Site Governance Submission Checklist for Clinical Trials, Registries and Biobanks

The following items are to be included in submissions for site governance review at Canberra Health Services (CHS)/ACT Health Directorate (ACTHD). For Specific advice on submitting a site specific application, please contact 02 5124 5659 or research.governance@act.gov.au

All site specific documents are available on the Research Ethics and Governance Office website.

☐ site governance clearance sheet (please complete most appropriate clearance sheet)

☐ Feasibility Assessment Form (please complete most appropriate feasibility form)

☐ All approval letters from lead HREC that relate to the documents below (must be NHMRC certified HREC)

☐ Most recent approved versions* of all documents listed on approval including lead HREC approval letter for superseded versions. Typical submissions will include the following items where applicable to your research: (not limited to this list)

- HREA
- Most recent approved version of the study protocol or project description
- Most recent approved version of the Investigator brochure (as applicable)
- Participant information and consent forms, Master Version and version updated for ACT Health (as applicable, see separate checklist)
- Participant recruitment materials
- Advertising materials

*where versions from the original approval letter have been superseded please include a copy of the HREC approval letter for the current version

☐ Insurance certificate (AU$20 million each and every occurrence, AU$20 million in the annual aggregate)

☐ Medicines Australia form of indemnity (click here for Medicines Australia website)

☐ Clinical trial research agreement or other agreement as appropriate (click here for Medicines Australia website)

☐ Signed quote/approval from Pharmacy Department

☐ Signed quote acceptance from ACT Pathology

☐ ACT Health radiation safety report (as applicable)

☐ Study budget – final version for CHS/ACTHD (may be included in the research agreement)

☐ Most recent CHS/ACTHD special purpose account (SPA) report

☐ Evidence of Good Clinical Practice training for all research staff

☐ Current CV for all research staff

☐ TGA CTN reference number (as applicable)

☐ Clinical Trial Registration Number (ANZCTR or ClinicalTrials.gov) (as applicable)

Name:_____Signature:_____Date:_____