

VARN Professional Development Day
Useful information sources

Regulatory:

National Statement on Ethical Conduct in Human Research

<http://www.nhmrc.gov.au/publications/synposes/e72syn.htm>

ICH GCP with TGA comments

<http://www.tga.gov.au/docs/pdf/euguide/ich/ich13595.pdf>

Declaration of Helsinki

<http://www.wma.net/e/policy/b3.htm>

Ethics:

all of the above

Emanuel EJ, Wendler D, Grady C, ‘What Makes Clinical Research Ethical’, JAMA, May 24/31, 2000-Vol 283, No.20 pp 2701 – 2711

Online self directed education course and certificated test:

Human Participant Protections Education for Research teams

<http://cme.cancer.gov/clinicaltrials/learning/humanparticipant-protections.asp> (USA focused but worthwhile)

Getting a Clinical Trial started:

The Australian Clinical Trial Handbook

<http://www.ag.gov.au/cca>

The Victorian Managed Insurance Authority Guidelines

<http://www.vmia.vic.gov> (includes templates for protocols, HREC submissions and PICFs)

<http://www.alfredresearch.org/ethic/applicat.htm> (excellent submission guidelines)

http://www.rch.gov.au/cebu/clinicaltrials.dfm?doc_id=9401 (stats and epidemiological advice)

The Australian Clinical trials Registry

<http://www.actr.org.au>

Writing Patient information and consent forms (PICF)

Rosemary Moore's work via the Cancer Council Victoria