Introduction to ethics – basic principles

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First Training Workshop and Symposium MURIA Group 27 – 29 July 2015

Outline

- Need for Ethics in Research
- Basic biomedical research principles
  - Respect for the autonomy of persons
  - Beneficence
  - Non-maleficence
  - Justice
- Informed consent (and the challenges of non-therapeutic research in children)
- Declarations, Codes, Guidelines
- Transparency
- Retrospective research and epidemiological research

Need for Ethics in Research

- The assumption that medical professions could not, by their very nature, engage in unethical research was proven false:
  - Nazi experimentation – revealed during the Nuremberg trials
  - Tuskejee syphilis study
  - And more recent examples ….

Useful summary of the general principles

- Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research (1979). http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html

Respect for persons

- “individuals should be treated as autonomous agents”
- “persons with diminished autonomy are entitled to protection”
- The principle of respect for persons thus divides into two separate moral requirements:
  - the requirement to acknowledge autonomy; and
  - the requirement to protect those with diminished autonomy

Respect (2)

- An autonomous person is an individual capable of deliberation about personal goals and of acting under the direction of such deliberation.
- To respect autonomy is to give weight to autonomous persons' considered opinions and choices while refraining from obstructing their actions unless they are clearly detrimental to others.
- However, not every human being is capable of self-determination.
- The capacity for self-determination matures during an individual's life, and some individuals lose this capacity wholly or in part because of illness, mental disability, or circumstances that severely restrict liberty.
- Respect for the immature and the incapacitated may require protecting them as they mature or while they are incapacitated.

Beneficence and non-maleficence

- Linked to the Hippocratic injunction “do no harm”
- Two general rules have been formulated:
  - do not harm; and
  - maximize possible benefits and minimize possible harms

Benefits – to whom and when?

- “In the case of particular projects, investigators and members of their institutions are obliged to give forethought to the maximization of benefits and the reduction of risk that might occur from the research investigation”
- “In the case of scientific research in general, members of the larger society are obliged to recognize the longer term benefits and risks that may result from the improvement of knowledge and from the development of novel medical, psychotherapeutic, and social procedures”

Belmont Report 1979

Justice

- Who ought to receive the benefits of research and bear its burdens? This is a question of justice, in the sense of "fairness in distribution" or "what is deserved"
- An injustice occurs when some benefit to which a person is entitled is denied without good reason or when some burden is imposed unduly
- Another way of conceiving the principle of justice is that equals ought to be treated equally
  - There are several widely accepted formulations of just ways to distribute burdens and benefits
    - to each person an equal share
    - to each person according to individual need
    - to each person according to individual effort
    - to each person according to societal contribution
    - to each person according to merit

Justice (2)

- Examples from Belmont:
  - the selection of research subjects needs to be scrutinized in order to determine whether some classes (e.g., welfare patients, particular racial and ethnic minorities, or persons confined to institutions) are being systematically selected simply because of their easy availability, their compromised position, or their manipulability, rather than for reasons directly related to the problem being studied
  - whenever research supported by public funds leads to the development of therapeutic devices and procedures, justice demands both that these not provide advantages only to those who can afford them and that such research should not unduly involve persons from groups unlikely to be among the beneficiaries of subsequent applications of the research.

Informed consent – the wording from South Africa's National Health Act (2003)

71. (1) Notwithstanding anything to the contrary in any other law, research or experimentation on a living person may only be conducted-

(a) in the prescribed manner; and

(b) with the written consent of the person after he or she has been informed of the objects of the research or experimentation and any possible positive or negative consequences on his or her health.

(2) Where research or experimentation is to be conducted on a minor for a therapeutic purpose, the research or experimentation may only be conducted-

(a) if it is in the best interests of the minor;

(b) in such manner and on such conditions as may be prescribed;

(*c*) with the consent of the parent or guardian of the child; and

(d) if the minor is capable of understanding, with the consent of the minor.

