What makes Clinical Research Ethical?

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Clinical Research

"Systematic investigation designed to produce generalizable knowledge to improve health and/or increase understanding of human biology"

“To protect the rights and welfare of the participants of research”

1. Produce generalizable knowledge to improve health and/or increase understanding of human biology

2. To protect the rights and welfare of the participants of research

Mission Statement

(ERC, UCFM)

"To safeguard the dignity, rights, safety and well-being of all actual or potential research participants. The goals of research will never be permitted to override the health, well-being and care of research participants"

- Respect for persons

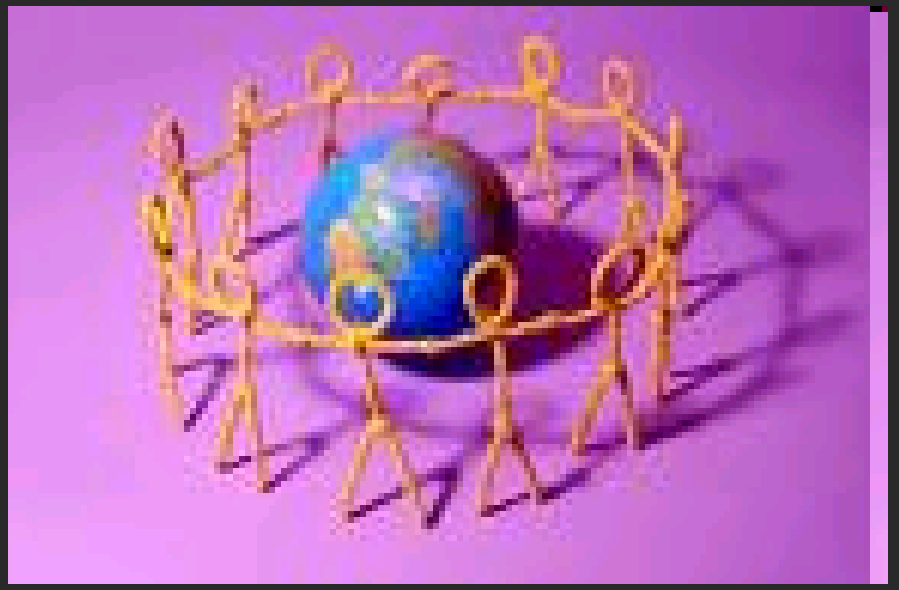
- Beneficence
(and Non-maleficence)

- Justice

- Collaborative partnership
- Social value
- Scientific validity
- Fair subject selection
- Favorable risk benefit ratio
- Independent review
- Informed consent
- Respect for human subjects

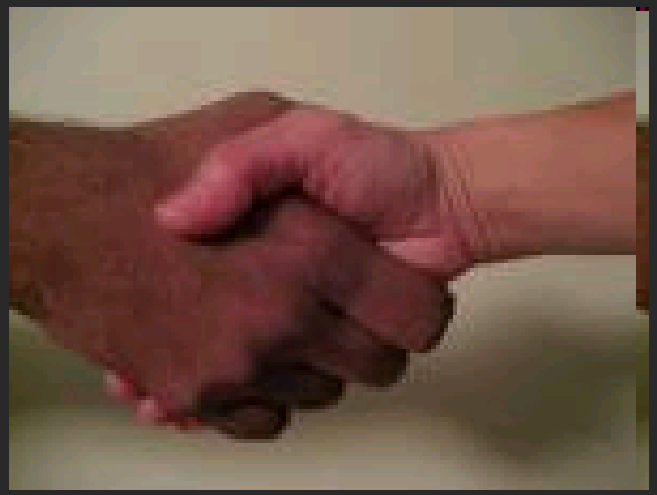
Collaborative partnership

- Sponsor
- Researchers at the sponsor site
- Researcher at the host site
- Policy makers at the host site
- Community at the host site

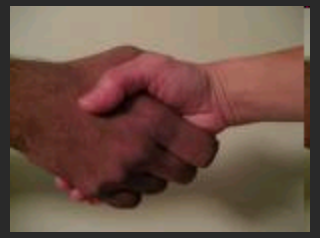


International collaborative research

Is this research being conducted by investigators from another country?



- That local collaborators who have equal responsibility for the research are involved
- Local collaborator are in touch with policy makers and the community
- The local collaborators should be involved in planning and conducting the study and for disseminating the results and ensuring they are used for health improvements



- That the research could not reasonably well be carried out in developed countries or that is justifiable that is conducted in that community
- That it is responsive to the health needs and the priorities of the community in which it is going to be carried out

- That the available guidelines, regulations and legal requirements been fulfilled eg Material transfer agreements regarding exchange of biological materials

- That ethical approval is obtained from ERCs from both countries

- That the distinctive values, culture and social practices of the country are recognized and incorporated into the design of the study

- Obtaining informed consent in a manner appropriate in our culture context

- That the benefits of the research are fairly distributed between the two countries for example that any product developed will be made reasonably available to the inhabitants of the community.

- The benefits could include capacity building of the community by improving health care services, or research capability or indeed ethics review capability.

- It is also important to ensure that the results of research are communicated to the local authorities

- That intellectual property, patents etc are shared with the local researchers.

International collaborative research

- Could this research be reasonably well carried out in developed countries or is it justified in this community?
- Is the research responsive to the health needs and the priorities of the community in which it is going to be carried out?
- Have the available guidelines, regulations and legal requirements been fulfilled eg regarding exchange of biological materials?
- Is there a local collaborator / institution that has equal responsibility for the research?
- Has ethical approval been obtained from the ERCs of the collaborating institution of that country?

International collaborative research

- Are the informed consent procedures appropriate for the country?
- Will the benefits of the research be fairly distributed between the two countries for example any product developed be made reasonably available to the inhabitants of the community?
- Will the research lead to capacity building in the less developed society?
- Will the results of the research be conveyed to the local authorities?