CONDUCTING RESEARCH – SOME BASIC POINTS TO CONSIDER

A carefully designed scientific research project is not only critical to good science, but is a key part of ethical research (National Statement, 1.1-1.3).

The following are some basic points to consider when undertaking a medically related research project. This list is not comprehensive or exhaustive. Potential investigators are strongly urged to refer to both the National Statement (NS) and Code for the Responsible Conduct of Research for more information.

1. Does the study involve reviews of records, observation, surveys, or interviews? If so, does it qualify for consideration as 'Low and Negligible Risk Research'? (NS 2.1.1-2.1.7; 5.18-5.1.23)

2. Is there a clear statement of research aims which defines the research question(s)? Are the research objectives clearly stated?

3. Is the scientific design adequate to answer the research questions asked? Are the endpoints clearly defined and relevant to the research question? Is the power and sample size (number of subjects) appropriate? Is the method proposed for selecting and assigning subjects to treatment groups unbiased? Is there a clear plan for how analyses will be conducted? If necessary, have you consulted with a study design expert?

4. Does the investigator have a role that may pose a conflict of interest (e.g. financial interests, providing medical care, personal or professional relationships) (NS 5.4)?

5. Is there a plan to appropriately manage data collected (e.g. protection of privacy)

6. Are there plans for approaching subjects (including obtaining consent) in a way that will allow them to ask questions, respect their privacy, and their right to refuse to participate in the study without it impacting their clinical care?

7. Does the recruitment process protect subjects from being coerced or unduly influenced to participate (e.g. pressure from treating clinician)? Are there clear and appropriate inclusion and exclusion criteria that are relevant to the research aims. If a subjects refuses to participate are there procedures in place to ensure appropriate clinical care continues?

8. Have the rights and interests of vulnerable subjects (e.g. children & young people, people in dependent or unequal relationships; people in highly dependent medical care; people with a cognitive impairment, an intellectual disability, or a mental illness; people of different ethnic backgrounds, for whom English is a second language, limiting their understanding/ comprehension of some questions; Aboriginal & Torres Strait Islander Peoples) been adequately considered? (NS 4)

9. Are all appropriate elements of informed consent (NS 2.2) including a patient information sheet clearly addressed (e.g. study design, protection of privacy & confidentiality, risk & benefits to patients and to community, option to withdraw from study)?

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10. Is the study a clinical trial? A clinical trial is defined as “a scientific study, or an organised test of medicines and new treatment options involving patient and non-patient human volunteers. Clinical trials confirm whether medicines are safe and effective to introduce as new treatments for a particular disease or condition… Clinical trials may also be used to determine whether an existing medicine can be safely and effectively used for other diseases and/or conditions” (www.medicinesaustralia.com.au)

11. If the study is a clinical trial, how will the trial be monitored? What will be done with preliminary data? Should an independent data and safety monitoring board be established? How will decisions about stopping the trial be made? By whom? On what basis?

References:

NHMRC (2007). National Statement on Ethical Conduct in Human Research. Commonwealth of Australia, Canberra.

http://www.nhmrc.gov.au/guidelines/publications/e72

NHMRC (2007). Australian Code for the Responsible Conduct of Research. Commonwealth of Australia, Canberra.

http://www.nhmrc.gov.au/guidelines/publications/r39

Clinical Trials

http://medicinesaustralia.com.au/issues-information/clinical-trials/

Further Reading:

The following chapter from The IRB Guidebook provides ‘some basic background information on scientific research design, some of the research techniques used by scientists, and some ethical considerations raised by these designs and techniques’. While it was last updated in 1993, it is still a good reference for researchers. As noted on the website “developments over the intervening years have made portions of the Guidebook information obsolete, while portions of the information remain valid. There is no errata document to indicate which information has been superseded”. As a result it is important to verify particular points in terms of current validity (i.e. check with the National Statement).

http://www.hhs.gov/ohrp/archive/irb/irb_chapter4.htm