Checklist - Site Specific Assessment (SSA) for a National Ethics Application Form (NEAF)

This checklist has been designed to assist with ensuring all relevant documentation required for the submission of a NEAF SSA has been provided.

Section 1: SSA Application and Supporting Study Documentation

1 copy of each listed applicable document

- ☐ **Completed Checklist** - Showing all documents that have been provided to the site.
- ☐ **NEAF SSA Form** - The signed form, via electronic or hardcopy submission.
- ☐ **NEAF** - A copy of the approved NEAF Form approved by the HREC.
- ☐ **Ethics Approval Letter** - The Ethics Approval Letter from a Lead NSW Health Human Research Ethics Committee (HREC), Queensland, Victorian or South Australian HREC and any subsequent amendment approval letters. Please note that the ethical review of a private Ethics Committee (e.g. Bellberry) cannot be accepted by a NSW Health Public Health Organisation (PHO) site or Service. ****The letter/s must list each of the sites at which the study will be undertaken.***
- ☐ **HREC Approved Master Participant Information Sheet(s) and Consent Form(s) including version number and version dates** - If the project is multi-centre please ensure the Master Participant Information Sheet and Consent Form, are provided.
- ☐ **Site Specific Participant Information Sheet(s) and Consent Form(s) including version number and version dates** - This is a copy of the Master Participant Information Sheet and Consent From which includes information pertaining to the site at which the research is to be undertaken. E.g. local contact telephone numbers, local investigators, local Logo's on documentation and a local contact for complaints (e.g. RGO) etc.
- ☐ **HREC Approved study documentation: protocol, questionnaire(s), survey questions, patient diaries, recruitment advert, interview topics to be covered etc. including version no and date (If applicable)** - All documents approved for use with the study; which have been listed on the Ethics Approval letter and/or any subsequent Amendment Approval letters.
- ☐ **Curriculum Vitae (CV)** - A short CV is required for all Investigators listed on the SSA. Once a CV has been provided this should be kept on file and linked to all research projects being undertaken by the researcher. CV renewals will be required at a minimum of every two years (consult relevant RGO for local PHO requirements). In lieu of a CV researchers may wish to submit a declaration of the last submitted CV if this has been in the previous two years.

Section 2: Departmental Approvals, Funding & Budgets

1 copy of each listed applicable document

- ☐ **Relevant Departmental Approval/s –** Appropriate signatories included on the SSA Form.
- ☐ **Authority for Data Provision** – Appropriate signatories included on the SSA Form.
- ☐ **Funding Confirmation** – A copy of written correspondence from the organisation or company providing funding for the research must be provided. If the funding is to be covered by a departmental cost centre written correspondence from the authority of the cost centre must be provided.
- ☐ **Budget** – A site specific budget signed by the relevant Business Manager/Head of Department/ or delegated authority must be submitted with a research project if there is any income or expenditure generated at the local site.
- ☐ **Pharmacy Budget & Approval** - For any studies involving the use of drugs, whether they are already approved for the intended indication or not. The reason for this is that the Pharmacy will be dispensing the drug regardless of the regulatory status of the drug.
- ☐ **Radiation Safety Committee Approval** - For any studies involving the Use of Radiation above standard levels that the patient would usually receive. This may be undertaken by the approving HREC or the Public Health Organisation's (PHO's) Radiation Safety Officer however will be dependent on the PHO's internal processes for these types of applications. Consultation with the relevant Research Governance Officer (RGO) is recommended prior to submission to ascertain individual requirements.
- ☐ **Pathology Budget and Authorisation** – For any studies engaging the use of Pathology services for a research project.
- ☐ **Biosafety Committee Approval** – For those projects involving the use of recombinant DNA. Consultation with the relevant PHO's RGO is recommended prior to submission to ascertain individual requirements.
- ☐ **Biomedical Engineering (or equivalent internal Department) Review & Approval** – For those projects involving the use of a medical device. Consultation with the relevant PHO's RGO is recommended prior to submission to ascertain individual requirements.
- ☐ **Guardianship Tribunal Approval** – For any clinical trials involving recruitment of participants who do not have the capacity to consent for themselves and/or require consent from a parent/guardian on their behalf.
- ☐ **Medical Records Budget & Approval** – For any studies requiring access to participant's medical records via the Medical Records Department.

