



PRE-TEST/POST-TEST FOR THE RESEARCH ETHICS TRAINING CURRICULUM

Name: _____

Please indicate if the following statements are True (T) or False (F).

The Principles of Research Ethics

1. The principle of respect recognizes the capacity and rights of all individuals to make their own decisions.
T ___ F ___
2. Consideration of any potential benefits to the communities where the research will be conducted is not part of the beneficence principle.
T ___ F ___
3. It is impossible to enroll research participants in an equitable manner.
T ___ F ___
4. The need to provide special protections to vulnerable persons is an essential element of the principle of respect.
T ___ F ___
5. Protection of the research participant is more important than the pursuit of new knowledge.
T ___ F ___
6. The principle of respect recognizes that not all persons are entitled to the same degree of autonomy.
T ___ F ___
7. The ideal of non-maleficence requires that risks associated with research participation must be reduced to a minimum.
T ___ F ___

8. Social and economic conditions that make persons vulnerable do not have to be considered by researchers or sponsors.
- T ___ F ___
9. Limited access to health services makes research participants vulnerable.
- T ___ F ___
10. Using research participants for the exclusive benefit of more privileged groups is not ethically correct.
- T ___ F ___
11. The principle of respect recognizes the dignity of all persons.
- T ___ F ___
12. The progress of science justifies any research study.
- T ___ F ___
13. It is acceptable to conduct research studies in low-resource communities for the benefit of more privileged communities that pay for the research.
- T ___ F ___
14. Respect for the communities where the research will be conducted is not currently considered an element of the principle of respect.
- T ___ F ___
15. Beneficence includes physical and mental well-being, but not social well-being.
- T ___ F ___
16. Research participants such as the poor and those with limited education need special protections.
- T ___ F ___

The Development of Contemporary Research Ethics

17. According to the Declaration of Helsinki, research with placebos is acceptable only in cases where proven prophylactic, diagnostic, or therapeutic methods do not exist.

T ___ F ___

18. The U.S. Code of Federal Regulations (CFR) governs all research conducted by international organizations.

T ___ F ___

19. The Belmont Report was developed in response to HIV/AIDS trials conducted in Africa.

T ___ F ___

20. Research using placebos is permitted if there is scientific justification.

T ___ F ___

21. International research guidelines do not require benefits for all research participants.

T ___ F ___

22. The Good Clinical Practice Guidelines were developed to ensure the appropriate protection of research participants.

T ___ F ___

23. The CFR governs all international research conducted with U.S. Government funds.

T ___ F ___

24. National regulations are essential to guide the conduct of research at the local level.

T ___ F ___

Informed Consent

25. Most research participants in developing countries are not capable of understanding the information presented in informed consent.

T ___ F ___

26. The informed consent form and the informed consent process are two distinct elements that complement each other.
- T ___ F ___
27. The principal investigator is the only person permitted to obtain informed consent.
- T ___ F ___
28. The information provided in the informed consent form must be reviewed and approved by a Research Ethics Committee (REC).
- T ___ F ___
29. Informed consent refers to a point in the research process when participants sign the informed consent document.
- T ___ F ___
30. It is recommended that researchers obtain evidence that the information presented in informed consent has been understood by the potential participant.
- T ___ F ___
31. The information contained in informed consent must be sufficient to avoid any legal liability to the research sponsor.
- T ___ F ___
32. Informed consent should be designed to empower the potential participant to make an informed choice to participate or not to participate in the study.
- T ___ F ___
33. The preparation of the informed consent process starts before the study is initiated.
- T ___ F ___
34. Local customs should not affect the development of informed consent.
- T ___ F ___
35. Members of the community where the research will be conducted should participate in the development of informed consent.
- T ___ F ___

36. The benefits that might come from the research are not known until the research is completed.

T ___ F ___

37. Research participants must be told very clearly that they are participating in an experimental study.

T ___ F ___

38. Dangerous research procedures must be carefully presented to the potential participant.

T ___ F ___

39. A research participant assumes a number of responsibilities by agreeing to participate in a study.

T ___ F ___

40. Participants in a randomized trial should not be told that they might not be receiving any actual treatment.

T ___ F ___

41. Receiving a free, safe, and effective treatment is an important benefit of participating in a clinical trial.

T ___ F ___

42. The expected benefits of the research to the community or to the society at large must be included in the informed consent.

