How do you ensure that your research is ethical?

There are many textbooks and articles on the ethics of research – below we give you the basics and advise that you also read the few references in the footnotes.

When you start planning your research you have to determine the following:

Social value[1,2]:

Your proposed research must have prospective value for the beneficiaries through improvement of their health or well being or adding to generalizable knowledge that may benefit beneficiaries in the future. The two major reasons why social value is important are to (1) avoid exploitation and (2) ensure responsible use of resources. You must clearly document who will benefit from the research and the importance of the health problem(s) that you want to investigate. Determine also how you will disseminate the information (see Step 13) to ensure that other persons with this health problem will benefit from your research.

Scientific validity[1,2]:

The only ethical way in which you can do your research, is to develop a study with a scientific design, rigorous research methodology, including statistics, that will generate valid, reliable data. When you compare two therapies or interventions there should be clinical equipoise, meaning that you truly do not know which is the better therapy/intervention.

TIP: Any unscientific study is unethical.

Fair selection of your study population[1,2]:

You must select a population that will meet the scientific study requirements of your study. Fair selection means that you select your participants according to the scientific goal and not because of privilege, vulnerability, availability or other factors unrelated to the study aim. For example, you cannot exclude an illiterate participant because the participant cannot read the informed consent. Under these circumstances you must use a witness to observe the full consent process.

1 Emanuel, Ezekiel J., David Wendler, Killen J et al. "What makes clinical research in developing countries ethical? The benchmarks of ethical research." Journal of Infectious Diseases 189.5 (2004): 930-937
2 Emanuel, Ezekiel J., David Wendler, and Christine Grady. "What makes clinical research ethical?." JAMA 283.20 (2000): 2701-2711

At the same time you have to ensure that you exclude participants where the potential for harm exceeds the potential benefits.

Favourable risk-benefit ratio[1,2]:

You have to carefully compare the potential benefits with the risks of your proposed study. You have to ensure that the benefits outweigh the risks and that the risks are acceptable within the context of the health risks. This is a multistep process, whereby you first identify all the risks involved, then you assess the potential benefits to the participants (remember that these benefits do not include unrelated benefits to the aim such as the payment of subjects or unrelated health care due to participation). The final step is to compare the risks with the potential benefit, and the potential benefits should outweigh the risks. Very often junior researchers are involved in studies that will lead to generalizable knowledge only, without direct benefit to the individual participant - if this is the case, you need to do a risk-knowledge assessment, which is often the case for non-therapeutic research[3].

Informed consent:

The main purpose of informed consent is to allow potential participants to decide whether to participate or not according to their own value system, preferences and interests. You show your respect towards your study participants' autonomy through the informed consent process. The informed consent document must accurately describe the objectives, procedures, the alternative treatment, as well as discuss both the potential benefits and the risks. You should provide a telephone number for yourself or one of the research team members for the participant to be able to contact you if there are queries or any emergencies related to the study. You have to use language that is understandable to the layperson and culturally appropriate. If you are dealing with children or mentally disabled persons your language needs to be even more simplified and you have to elicit both their assent, as well as their parent or legal guardian's consent. See Template 4 for examples of consent and assent forms for children.

Respect for recruited participants[1,2]:

As part of respect for your participants you have to ensure confidentiality of their information. You have to document how you will ensure that confidentiality is protected throughout the research project and thereafter, in sharing the findings of your research project. You should create a unique study number for each participant which is linked to the actual patient/participant record and this generated list should be kept locked in a safe storage space. It is also important to link your raw data to this unique study number and analyse anonymously,

3 Weijer, Charles. "I need a placebo like I need a hole in the head." The Journal of Law, Medicine & Ethics 30.1 (2002): 69-72.

which means that the list with the linking to the actual name of the participant is not available during the analysis process. Part of respect for participants is also to ensure that they know that they may not give consent, or that they can withdraw from the research study without any influence on their health care ("no penalty") at any time including the future. You need to also share your results during the course of the study or thereafter with your research participants (Step 13).

Remember that each section in your proposal links to the other sections – the ethics section must link to data management, communication of results etc. If you write in the ethics section that you will collect data in an ethical and confidential way, then you must give the detail of how you will do this, in the data management section.

Independent review[1,2]:

Your research study must be reviewed by an independent ethics review committee. This is stipulated in the South African National Health Act[4] and ensures public accountability and also builds the trust of the community in you as a researcher. We all have diverse interests which let us embark on research and which may generate conflicts, which may influence our judgement.

Collaborative partnerships[1,2]:

In the process of undertaking your research it is important to form partnerships with other researchers, policy makers and the community where you conduct your research. Involve these partners when you determine the importance of the health problem, the planning and conducting of the study, as well as integrating with the existing health system. Often you will have to assist in capacity building of especially the community you deal with that will assist them to become partners in the research process. Respect the culture and traditions of the community at all times.

Ethical principles including children

There are several important guiding documents that you need to familiarize yourself with before embarking on research. Two important documents are the (1) Helsinki Declaration[4] and (2) National Health Act of South Africa no 61 of 2003 section 71[5]. The four important ethical principles are:

- respect for persons
- beneficence
- non-maleficence
- justice

4 World Medical Association. Declaration of Helsinki: Ethical principles for medical research involving human subjects. WMA Policy. Seoul: World Medical Association [Online] 2008 [access 2012, July 9]; Available: www.wma.net/e/policy/pdf/17c.pdf

5 National Health Act. South Africa. No 61. 2003 Section 71

The informed consent is the manifestation of respect for persons in research, the risk-benefit assessment is for beneficence/non-malfeasance and fair selection is for justice. Children are particularly vulnerable since their ability to assent/consent is linked to their cognitive and developmental stage and a third party (usually their parents) are the decision-makers. You have to determine if the decision-maker for the child is truly acting in the best interest of the child and that the child also assents if cognitively able to. It is useful to use a checklist for paediatric research as found in "Research Ethics in Africa: a resource for research ethics committees" chapter 13 page 97[6].

When can you apply for a waiver of consent?

When you are using data that have already been collected and you do not have contact with the child or their caregivers you can apply for a waiver of consent from the ethics committee. A waiver of consent does not however mean that you do not need to abide by the confidentiality requirements and the children's identity must be protected at all times.

TIP: If you are treating a very interesting patient you would consider writing up as a case report collect the consent from the parent and the assent from the child (if appropriate) as many journals will not consider your article if the consent is not sent to them. It can be very frustrating looking for the patient afterwards.

How to submit to ethics (SU website)

The Health Research Ethics Committees of Stellenbosch University have a website dedicated to guide researchers in the submission of their research proposals for ethics review. Please go to the website to download the ethics application package that will guide you through the process. *http://sun025.sun.ac.za/portal/page/portal/Health_Sciences/English/Centres%20and%20Institutions/Research_Development_Support/Ethics*

You will also have to check the meeting and submission dates found on this website to guide you in time management of your research process. You have to submit an updated curriculum vitae with your application with a statement of your understanding of the research ethics guidelines as discussed in the Helsinki Declaration[4]. If you embark on research involving medicines or interventions, you will need to submit proof of a Good Clinical Practice course attended. Added to the Templates is an example of the consent forms you would require for research trials involving children (Template 4).