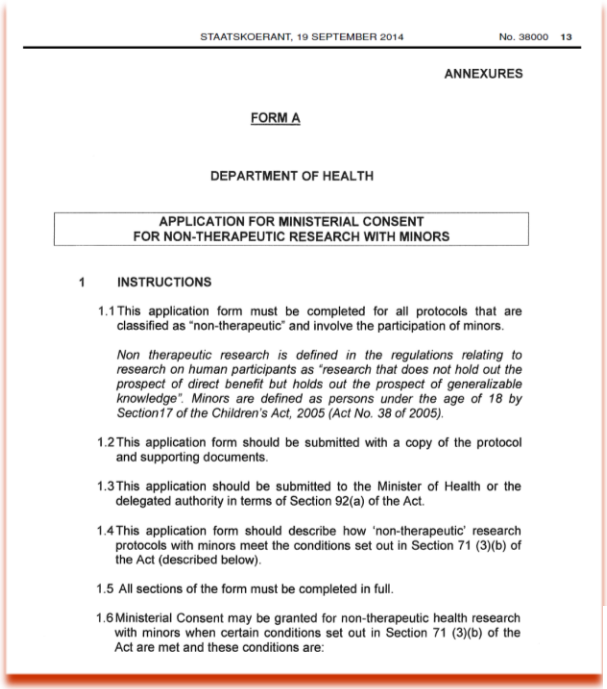
(3) *(a)* Where research or experimentation is to be conducted on a minor for a non-therapeutic purpose, the research or experimentation may only be conducted-

(i) in such manner and on such conditions as may be prescribed;

(ii) with the consent of the Minister;

(iii) with the consent of the parent or guardian of the minor; and

(iv) if the minor is capable of understanding, the consent of the minor.



STAATSKOERANT, 19 SEPTEMBER 2014 No. 38000 13

ANNEXURES

FORM A

DEPARTMENT OF HEALTH

APPLICATION FOR MINISTERIAL CONSENT
FOR NON-THERAPEUTIC RESEARCH WITH MINORS

1 INSTRUCTIONS

1.1 This application form must be completed for all protocols that are classified as "non-therapeutic" and involve the participation of minors.

Non therapeutic research is defined in the regulations relating to research on human participants as "research that does not hold out the prospect of direct benefit but holds out the prospect of generalizable knowledge". Minors are defined as persons under the age of 18 by Section17 of the Children's Act, 2005 (Act No. 38 of 2005).

1.2 This application form should be submitted with a copy of the protocol and supporting documents.

1.3 This application should be submitted to the Minister of Health or the delegated authority in terms of Section 92(a) of the Act.

1.4 This application form should describe how 'non-therapeutic' research protocols with minors meet the conditions set out in Section 71 (3)(b) of the Act (described below).

1.5 All sections of the form must be completed in full.

1.6 Ministerial Consent may be granted for non-therapeutic health research with minors when certain conditions set out in Section 71 (3)(b) of the Act are met and these conditions are:

3.1 Condition 1: The research objectives cannot be achieved except by the participation of minors

Describe the scientific justification for the enrolment of minors. Explain why this research must be done with minors as participants:

3.2 Condition 2: The research is likely lead to an improved scientific understanding of certain conditions, diseases or disorders affecting minors

Describe how the research might, or aims to, advance knowledge affecting the health and welfare of minors as a class. Note that 'condition' is defined in the Regulations as 'physical and psycho-social characteristics understood to affect health' allowing that this research does not only involve children with an illness.

