is self-paced, meaning that the participants will learn the content by reading their participant workbook and applying what they learned by completing four practice exercises and four skill assessments. For the practice exercises, participants will work with a sample proposal and protocol; for the skill assessments, they will use the information they brought to class about an NCD study they are conducting.

As a *facilitator*, you will *facilitate* or assist in the participants' learning. Your main roles will be as follows:

- **Introduce** the module topic.
- **Lead** group discussions to review or elaborate on what participants read.
- **Answer** questions that participants may have during the training.
- **Review** participants' work and provide feedback.
- **Be a timekeeper**, ensuring participants stay within a general schedule.

As a *mentor*, you will perform the same tasks, and play a more active role in supporting the learner *after* the training with his or her field work.

SECTIONS 1 & 2: INTRODUCTION AND OVERVIEW

Total Estimated Time: 50 minutes

Introductions and module overview: 30 minutes

Readings: up to 20 minutes

Duration/Session Type	What to Do/What to Say
 <p>Group Discussion</p> <p>30 minutes</p>	<p>Introduction and overview</p> <ul style="list-style-type: none"> • Introduce yourself and ask participants to introduce one another by providing: <ul style="list-style-type: none"> ○ Their name ○ Where they work ○ Experience writing protocols or proposals ○ Expectations for the module • Distribute the Participant Workbook and Activity Workbook. • Explain how participants will learn the skills by reading the participant workbook and apply what they have learned by completing four practice exercises and four skill assessments. • Provide an overview of what they will learn in the module and how the skills and knowledge they acquire will help them write proposals and protocols.
 <p>Reading</p> <p>20 minutes</p>	<p>Readings</p> <p>Tell participants to read sections 1 and 2 (approximately 4 ½ pages) and complete one brief activity.</p>

SECTION 3: WRITING A PROPOSAL OR CONCEPT PAPER

Total estimated time: 3 hours, 10 minutes

Readings: up to 45 minutes

Group discussion: 15 minutes

Practice Exercise #1: 30 minutes

Debrief: 10 minutes

Skill Assessment #1: 1 ½ hours (including a 30-minute peer review)

Duration/Session Type	What to Do/What to Say
 <p>Reading</p> <p>45 minutes</p>	<p>Readings</p> <p>Tell participants to read section 3 (approximately 10 pages).</p>
 <p>Group Discussion</p> <p>15 minutes</p>	<p>Group discussion</p> <p>You may lead a brief group discussion to make sure participants know how to:</p> <ul style="list-style-type: none"> • Identify the topic, study justification, research question or hypothesis, and objectives of a study. • Develop a 1-3 page proposal.
 <p>Activity</p> <p>30 minutes</p>	<p>Practice Exercise #1</p> <p>Tell participants to spend approximately 30 minutes completing the practice exercise with a colleague.</p>
 <p>Group Discussion</p> <p>15 minutes</p>	<p>Debrief</p> <p>Ask participants to present their responses to the entire class or to another pair for feedback. (See possible answers on the following page.)</p> <p>Possible answers (in italics):</p> <ol style="list-style-type: none"> 1. Does the proposal include a clear description of the health problem? Circle some of the relevant sentences that helped you

Duration/Session Type	What to Do/What to Say
	<p>to understand the health problem.</p> <p><i>Yes, the proposal includes a clear description of the health problem. Some relevant sentences circled might be:</i></p> <p><i>“Tobacco use is associated with many chronic diseases, such as cardiovascular disease, cancer, chronic respiratory diseases,”</i></p> <p><i>“...the issue of smoking among women has attracted growing attention because recent reports have shown a high level of tobacco use among girls.”</i></p> <p><i>“... women face additional health risks, including hazards during pregnancy ...”</i></p> <p>2. Did the proposal provide adequate justification for the study to be approved? Circle the sentences in this section that would help someone decide whether or not to approve or fund the study.</p> <p><i>Yes, the proposal provided adequate justification for the study to be approved. A relevant sentence would be the last sentence in the second paragraph: Problems associated with smoking in Asia among women and girls will continue to be evident until well into the 21st century if no action is taken now to curb the smoking epidemic.</i></p> <p>3. Did the authors provide a clear and concise research question that the study will address and/or a hypothesis that they will test? Explain your answer. Do you have another research question that you would ask if you were conducting this study?</p> <p><i>The authors did provide a clear and concise research question. It included the specific population to study (i.e., female students aged 13-15) and a clear description of the research (i.e., to determine the prevalence of and susceptibility to cigarette smoking).</i></p> <p>4. Did the study objectives include the following criteria? Place a check mark next to all that apply:</p>

