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Dear colleagues

Dr Towers has been so kind to work through the TRREE online course for ethics training after having a query about which modules needs to be done as proof of ethics training.

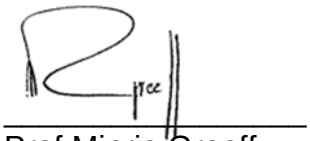
Each researcher who uses this online resource to complete the ethics training course should provide proof of completion of the following modules:

1. **Module 1 Introduction to research ethics**
2. **Module 2.1 Research ethics evaluation**
3. **Module 3.1 Informed consent**
4. **National supplement for South Africa**

If a researcher performs clinical trials they should also complete **Module 3.2** (Good clinical practice) as well if they *have not completed* an accredited GCP course.

The website only provides certificates if you get more than 70% for each of the modules.

Kind Regards,



Prof Minrie Greeff
Ethics Office Head

Note: We have setup a breakdown of the content of the different sections in each of the modules for your convenience (see below).

Module 1.1 Introduction to research ethics

Part 1 - Historical overview

1.1. Why research is important

1.2. The evolution of research ethics

1.2.1 The evolution of research ethics – The emergence of rules specific to research

1.2.2 The evolution of research ethics – The emergence of formal requirements for ethics evaluation

1.3. Why research ethics is important

Part 2 - Core values and concepts of ethics for research involving humans

2.1. Justifying the inclusion of humans in research: social value and scientific validity

2.2. Bringing about more good than harm

2.3. The interests of humans who participate in research must come before the interests of science and society

2.4. Voluntary participation: choosing to take on the risks of research

2.5. Fair distribution of the risks and potential benefits of research

2.6. Showing ongoing respect for persons

2.7. Upholding transparency during the research process

Part 3. Overview of normative frameworks applicable to health research involving humans

3.1. International instruments

3.2. National instruments

3.3. Institutional requirements

Part 4. Introduction to research ethics evaluation

4.1. What is research ethics evaluation

4.2. Why research ethics evaluation is important

4.3. Role and mandate of research ethics committees (REC)

4.4. Authority of RECs

Module 2 Research ethics evaluation

Part 1. Research Ethics Committees (RECs)