T ___ F ___

43. Social risks associated with research participation are not the responsibility of the researcher or the sponsor.

T ___ F ___

44. The sponsor is responsible for deciding which risks need to be included in informed consent.

T ___ F ___

Responsibilities of Research Ethics Committees

45. Most national and international regulations require approval of a research study by an REC only when the research involves considerable risks to the participants.

T ___ F ___

46. The main responsibility of an REC is to assure the scientific correctness of a research study.

T ___ F ___

47. The main responsibility of an REC is the protection of research participants.

T ___ F ___

48. RECs are not responsible for the vigilance of ethical issues related to medical practice.

T ___ F ___

49. All members of an REC must have extensive experience in biomedical research and health care.

T ___ F ___

50. All members of an REC must be affiliated with the institution where the REC operates.

T ___ F ___

51. Community representative members of an REC are allowed to participate only as observers.

T ___ F ___

52. All REC members should have basic training in research ethics.

T ___ F ___

53. RECs must receive evidence that the researchers are qualified to conduct the research.

T ___ F ___

54. RECs do not have to approve any publication plans of the research results.
T ___ F ___
55. The REC's role does not include the consideration of any potential research benefits to the communities where the research will be conducted.
T ___ F ___
56. Protection of participant confidentiality is the responsibility of the researchers and not of the REC.
T ___ F ___
57. It is recommended that REC approval of a research study be limited to no more than one year and not for the entire duration of the study.
T ___ F ___
58. Changes in the number of research participants do not require REC review and approval.
T ___ F ___
59. RECs should establish regular surveillance mechanisms for the duration of the research.
T ___ F ___
60. Investigation of allegations of violations to the rights of research participants is not the responsibility of the REC.
T ___ F ___
61. Research studies may be monitored by sponsors or international organizations.
T ___ F ___
62. A Data Safety Monitoring Board (DSMB) reviews data to determine whether or not it is safe to continue a study.
T ___ F ___
63. A DSMB duplicates the work of an REC in protecting research participants.
T ___ F ___

64. DSMBs are established with members of the research team and the REC.
T ___ F ___
65. RECs should not allow the review of scientific aspects of the research by an independent scientific committee.
T ___ F ___
66. RECs may call upon special consultants, but these consultants should not have a vote in REC deliberations.
T ___ F ___
67. RECs must be able to make independent decisions.
T ___ F ___
68. RECs should not charge for their services.
T ___ F ___

Responsibilities of Sponsors and Researchers

69. The REC, not the researcher, is responsible for the protection of research participants.
T ___ F ___
70. Researchers must be guided by scientific design requirements and not by ethical norms.
T ___ F ___
71. RECs are not responsible for ensuring that participants will not be enrolled in the study before giving informed consent.
T ___ F ___
72. The researcher must report to the REC all unanticipated problems representing nonphysical risks to the participants.
T ___ F ___

73. A researcher cannot make changes to a research protocol without REC approval.
T ___ F ___
74. When necessary, the researcher should place the interests of science and society above the welfare of research participants.
T ___ F ___
75. Researchers are not responsible for the management of serious adverse experiences associated with participation in the study.
T ___ F ___
76. Researchers have the responsibility of minimizing any social risks associated with participating in a research study.
T ___ F ___
77. Sponsors are responsible for ensuring the availability of any technical equipment necessary to conduct the research.
T ___ F ___
78. Requiring review and approval of the research protocol by an existing local REC is a responsibility of the sponsor.
T ___ F ___
79. Sponsors are responsible for monitoring the technical and methodological aspects of a research study.
T ___ F ___
80. Sponsors are not responsible for monitoring the ethical aspects of a research study.
T ___ F ___
81. Sponsors need to comply only with the regulations of the country where the sponsor is legally based.
T ___ F ___
82. The local relevance of the research is not the responsibility of the sponsors.
T ___ F ___

83. Sponsors are not responsible for increasing local technical capabilities necessary to conduct the research study.

T ___ F ___

84. The sponsors are accountable for any study-related problems that might occur once the research study is completed.

T ___ F ___

Community Participation in the Research Process

85. At present, it is not possible to involve community representatives in the research process.

T ___ F ___

86. Identifying appropriate community representatives is not easy to do.

T ___ F ___

87. Communities are not interested in participating in the development and conduct of local research studies.

T ___ F ___

88. The main partners in a research study are the researchers, the REC, and the community where the research will be conducted.