Duration/Session Type	What to Do/What to Say
	<ul style="list-style-type: none"> ✓ declarative statement ✓ concise ✓ positive terms ✓ easily understood
 <p>Activity</p> <p>1 ½ hours</p>	<p>Skill Assessment #1</p> <ul style="list-style-type: none"> • Participants fill out a proposal template based on the information they brought to class about a public health problem they are researching. • Remind participants that they can finish completing the proposal when they return to their job. • If participants have access to a computer, they may use it to write their proposal rather than the template. • Tell participants that when they complete the Skill Assessment they should find a colleague with whom to conduct a peer review. They will use a Peer Review Worksheet in Appendix A of their peer’s Activity Workbook to critique the proposal. Encourage participants to write comments on the worksheet and to discuss those comments with their peers. The peer review should take a total of 30 minutes, including a discussion of each participant’s proposal.

SECTION 4: WRITING A DRAFT OF THE PROTOCOL

Total estimated time: 6 ½ hours

Readings: up to 25 minutes

Practice Exercise #2: 1 hour

Debrief: 15 minutes

Skill Assessment #2: 1 hour (including a 15-minute peer review)

Readings: up to 30 minutes

Practice Exercise #3: 50 minutes

Debrief: 15 minutes

Skill Assessment #3: 65 minutes (including a 15-minute peer review)

Readings: up to 5 minutes

Practice Exercise #4: 10 minutes

Debrief: 5 minutes

Skill Assessment #4: 20 minutes (including a 5-minute peer review)

Conclusion: 15 minutes

Duration/Session Type	What to Do/What to Say
 <p>Reading</p> <p>25 minutes</p>	<p>Readings</p> <p>Tell participants to read about writing sections 1 and 2 of a protocol (approximately 5 pages).</p>
 <p>Activity</p> <p>1 hour</p>	<p>Practice Exercise #2</p> <p>Tell participants to spend approximately 1 hour completing the practice exercise individually or with a colleague.</p>
 <p>Group Discussion</p> <p>15 minutes</p>	<p>Debrief</p> <p>Ask participants to present their responses to the entire class or to another pair for feedback. (See possible answers below.)</p> <p>Possible answers (in italics):</p> <ol style="list-style-type: none"> 1. Did the authors explain the public health and scientific importance of the study and the health problem? <i>Circle the relevant sentences that support your findings.</i>

Duration/Session Type	What to Do/What to Say
	<p><i>Yes, the authors did a very good job describing the importance of the study and health problem.</i></p> <p><i>Participants may have circled any number of relevant sentences that describes the prevalence of tobacco consumption, economic losses due to the deaths caused by tobacco consumption, the results of Global Youth Tobacco Survey (GYTS), and the prevalence of secondhand smoke.</i></p> <p>2. Did the protocol provide adequate justification for the study? Circle the sentences in this section that support the justification. <i>Yes, the protocol provided adequate justification for the study. Participants may have circled any number of sentences that support the justification, for example, the environment of bars, restaurants and nightlife promoting an atmosphere of tobacco consumption, the difficulty in controlling the sale of cigarettes to minors, and previous studies in neighboring cities on the level of tobacco consumption amount students between 13 and 15 years of age.</i></p> <p>3. Did the authors describe the contribution this study will make? Circle the relevant sentences that support your findings. <i>Yes, the authors described the contribution the study will make. Participants may have circled the sentence “...research will provide update information on the indicators that were measured during the previous studies. This will allow us to set the prevalence trend of tobacco use.....”</i></p> <p>4. What is the study design and location (locality)? <i>A cross-sectional survey is being planned among middle level students of the city of Antigua Guatemala.</i></p> <p>5. Did the study objectives include the following criteria? Place a check mark next to all that apply:</p> <ul style="list-style-type: none"> ✓ declarative statement ✓ concise ✓ positive terms ✓ easily understood