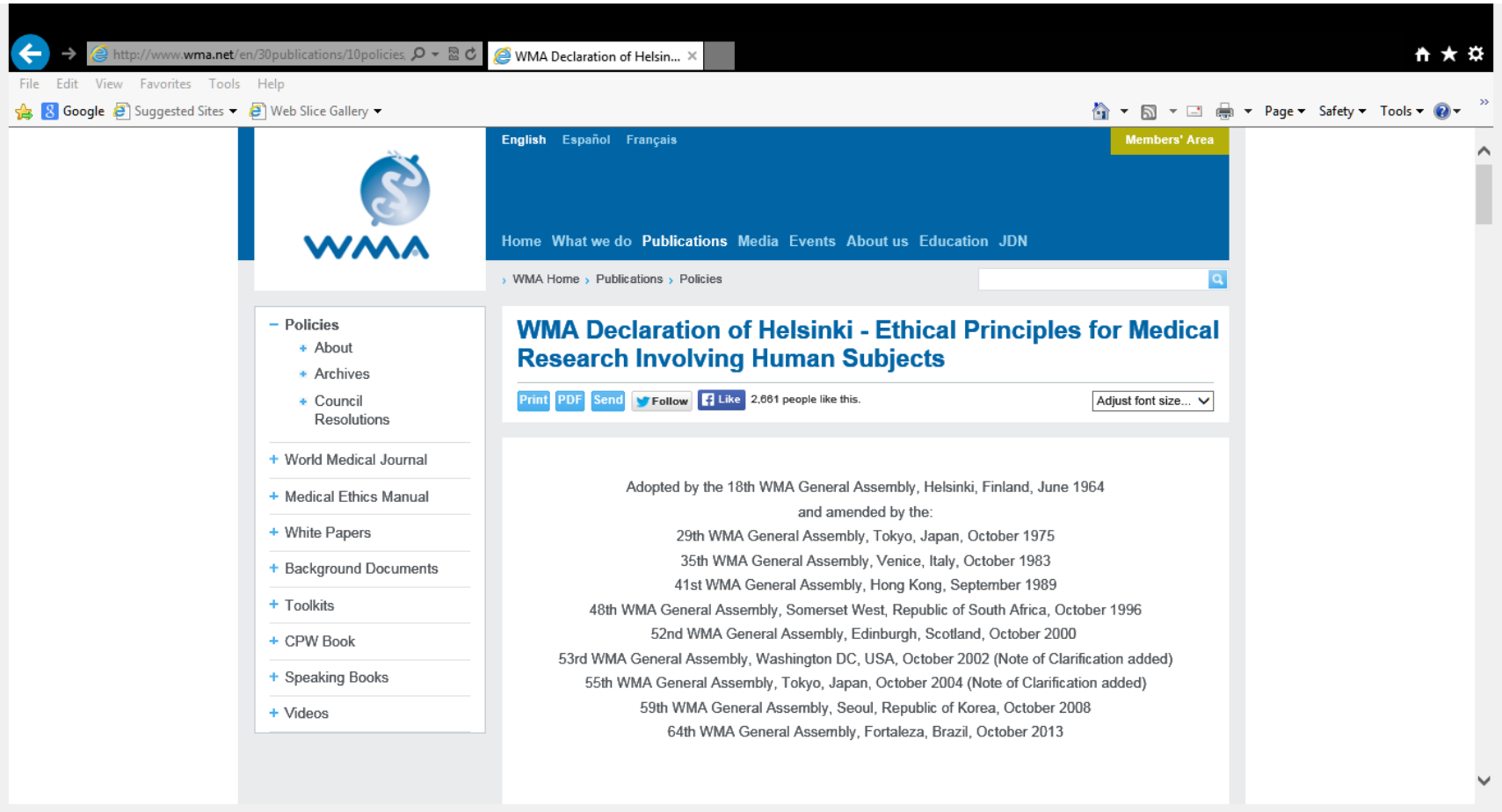
3.3 Condition 3: Any consent given to the research is in line with public policy

Consent given by authorised persons must be in line with public policy considerations. Describe how consent to the research will be in line with public policy or would be acceptable, for example, show how the research poses acceptable risks and promotes the rights of minors:

3.4 Condition 4: The research does not pose a significant risk to minors; and if there is some risk, the benefit of the research outweighs the risk.

Describe how the potential risks from the research procedures and/or intervention to minor participants will be minimized and describe any possible benefits from the research to society in the form of knowledge:

Codes …. various



…. just 37 clauses

http://www.wma.net/en/30publications/10policies/b3/index.html

Transparency – the Helsinki standard

Research Registration and Publication and Dissemination of Results

35. Every research study involving human subjects must be registered in a publicly accessible database before recruitment of the first subject.