T ___ F ___

89. At present, formal community representative groups, such as a Community Advisory Board (CAB), have been established in many countries to participate in the research process.

T ___ F ___

90. Community is a vague concept that is difficult to define.

T ___ F ___

91. Communities have a sense of place or location with their own boundaries.

T ___ F ___

92. Community applies only to a specific geographic location and not to specific groups of individuals.

T ___ F ___

93. Religion, social norms, and special interests or needs should not be seen as characteristics defining a community.

T ___ F ___

94. Community representatives can build a bridge between the researchers and the community.

T ___ F ___

95. Informed consent is a highly technical document that adheres to strict regulations and might not be affected by unique local community requirements.

T ___ F ___

96. Community representatives might be valuable members of an REC.

T ___ F ___

97. Community representatives tend to create unnecessary problems for the research team.

T ___ F ___

98. The introduction of research findings might be facilitated by community representatives.

T ___ F ___

99. It is very important to ensure that a research study is sensitive to community needs, social values, and norms.

T ___ F ___

100. A certain degree of social and economic development is necessary for a community to participate in the research process.

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ANSWER KEY TO THE PRE-TEST/POST-TEST FOR THE RESEARCH ETHICS TRAINING CURRICULUM

True (T) or False (F)

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READER'S EVALUATION OF THE RESEARCH ETHICS TRAINING CURRICULUM

Please answer the questions below after completing the *Research Ethics Training Curriculum*. The information you provide will help FHI 360 improve future presentations.

Please print your information below and include a business card.

Name	
Address (including country)	
Phone	
Fax	
E-mail	
Country(ies) where you work	

What are your current job responsibilities? (Please mark all that apply.)

- Ethics committee member
- Health trainer
- Health care provider
- Medical faculty
- Student (medical, nursing, midwifery, behavioral/medical research)
- Biomedical researcher
- Social science researcher
- Other (please specify) _____

Did you take the course: (Please mark one box.)

- In a group setting On a computer/electronic version

Did the curriculum address what you consider to be the most important research ethical issues? (Please mark one box.) Yes No

What information, if any, should have been covered but was not included?

What part of the curriculum, if any, should have been excluded?

How familiar were you with the information in the curriculum prior to this training? (Please mark one box.)

- Very familiar Somewhat familiar Not at all familiar

Which two curriculum messages do you think will be the most useful to you?

1. _____
2. _____

How did you benefit from taking this training? (Please mark all that apply.)

- Learned more about basic research ethics principles
 Learned more about informed consent
 Learned more about ethical review committees
 Improved understanding through the case studies
 Gained a new perspective of research ethics
 Have increased confidence in working with human research participants
 Did not benefit
 Other (specify) _____

Based on the information presented in this curriculum, would you consider making any changes to the conduct of research at your institution? Yes No

If *Yes*, what changes would you consider?

If *No*, why would you not consider making any changes?

Mark the box that best describes your feelings about the following statements:

The slides and other visual aids enhanced my understanding of the curriculum content.

- Strongly agree Agree Disagree Strongly disagree

The training activities enhanced my understanding of the curriculum content.

- Strongly agree Agree Disagree Strongly disagree

The case studies were relevant to my field of research.

- Strongly agree Agree Disagree Strongly disagree

The duration of the training was appropriate.

- Strongly agree Agree Disagree Strongly disagree

Rate the following curriculum components:

	Excellent	Good	Fair	Poor	Non-applicable
Slides					
Note pages					
Articles/additional resources					
Pre-test/post-test					
Training activities					
Case studies					
Other (specify)					

Would you recommend the curriculum to colleagues? Why or why not?

Please add any additional comments or suggestions.

Thank you for your assistance.

Please return the completed form by mail to:



Office of International Research Ethics
FHI 360
P.O. Box 13950
Research Triangle Park, NC 27709
USA

or electronically at:

ethics@fhi360.org