Duration/Session Type	What to Do/What to Say
	<p>6. Did the authors provide a clear and concise research question that the study will address and/or a hypothesis that they will test? Explain your answer. Do you have another research question that you would ask if you were doing this study? <i>Yes, the authors provided a clear null hypotheses and an alternative hypothesis regarding the current prevalence of tobacco consumption among students of the middle level in Antigua Guatemala.</i></p> <p>7. Did the authors explain the approach they will use? If so, what is their approach? <i>The authors did not include a separate section on “General Approach” or “Focus of the Study”, but it is assumed that the approach will be <u>descriptive</u>.</i></p> <p>If not, which of the following approaches would you use if this was your study?</p> <ul style="list-style-type: none"> ✓ descriptive: information on time, place and person is collected, <input type="checkbox"/> exploratory: hypothesis-generating, <input type="checkbox"/> confirmatory: hypothesis-testing, or <input type="checkbox"/> developmental: focused on corrective action.
<div data-bbox="266 1444 371 1549" style="text-align: center;"></div> <p data-bbox="261 1564 376 1598" style="text-align: center;">Activity</p> <p data-bbox="191 1654 451 1759">1 hour (including a 15-minute peer review)</p>	<p>Skill Assessment #2</p> <ul style="list-style-type: none"> • Participants work individually and refer to their responses to Skill Assessment # 1. They are asked to provide additional information to include when writing the sections for a protocol. • Remind participants that they can finish completing the protocol when they return to their job. • If participants have access to a computer, they may use it rather than the template. • Tell participants that when they complete the Skill Assessment they should find a colleague with whom to conduct a peer review. (It can be the same peer they worked with for the previous peer review or a different one.) They will

Duration/Session Type	What to Do/What to Say
	continue using the worksheet in Appendix A. The peer review should take a total of 15 minutes, including a discussion of each participant's protocol sections.
 Reading 30 minutes	Readings Tell participants to read about writing section 3 of a protocol (approximately 6 pages).
 Activity 50 minutes	Practice Exercise #3 Tell participants to spend approximately 50 minutes completing the practice exercise individually or with a colleague.
 Group Discussion 15 minutes	Debrief Ask participants to present their responses to the entire class or to another pair for feedback. (See possible answers below.) Possible answers (in italics): 1. How does the choice of study design address the research questions and objectives previously indicated? <i>A cross-sectional study is designed to estimate prevalence, and in this case, prevalence of tobacco use. It addresses the hypotheses related to prevalence of tobacco consumption among students of the middle level in Antigua Guatemala.</i> 2. In the Sampling Procedure Section / Sample Size of the protocol, the authors explain that they used a calculation sheet from WHO STEPS to calculate sample size. Is this method an adequate way to calculate sample size so that it answers the research questions and tests the hypothesis? Please explain. <i>Yes, this is an adequate method to calculate sample size and the appropriate equations and references are given. Note that although there are many equations and methods for calculating</i>

Duration/Session Type	What to Do/What to Say
	<p><i>sample size it is most important that the authors clearly state the method use and provide a way so that others can replicate their work to ensure accuracy/transparency.</i></p> <p>3. What study instrument will be used? Does the protocol address the question of whether any controversy exists about the methods to be used? If so, what are they?</p> <p><i>The standard WHO Global Youth Tobacco questionnaire will be adapted and used. The protocol does not address the question of controversy of the methods per se, but in the Enrollment section of the protocol, it discussed confidentiality of the study,</i></p> <p>4. How effectively does the protocol describe the handling of data entry, editing and management, including the handling of data collection forms, different versions of data, and the storage and disposal of data? Would you include any additional information in this section if you were conducting this NCD study?</p> <p><i>Section H. Data Management and Analysis, sub-section 3, does a good job explaining how the data will be entered, edited and managed, for example, they will double enter 10% of the data to ensure the quality of digitalization.</i></p> <p>5. How effectively does the protocol describe quality assurance and control? Would you include any additional information in this section if you were conducting this NCD study?</p> <p><i>The protocol effectively describes quality assurance and control.</i></p>

Duration/Session Type	What to Do/What to Say
 <p>Activity</p> <p>65 minutes (including a 15-minute peer review)</p>	<p>Skill Assessment #3</p> <ul style="list-style-type: none"> Participants will begin to develop the Procedures and methods section of the protocol by briefly describing what information they would write in each of the sub-sections. They may use bullets rather than complete sentences for this exercise. Participants should spend approximately 5 to 10 minutes on each section (A-F). They will finish writing the protocol after the training. After approximately 45 minutes, give participants a 5-minute warning to finish up their work. Tell participants that when they complete the Skill Assessment they should find a colleague with whom to conduct a peer review. (It can be the same peer they worked with for the previous peer review or a different one.) They will continue using the worksheet in Appendix A. The peer review should take a total of 15 minutes, including a discussion of each participant's protocol sections.
 <p>Reading</p> <p>5 minutes</p>	<p>Readings</p> <p>Participants read about writing sections 4 and 5 of the protocol (approximately ½ page).</p>
 <p>Activity</p> <p>10 minutes</p>	<p>Practice Exercise #4</p> <p>Tell participants to spend approximately 10 minutes completing the practice exercise individually or with a colleague.</p>