36. Researchers, authors, sponsors, editors and publishers all have ethical obligations with regard to the publication and dissemination of the results of research. Researchers have a duty to make publicly available the results of their research on human subjects and are accountable for the completeness and accuracy of their reports. All parties should adhere to accepted guidelines for ethical reporting. Negative and inconclusive as well as positive results must be published or otherwise made publicly available. Sources of funding, institutional affiliations and conflicts of interest must be declared in the publication. Reports of research not in accordance with the principles of this Declaration should not be accepted for publication.

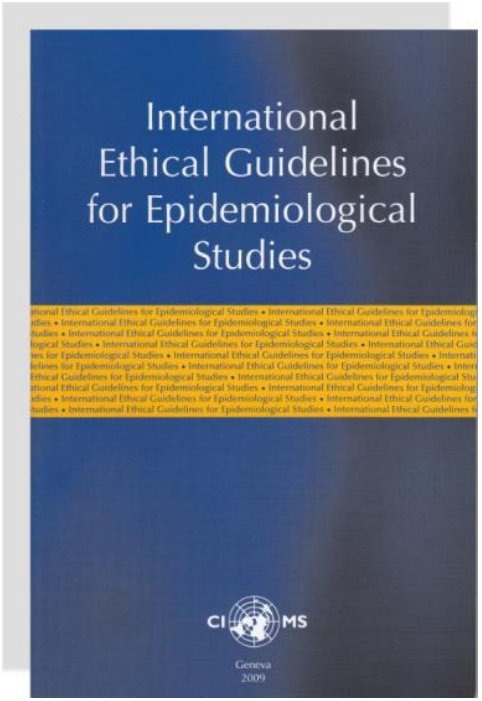
Council for International Organizations of Medical Sciences (CIOMS)

http://www.cioms.ch/publications/layout_guide2002.pdf

Some aspects of relevance:

- Research in populations and communities with limited resources
- Choice of control in clinical trials
- Research involving vulnerable persons
- Women as research participants
- Pregnant women as research participants
- Safeguarding confidentiality
- Right of injured subjects to treatment and compensation
- Ethical obligation of external sponsors to provide health-care services

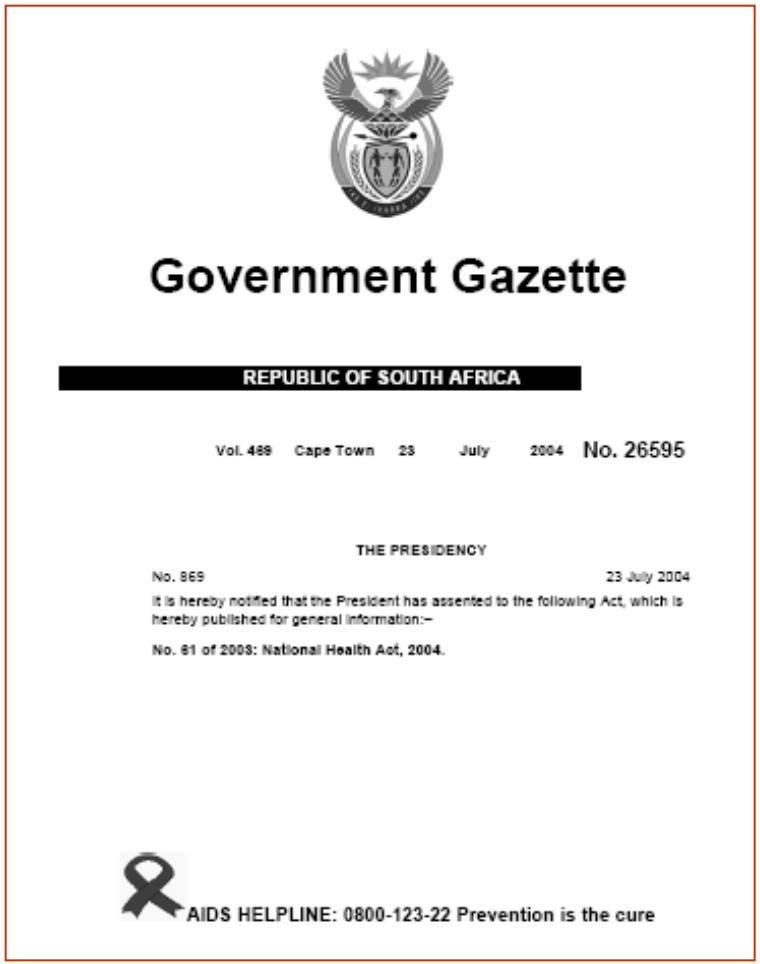
Council for International Organizations of Medical Sciences (CIOMS)



