EARLY CONSIDERATIONS FOR INVESTIGATOR INITIATED CLINICAL TRIALS

Barwon Health

Principal Investigator

Investigator responsibilities are outlined in section 4 of the TGA's Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95). As the Principal Investigator, you acknowledge you have read, understand and will comply with these responsibilities.

- Position/location – Deakin University/Barwon Health (e.g. contracts (with BH REGI Unit))
- CV must clearly outline qualifications and experience for investigators to perform the role delegated to them on the trial
- Protocol development – in accordance with SPIRIT (linked below)
- For intervention study – reviewing all required pre-clinical and clinical safety and efficacy information in line with Investigator Brochure or product information

Feasibility issues

- Research team (e.g. collaborative issues) – clear roles, delegated responsibilities and training in line with current experience and qualifications
- Collaborating institutions and sponsor responsibilities
- Population – participant recruitment, methods and timeframes
- Financial – contracts, sources of funding, study budget, budget tracking and reporting
- Resources and infrastructure – time to conduct the study and where to see participants
- Indemnity and insurance
- Regulatory requirements – maintenance of essential document, safety reporting, data management responsibilities (e.g. TGA, ANZCTR)
- Training requirements – e.g. Good Clinical Practice (GCP), protocol specific, data management, sample processing

Useful contacts

- Barwon Health Research Ethics, Governance & Integrity (REGI) Unit (http://www.barwonhealth.org.au/research/column-1/regi)
- Biostatistician – Dr Stephen Lane (stephen.lane@barwonhealth.org.au)
- Pharmacy, Clinical Trial Pharmacist – Paul Muir (paulm@barwonhealth.org.au)
- Radiology, BMI Trials Administration Assistant – Kate Maddocks (kmaddocks@BarwonHealth.org.au)
- St John of God Pathology, Clinical Trials Coordinator – Rhiannon Kowalik (Rhiannon.kowalik@sjog.org.au)
- Clinical Coordinator in your department or program, as listed on the Barwon Health website

Useful links

- The National Statement (http://www.nhmrc.gov.au/guidelines/publications/e72)
- The Australian Code (https://www.nhmrc.gov.au/guidelines/publications/r39)
- The Therapeutic Goods Administration (TGA) (http://www.tga.gov.au/industry/clinical-trials.htm#.VDsauGeSyQ0)
- GCP (http://www.tga.gov.au/industry/clinical-trials-note-ich13595.htm#.U04VMFUWZVM)
    - NIH (https://gcp.nihtraining.com/login.php)
- VMIA (http://www.vmia.vic.gov.au/Risk-Management/Clinical-trials.aspx)
- Medicines Australia (http://medicinesaustralia.com.au/issues-information/clinical-trials/)
- SPIRIT Statement (http://www.spirit-statement.org/)
- Online Forms (https://www.ethicsform.org/au/SignIn.aspx)