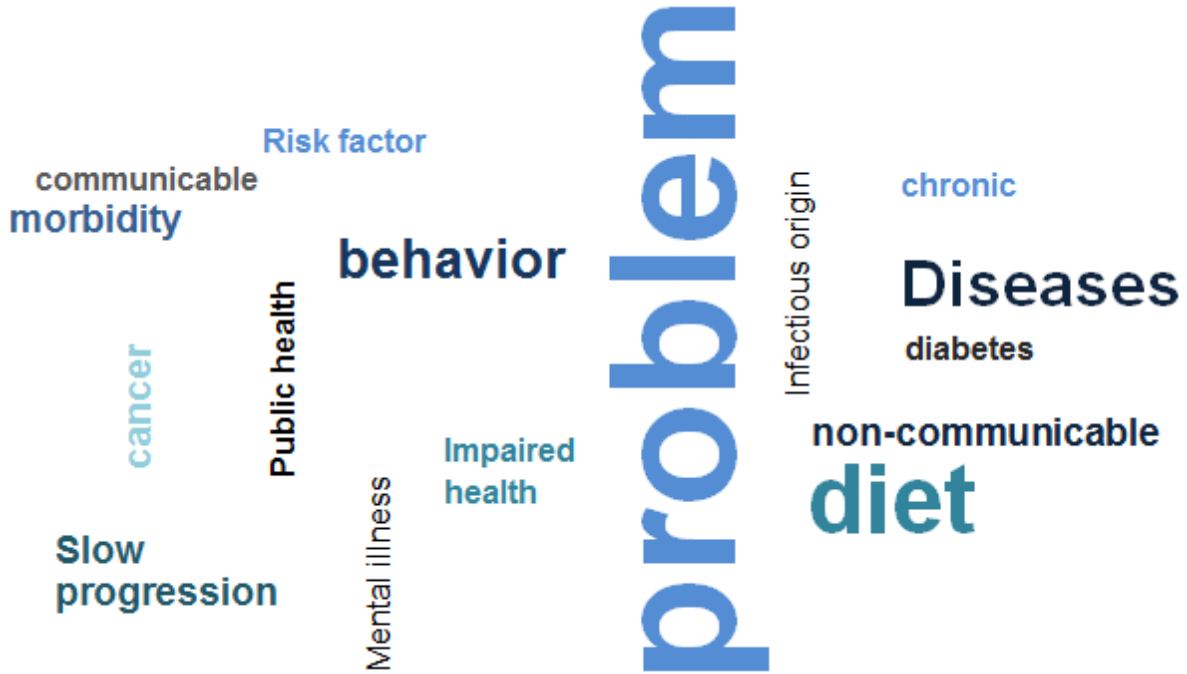


ACTIVITY WORKBOOK



Developing a Protocol

Created: 2013



Developing a Protocol. Atlanta, GA: Centers for Disease Control and Prevention (CDC), 2013.

Skill Assessment #1

Estimated time: 1 hour (plus 30-minute peer review)

Background:

For this exercise, you will work individually and use the information you have collected (and brought to class) for your NCD study.

Instructions:

1. Use the information about the public problem you are researching to complete the proposal template in the space below. You may finish completing the proposal when you return to your job. (NOTE: If you have access to a computer, you may use it to write your proposal rather than the template below.)
2. If you are in a classroom setting, find a colleague and review each other's work, providing feedback, as appropriate.
3. **Find a colleague with whom to conduct a peer review. Refer to Appendix A of this Activity Workbook for a worksheet to use for the peer review. (You will fill out the worksheet in *your colleague's* Activity Workbook).**

Project Title:

Background:

Skill Assessment #1

Estimated time: 1 hour (plus 30-minute peer review)

Justification for the study:

Research question or hypothesis:

Study objectives:

Skill Assessment #1

Estimated time: 1 hour (plus 30-minute peer review)

Proposed methods:

Study population:

Study design:

Skill Assessment #1

Estimated time: 1 hour (plus 30-minute peer review)

Operational definition:

Sampling procedure:

Sample size:

Skill Assessment #1

Estimated time: 1 hour (plus 30-minute peer review)

Data collection:

Analysis plan (What type of analysis would you perform?):

Skill Assessment #1

Estimated time: 1 hour (plus 30-minute peer review)

Expected benefit:

Skill Assessment #2

Estimated time: 45 minutes (plus a 15-minute peer review)

Background:

For this exercise, you will work individually and use the information you have collected (and brought to class) for your NCD study.

Instructions:

1. Refer to your responses for Skill Assessment # 1. What additional information would you include when writing the following sections of the protocol? You may use bullet points rather than complete sentences; then complete the sections after the training.

a. Literature review/current state of knowledge of the research topic (See *Background* section of proposal.)

b. Justification for study/Anticipated use of study results

Skill Assessment #2

Estimated time: 45 minutes (plus a 15-minute peer review)

c. Study design and location(s)

d. Objectives

e. Hypotheses or questions

Skill Assessment #2

Estimated time: 45 minutes (plus a 15-minute peer review)

f. General approach or focus of the study

Find a colleague with whom to conduct a peer review. Use the worksheet in appendix A to provide comments on each other's work.

Skill Assessment #3

Estimated time: 50 minutes

Background:

For this exercise, you will work individually and use the information you have collected (and brought to class) for your NCD study.