International Ethical Guidelines for Epidemiological Studies (2009)

http://www.ufrgs.br/bioetica/cioms2008.pdf

The legal backing – an example



Government Gazette

REPUBLIC OF SOUTH AFRICA

Vol. 469 Cape Town 23 July 2004 No. 26595

THE PRESIDENCY

No. 869 23 July 2004

It is hereby notified that the President has assented to the following Act, which is hereby published for general information:–

No. 61 of 2003: National Health Act, 2004.

AIDS HELPLINE: 0800-123-22 Prevention is the cure

- Passed in 2003
- Now mostly promulgated

73. (1) Every institution. health agency and health establishment at which health research is conducted, must establish or have access to a health research ethics committee, which is registered with the National Health Research Ethics Council.

Confidentiality

14. (1) All information concerning a user, including information relating to his or her health status, treatment or stay in a health establishment, is confidential.

(2) Subject to section 15, no person may disclose any information contemplated in sub-section (1) unless-

(a) the user consents to that disclosure in writing;

(b) a court order or any law requires that disclosure; or

(c) non-disclosure of the information represents a serious threat to public health.

Access to health records

15. (1) A health worker or any health care provider that has access to the health records of a user may disclose such personal information to any other person, health care provider or health establishment as is necessary for any legitimate purpose within the ordinary course and scope of his or her duties where such access or disclosure is in the interests of the user.

(2) For the purpose of this section, "personal information" means personal information as defined in section 1 of the Promotion of Access to Information Act, 2000 (Act No. 2 of 2000).

Access for “study”

16. (1) A health care provider may examine a user’s health records for the purposes of-

(a) treatment with the authorisation of the user; and

(b) study, teaching or research with the authorisation of the user, head of the health establishment concerned and the relevant health research ethics committee.

(2) If the study, teaching or research contemplated in subsection (1)*(b)* reflects or obtains no information as to the identity of the user concerned, it is not necessary to obtain the authorisations contemplated in that subsection.

Guidance from the SA MRC 2004 guidelines

Data gathered for administrative purposes or audit does not require the participants' consent if obtaining the consent could cause undue concerns, be impractical or too expensive. However, where publication of audited results may have potentially adverse consequences for study participants or for particular social groups, consent to use such data must be sought. Researchers should always seek the advice of a research ethics committee to decide whether record review requires individual consent.

SA MRC 2004 guideline contd (2)

A research ethics committee may approve the collection of data from records, either retrospectively or prospectively, that is identified or potentially identifiable if:

- It is satisfied that the scientific validity of the study would be compromised by de-identifying the data (i.e. that the objectives of the study could not be attained by de-identifying the data), or that
- An alternative study design which allowed for the use of de-identified data to meet the same objective was not possible, and that confidentiality of data collected could be assured.

Conclusions

- Health research has the potential to be exploitative, for many reasons, and in relation to any number of vulnerable groups/populations.
- Globally and nationally, structures are in place to protect the vulnerable, and hold researchers to high standards of ethical behaviour.
- However, such provisions can also hamper necessary research, and limit our ability to find the answers to important questions.
- Pharmacoepidemiological research is no different – it still needs to be done ethically and carefully.