1.1. Authority, role and mandate of RECs

1.2. Independence of ethics committees and committee members: a key feature

1.3. Composition and operational aspects

1.3.1 Composition

1.3.2. Properly constituted RECs and standard operating procedures

1.4. Ethical deliberation & decision-making

1.4.1. Ethical deliberation

1.4.2. Reaching a decision

1.4.3. Due process

1.5. Follow up of ongoing research

1.6. Accountability

Part 2. Research and ethics evaluation

2.1. What research requires ethics evaluation

2.2. Particular cases

2.3. What aspects get evaluated and why

2.4. Levels of evaluation

2.5. Ethics review of international collaborative research

Part 3. Ethics evaluation of research projects

3.1. Community participation or collaborative partnership

3.2. Social value: relevance of research to local health needs & expectations

3.3. Scientific validity

3.4. Qualifications of researchers

3.5. Participant selection process

3.6. Acceptable balance of risks and potential benefits

3.6. Acceptable balance of risks and potential benefits (continued)

3.7. Informed Consent

3.7. Informed Consent (continued)

3.8. Fair compensation / reimbursement

3.9. Privacy and confidentiality

3.10. Researcher conflicts of interest

3.11. Scientific integrity

3.12. Ongoing respect for research participants and collaborating communities

Part 4. Documents to be reviewed

Module 3.1 Informed consent

Part 1. Informed consent: what it is and why it is important

1.1. Definition

1.2. Elements

1.3. History

1.4. A Western imposition or a universal human right

1.5. Individual, community, family

Part 2. The Informed Consent Process

2.1. Invitation to participate in research

2.2. Provision of information

2.3. Answering questions

2.4. Avoiding coercion and undue inducement

2.5. The decision and next steps

Part 3. When potential research participants are unable to give consent

3.1. Minors, mentally or emotionally challenged adults, demented, comatose or unconscious patients, captive populations

3.2. When can these individuals be allowed to participate in research

3.3. Who can give consent for these individuals

Part 4. Exceptions to Informed Consent Requirements

4.1. Waiver of consent must be justified

4.2. Public health requirements

4.3. Research on human material or personal data

4.4. Additional safeguards

5.1. Understandable Language

5.2. What Must be Included

5.3. Extra information for certain types of research (e.g., vaccines, genetic studies, phase I trials)

Module 3.2 GCP

Introduction to Clinical Research

Part 1. Objectives of good clinical practice in clinical research

Part 2. Preclinical activities

2.1 Introduction

2.2 Preclinical toxicity studies

Part 3. Clinical trials

3.1 Definitions

3.2 GCP in non-interventional clinical studies

3.3 Clinical Trial Principles

3.4 Clinical Trial Phases

Part 4. Avoid bias

4.1 Principles

4.2 Blinding

4.3 Randomization

4.4 Stratification

4.5 Sample Size

4.6 Type I & II Errors

4.7 Power

4.8 P value

Part 5. Basic clinical trial methodology: Trial designs

Introduction to Good Clinical Practice

Part 6. Historical background

6.1 Historical Development of Reference Documents used in Clinical Trials

6.2 ICH Approach

Part 7. GCP in clinical trials

7.1 Applicability of GCP

7.2 GCP Principles

7.3 GCP Summary

Part 8. RESEARCH ETHICS COMMITTEE (REC)/INDEPENDENT ETHICS COMMITTEE (IEC)/INSTITUTIONAL REVIEW BOARD (IRB)

8.1 Foreword

8.2 Reminder

8.3 REC Record Keeping: Variations in Rules and Laws

Part 9. Investigator

9.1 Be an Investigator

9.2 Investigational Site Organization

9.3 Pre-trial Processes

9.3.5 Investigator Site File (ISF):

9.4 During the Trial

9.4.2 Communication with the REC

9.4.3 Informed Consent

9.4.4 Investigational Medicinal Product

9.4.5 Adverse Event and Serious Adverse Event

9.4.6 Premature Discontinuation of the Trial

9.4.7 Investigator Site File during the Course of the Trial

Part 11. Monitor

11.1 Be a Monitor

11.2 Monitor's Responsibilities

11.3 Monitor's Tasks

11.3.1 Investigational Site Selection

11.3.2 At the Sponsor Site

11.3.3 At the Investigational Site

11.3.3.3 At the end of the trial

11.4 Monitor Summary

Part 12. Safety and Pharmacovigilance

12.1 Safety Definition

12.1 Safety Definition

12.1 Safety Definition

12.2 Manufacturer's Responsibilities

12.3 Sponsor's Responsibilities

12.4 Investigator's Responsibilities

12.5 Independent Data Monitoring Committee Responsibilities

12.6 REC Responsibilities

12.7 Use of Dictionary

12.8 International collaboration

12.9 Pharmacovigilance in Europe

12.10 Pharmacovigilance in the United States

National supplement

1. Type of research

1.1. Biomedical research

1.2. Research involving humans other than health research

1.3. Health related social science research

2. Ethics review

2.1. Research ethics committee

2.1.1. Jurisdiction of the REC

2.1.2. Independence of ethics review

2.1.3. Composition of the REC

2.1.4. Functioning of the REC

2.1.5. Ongoing review of research

2.1.6. Responsibility of the REC

2.2. Ethics review criteria

2.2.1. Social value of the research project

2.2.2. Scientific validity of the research project

2.2.3. Investigator’s qualification

2.2.4. Compensation for damages

2.2.5. Selection of research participants

2.2.6. Informed consent

2.2.7. Risk to benefit ratio

2.2.8. Conflicts of interest

2.2.9. Protection of privacy & confidentiality

2.2.10. Ongoing respect for research participants