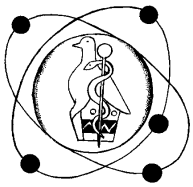
MEDICAL RESEARCH COUNCIL OF ZIMBABWE



ETHICAL GUIDELINES ON THE COLLECTION OF BLOOD SAMPLES FOR RESEARCH PURPOSES

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MEDICAL RESEARCH COUNCIL OF ZIMBABWE GUIDELINES ON ETHICS IN THE COLLECTION OF BLOOD SAMPLES FOR RESEARCH PURPOSES.

The following statements which may be collectively referred to as the MRCZ Article no. 1 of 1999 are offered as guidance to researchers whose studies involve the collection of blood samples for analysis; to ensure that they maintain the highest level of ethical conduct in their studies. These guidelines should be reviewed from time to time as appropriate, as procedures and scientific information are developed in the future.

1. Researchers/Research workers may only collect blood samples for research purposes if their activities are part of a **competently designed** study which will have been **approved** by the **Institutional Ethical Review Committee** (IERC) in that particular area/Institution and the **MRCZ** under accepted standards of scientific research which are aimed at producing data which are scientifically valid and significant.

2. Research workers conducting research in the field should carry a letter listing the Principal researcher, title of the research, the proposed duration, project sites and summary of research objectives. Research Staff should also carry identifying documents/cards with photographs linking them with the particular research project and institution.

3. Access to communities for blood sampling should be done with written permission from the relevant Provincial Medical Director 's Office or local authority's health services department and/or the local District Hospital. Communities should be accessed after sensitising local community leaders and staff at local health facilities. Environmental Health Technicians and Nursing Staff at local health facilities can also be used as liaison personnel between the researchers and the local communities.

4. The researcher/research worker should explain to the subjects the real purpose for the collection of the blood samples. (including an explanation on how blood is linked to the disease being researched upon). Researchers may not mislead subjects into believing that they are seeking blood donations for blood banks. Researchers/research workers should take their time to truthfully answer the subjects' questions before the collection of the blood samples.

5. Voluntary and informed consent in writing should be obtained from the subject or his or her legally authorized representative if the subject lacks the capacity to consent following :

(a) A disclosure that the researcher intends to collect a blood sample for research.
(b) A reasonable explanation of the nature of the procedure to be used, risk(s) to be expected, (pain and discomforts that may be anticipated and known risks) and possible therapeutic benefits.
(c) An offer to answer any inquiries concerning the procedure
(d) And the alternatives,
(Researchers should not use persuasion to obtain consent that otherwise might not be forthcoming.)

6. The collection of blood samples for analysis should be done only by persons who possess special knowledge and technical competence developed through study, special training, laboratory practice or experience and under conditions adequate to protect the health and well being of the subjects.

7. The research worker collecting the blood sample should demonstrate concern and caution for the welfare, safety and comfort of the persons involved.

8. The quantity of blood taken should be such that it does not cause any significant risk to the subject.

9. Blood samples may not be provided in exchange for financial remuneration above that which is necessary to cover reasonable expenses. Such items as food, soft drinks or other non-resale items can be offered.

10. Researchers may use without obtaining prior informed consent, left over blood for other studies provided the left over specimens:

i. Are not linked to an identifiable person, and
ii. Would normally be discarded.

The use of left over blood samples for other purposes beside the original purpose for which they were collected should however be done after obtaining prior clearance from the MRCZ.

11. If it is intended or likely that blood obtained from research will be used for Commercial or other purposes, this must be disclosed in the research proposal and on the consent form.

12. Research workers should take steps to ensure the confidentiality of any personal information obtained from the study. Apart from situations where disclosure is mandatory e.g. notification of infectious diseases, there must always be the most compelling reasons before a physician discloses such information without the consent of the subject. In such cases, the researcher must always notify the patient of the intention to disclose the information. When seeking the patient's consent to disclose confidential information the researcher must ensure that the patient understands the reasons for disclosure and its likely consequences.

13. Where a research worker identifies a disease during the study, he/she should take steps to have the person treated e.g. by administering treatment if he/she is qualified or by reporting to the local health centre after complying with (12) above. *Wherever possible, the results of the blood tests should be explained to the individuals.*

14. No blood samples or products may be taken outside the country for whatever reasons without the written permission of the MRCZ. If the blood samples or products are to be taken out side the country for whatever reason, this should be explicitly stated in the research proposal submitted to the MRCZ for review.

15. For any deviation from the above researchers should seek prior permission from the MRCZ.

16. The MRCZ shall notify in writing any researcher(s) violating the above guidelines. The MRCZ may suspend or stop any research that does not comply with the above guidelines, and shall notify the researcher in writing accordingly.

Signed.

Prof. F. W. G. Hill
CHAIRMAN MEDICAL RESEARCH COUNCIL OF ZIMBABWE
29 July 1999