Instructions:

1. Begin to develop the Procedures and methods section of the protocol by briefly describing what information you would write in each of the following sections. You may use bullets for this exercise. Spend approximately 5 to 10 minutes on each section (A-F). You will finish writing the protocol after the training.

Procedures and methods:

A. Study design

Skill Assessment #3
Estimated time: 50 minutes

B. Study population

C. Variables/interventions

Skill Assessment #3
Estimated time: 50 minutes

D. Analysis and data management

E. Management of adverse or unexpected events

Skill Assessment #3
Estimated time: 50 minutes

F. Dissemination, notification, and reporting of results

Find a colleague with whom to conduct a peer review. Use the Worksheet in Appendix A to provide comments on each other's work.

Skill Assessment #4

Estimated time: 15 minutes

Background:

For this exercise, you will work individually and use the information you have collected (and brought to class) for your NCD study.

Instructions:

1. List at least three forms, documents, and/or tables that you would include in the Appendix of your protocol: **Find a colleague with whom to conduct a peer review. Use the Worksheet in Appendix A to provide comments on each other's work.**

Appendix A

Peer Review Worksheet: Skill Assessments #1 - 4

Instructions: Complete the following worksheet by answering all the questions (yes or no answers) and including a specific comment, as needed.

Criteria:	Yes/No	Comment
1. Skill Assessment #1: 2. Can the title stand alone as an explanation of the study?		
3. Does the background section describe relevant information about the health problem to be studied based on a review of the literature?		
4. Does the justification section, at a minimum, explain the public health and scientific importance of the study and the health problem being addressed?		
5. Is the research question or hypothesis clear and specific?		
6. Do the study objectives clearly and concisely state what the study will demonstrate, test, evaluate, confirm, or compare?		
7. Does the proposed methods section specify the population in which you will undertake the study will be undertaken?		
8. Does the study design include the type of descriptive or analytic study to be conducted?		

<p>9. Do the operational definitions include information about key case definitions, criteria and/ or control recruitment strategy?</p>		
<p>10. Does the sampling procedure describe the type of sampling you will use, such as convenient, simple random, systematic, cluster, multistage, non-probability?</p>		
<p>11. Does the sampling size include the main assumptions used to calculate it?</p>		
<p>12. Does the data collection section explain the type of data to collect, who will collect the data, the timeline, and the quality assurance mechanism?</p>		
<p>13. Does the analysis plan include the type of analysis to be performed?</p>		
<p>14. Does the expected benefit include how the results may influence prevention and control activities for the health problem?</p>		

<p>For Skill Assessment #2:</p> <p>15. Did the literature review/current state of knowledge of the research topic include any of the following components:</p> <ul style="list-style-type: none"> • What is the health problem • Who is being affected • How much of the population is affected • When did the problem occur or when was it identified • Where does the problem generally occur 		
<p>16. Does the justification section explain the public health and scientific importance of the study and the health problem being addressed? In</p>		
<p>17. Does the anticipated use of study results define the primary target audiences and discuss the expected applicability of study findings?</p>		
<p>18. Does the study design and location(s) include a brief description of the study design and the location where the study will be carried out?</p>		
<p>19. Do the study objectives clearly and concisely state what the study will demonstrate, test, evaluate, confirm, or compare?</p>		
<p>20. Is the research question or hypothesis clear and specific?</p>		

<p>21. Was a general approach or focus of the study included, for example :</p> <ul style="list-style-type: none"> • descriptive • exploratory • confirmatory • developmental 		
<p>For Skill Assessment #3:</p> <p>22. Does the study design description address research questions and objectives?</p>		
<p>23. Does the study population section include one or more of the following:</p> <ul style="list-style-type: none"> • Description and source of study population and the target study area • Case definition • Participant inclusion criteria • Participant exclusion criteria • Justification for excluding a population group • Estimated number of participants • Description of sampling, including sample size and statistical power • Description of enrollment 		

<p>24. Does the variables / interventions section include a description of one or more of the following:</p> <ul style="list-style-type: none"> • Variables • Study instruments, including questionnaires, laboratory instruments and analytic tests • Intervention or treatment • Results and minimum significant differences • Training of all study personnel 		
<p>25. Does the analysis and data management section include a description of one or more of the following:</p> <ul style="list-style-type: none"> • Data analysis plan, including statistical methodology • Data collection • Information management and analysis software • Data entry, editing and management, including handling of data collection forms, different versions of data, and the storage and disposal of data • Quality control and assurance • Bias in data collection, measurement and analysis • Review and analysis during the process • Study limitations 		

<p>26. Does the management of adverse or unexpected events section include a description of one or more of the following:</p> <ul style="list-style-type: none"> • Response to new or unexpected findings and changes in the study environment • Identifying, managing and reporting adverse events • Emergency care 		
<p>27. Does the dissemination, notification, and reporting of results section include a description of one or more of the following:</p> <ul style="list-style-type: none"> • Notifying participants of their individual results • Notifying participants of study findings • Anticipated products or interventions resulting from the study and their use • Disseminating results to public 		
<p>For Skill Assessment #4:</p> <p>28. Is the list of forms, documents, and/or tables to include in the Appendix appropriate for data collection and presentation of study results?</p>		
<p>29. Are all relevant documents to include in the Appendix listed, for example, informed consent forms, letters of endorsement for the study?</p>		