 <p>Group Discussion</p> <p>5 minutes</p>	<p>Debrief</p> <p>Ask participants to present their responses to the entire class or to another pair for feedback. (See possible answers below.)</p> <p>Possible answers (in italics):</p> <p>List at least two other forms, tables, figures, and/or documents that you would include in the Annex section of this protocol.</p> <p><i>Consent form, Analysis Plan, Work plan or Gantt chart.</i></p>
 <p>Activity</p> <p>20 minutes (including a 5-minute peer review)</p>	<p>Skill Assessment #4</p> <ul style="list-style-type: none"> • Participants will list at least three forms, documents, and/or tables that they would include in the Appendix of their protocol. • Tell participants that when they complete the Skill Assessment they should find a colleague with whom to conduct a peer review. (It can be the same peer they worked with for the previous peer review or a different one.) They will continue using the worksheet in Appendix A. The peer review should take a total of 15 minutes, including a discussion of each participant’s protocol sections.



Group Discussion

15 minutes

Conclusion

- Ask for volunteers to recall the steps to writing a protocol:
 1. Identify the topic, study justification, research question or hypothesis, and objectives of the study.
 2. Write a 1-3 page proposal (or concept paper) for approval and/or funding.
 3. Create tables for data collection to anticipate the data you will collect and how you will use it.
 4. Write a draft of the protocol.
 5. Prepare the data collection instruments.
 6. Send the protocol (including data collection form, tables, and consent forms) to applicable partners / stakeholders to review.
 7. Present the protocol to the ethics committee; revise as necessary until approved.
- Discuss any country-specific information about sending the protocol to partners and stakeholders to review and presenting the protocol to the ethics committee. Ask participants what challenges they may face writing a protocol and how might they overcome those challenges.

NOTE: If your participants will be submitting a proposal for a mini-grant, you may distribute the ***Checklist: Development of a Mini Grant Proposal*** (located in Appendix A of this workbook).

Appendix A

Check List Development of a Mini Grant Proposal: Summary of Steps

As you develop your proposal, use the check list below to ensure that you have included all of the components.

Proposal Components	Included in your proposal?
<p>1. Problem Identification</p> <ul style="list-style-type: none"> • Why problem requires study • Discrepancy between the real/observed situation and the desired situation <p>Problem Definition</p> <ul style="list-style-type: none"> • Summary of current research about the problem (magnitude, time frame, geographic area, population) 	
<p>2. Justification of the Project</p> <ul style="list-style-type: none"> • Describe what you want to study and why • Relevant questions to address might include: Is the problem current/timely? Is it life threatening? Does it affect many people? Is it a concern by many different people? Have other studies already addressed this problem? • Organize this section into a few concise paragraphs 	
<p>3. Goal</p> <ul style="list-style-type: none"> • Broad statement of the public health purpose of the study/project <p>Objectives</p> <ul style="list-style-type: none"> • Describe the results to be achieved, and how you will achieve them 	

Proposal Components	Included in your proposal?
<ul style="list-style-type: none"> • Develop “SMART” objectives (to the extent possible) 	
<p>4. Study Questions/Hypotheses</p> <ul style="list-style-type: none"> • An explicit statement of what will be investigated 	
<p>5. Study Design</p> <ul style="list-style-type: none"> • State whether your study is descriptive or analytic • Describe your study design 	
<p>6. Methods</p> <ul style="list-style-type: none"> • Specify your study population • Describe the type of data you will collect • Describe your data collection procedures • Identify data quality procedures • Describe partners you will collaborate with 	
<p>7. Analysis Plan</p> <ul style="list-style-type: none"> • Include a few key Table Shells that show how you want to organize your data 	
<p>8. Plans for Interpreting the Data</p> <ul style="list-style-type: none"> • Describe the population to which you can generalize the results • Identify the limitations of this study • Describe the potential contributions of your study 	
<p>9. Plans to Report Study Findings</p> <ul style="list-style-type: none"> • Discuss how you will disseminate your results 	

Proposal Components	Included in your proposal?
<p>10. Budget</p> <ul style="list-style-type: none"> • Provide an overall (estimated) cost of your study • Organize the cost items by: Salaries, Supplies & Equipment, Travel, and Miscellaneous Costs 	
<p>11. Timeline</p> <ul style="list-style-type: none"> • Outline the major steps – and time required – for your study 	
<p>12. Appendices</p> <ul style="list-style-type: none"> • Describe the key items not in the text of your proposal that will be included 	

Note: Additional components may be required in grant proposals, including:

- Proposal Abstract
- Logistics
- Bibliography