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International Federation for Emergency Medicine

Ethical Conduct in Research

IFEM Research Committee Checklist

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Preamble:

The International Federation of Emergency Medicine (IFEM) was established to foster mutually beneficial relationships between countries, societies, and professional men and women dedicated to the care of the acutely ill and injured throughout the world. It is imperative, therefore, that our shared commitment to new learning, new knowledge, and scientific discovery be mutually beneficial as well.

To better define the principles of research ethics, IFEM has provided the following checklist as a foundation. It is expected that IFEM members, either individuals or countries, would subscribe to these principles in the conduct of ethically sound research.

As these principles are broad, they are applicable to a range of research organisations (single-centre investigator groups through to multi-national collaborations), research study designs (observational through to clinical trials) and research material (human, animal, stem cell or existing scientific evidence).

IFEM Research Committee Checklist

- The project will be undertaken in accordance with the general principles of the Declaration of Helsinki and International Conference on Harmonization Good Clinical Practice.

- The project must be approved by an Ethics Committee(s)/Institutional Review Board(s) prior to data collection.

- The Ethics Committee(s)/Institutional Review Board(s) will be accredited by the appropriate national research institution of the respective country(ies) e.g. NIH, NHMRC.

- There is adequate resource and infrastructure to undertake ongoing research governance.

- The investigators have the necessary experience to undertake the project.

- The project is adequately resourced to achieve its aims.

- The project methodology will adequately answer the research question.

- There is adequate provision for informed participant consent (where appropriate) or adequate justification for waiver of consent (as determined by Ethics Committee(s)/Institutional Review Board(s)).

- There is no disproportionate inducement for enrolment that could be perceived as coercion to participate or take risk.

- The Participant Information and Consent form contains adequate detail of:
    - The reason the project is being undertaken
    - Why the participant is being invited to participate
    - All procedures and burdens required of the participant
    - The potential risks (and their likelihood) that participants may be exposed to.
    - That participants may terminate their participation at any time without consequence

- There is adequate provision for:
    - medical care and/or compensation for a participant in the event of injury
    - the confidentiality of all enrolled participants
    - the security of all hard copy and electronic data
    - the secure disposal of all data after the required storage period

- There is confirmation that only the investigators will have access to the data until fully de-identified. IFEM encourages making the database open-access to other researchers after de-identification and after the researchers have prepared their first publication.

RESOURCES

World Medical Association's Declaration of Helsinki (2008).
http://www.wma.net/en/30publications/10policies/b3/index.html

WHO: Operational Guidelines for Ethics Committees that Review Biomedical Research (2000) http://whqlibdoc.who.int/hq/2000/TDR_PRD_ETHICS_2000.1.pdf

Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO). International Ethical Guidelines for Biomedical Research Involving Human Subjects (2002)
http://www.cioms.ch/publications/layout_guide2002.pdf

Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, 2010.
http://pre.ethics.gc.ca/pdf/eng/tcps2/TCPS_2_FINAL_Web.pdf

Australian Code for the Responsible Conduct of Research
http://www.austin.org.au/Assets/Files/REU_Australian_Code_Research_2007.pdf

Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO). International Ethical Guidelines for Epidemiological Studies (2008)
http://www.ufrgs.br/bioetica/cioms2008.pdf

United Nations Educational, Scientific and Cultural Organisation (UNESCO). Universal Declaration on Bioethics and Human Rights (2005)
http://unesdoc.unesco.org/images/0014/001461/146180E.pdf

UNAIDS: Ethical Considerations in Biomedical HIV Prevention Trials (2007):
http://data.unaids.org/pub/Report/2007/JC1399_ethical_considerations_en.pdf