Section 3: Additional Requirements for Clinical Trials Involving Investigational Medications or Devices

Copies of each listed document from the section relevant to the clinical trial

Clinical Trials supported by a Commercial Sponsor

- ☐ **Clinical Trial Research Agreement (CTRA) – Medicines Australia Standard Form/Contract Research Organisation acting as the Sponsor/ Phase 4 –** Please note that any Schedule 7 conditions should be approved by the Eastern Border States, alternatively these can be sent for external legal review at the sponsor's expense. Please find the CTRA templates at: http://medicinesaustralia.com.au/issues-information/clinical-trials/clinical-trials-research-agreements/
- ☐ **Medicines Australia Form of Indemnity (Standard)** between the sponsor and the NSW Public Health Organisation (PHO) or Service. Please see the template at: http://medicinesaustralia.com.au/issues-information/clinical-trials/indemity-and-compensation-guidelines/
- ☐ **Certificate of Currency/Insurance –** Covering a **minimum of $20 million (AUS) per occurrence and in the aggregate with an Australian named sponsor and excess/deductible or self-insured retention amount not greater than $25,000 for each and every claim or series of claims.** The policy must meet the requirements of **Section 2.2.2** of the NSW Clinical Trials Insurance and Indemnity Policy- PD2011_006.
- ☐ **Clinical Trial Notification (CTN) Form/Clinical Trial Exemption (CTX) Form** - For clinical trials that involve the use of a drug or device not yet approved by the TGA or not yet approved for its proposed indication, it is necessary to submit a CTN or CTX Form signed by the HREC. Further information on these schemes can be accessed via the TGA website at: http://www.tga.gov.au/industry/clinical-trials-forms-ctn.htm
- ☐ **Clinical Trial Study Protocol –** Version as approved by the HREC or in any subsequent amendment approval letters.
- ☐ **Clinical Trial Investigator Brochure and/or Product Information –** Version as approved by the HREC or in any subsequent amendment approval letters.

Clinical Trials supported by a Collaborative Group

- ☐ **Clinical Trial Research Agreement (CTRA) – Medicines Australia Collaborative or Cooperative Research Group –** Please note that any Schedule 4 conditions should be approved by the Eastern Border States, alternatively these can be sent for external legal review at the sponsor's expense. Please find the CTRA templates at: http://medicinesaustralia.com.au/issues-information/clinical-trials/clinical-trials-research-agreements/ or
- ☐ **Medicines Australia Form of Indemnity (Standard)** between the sponsor and the NSW Public Health Organisation (PHO) or Service. Please see the template at: http://medicinesaustralia.com.au/issues-information/clinical-trials/indemity-and-compensation-guidelines/
- ☐ **Certificate of Currency/Insurance – The optimal cover would be $20 million (AUS) per occurrence and in the aggregate, however should be discussed with the individual Public Health Organisation (PHO).** The policy must meet the requirements of **Section 2.3.2 (28)** of the NSW Clinical Trials Insurance and Indemnity Policy- PD2011_006.
- ☐ **Clinical Trial Notification (CTN) Form/Clinical Trial Exemption (CTX) Form** - For clinical trials that involve the use of a drug or device not yet approved by the TGA or not yet approved for its proposed indication, it is necessary to submit a CTN or CTX Form signed by the HREC. Further information on these schemes can be accessed via the TGA website at: http://www.tga.gov.au/industry/clinical-trials-forms-ctn.htm
- ☐ **Clinical Trial Study Protocol –** Version as approved by the HREC or in any subsequent amendment approval letters.
- ☐ **Clinical Trial Investigator Brochure and/or Product Information –** Version as approved by the HREC or in any subsequent amendment approval letters.

Investigator Initiated Clinical Trials

- ☐ **Indemnity Assessment** – The process of Indemnity assessment varies between PHO's, consultation is therefore recommended with the relevant RGO/s prior to submission. Investigators who are conducting investigator-initiated clinical trials (no sponsor) must make an application to the Chief Executive Officer (CEO) of the relevant NSW Public Health Organisation (PHO) or Service for consideration to assess whether the organisation will accept the indemnity for the trial under Treasury Managed Funds (TMF). The CEO is the only one who can bind the use of TMF in this circumstance. Individual requirements should be discussed with the relevant PHO.
- ☐ **Clinical Trial Notification (CTN) Form/Clinical Trial Exemption (CTX) Form** - For clinical trials that involve the use of a drug or device not yet approved by the TGA or not yet approved for its proposed indication, it is necessary to submit a CTN or CTX Form signed by the HREC. Further information on these schemes can be accessed via the TGA website at: http://www.tga.gov.au/industry/clinical-trials-forms-ctn.htm
- ☐ **Clinical Trial Study Protocol –** Version as approved by the HREC or in any subsequent amendment approval letters.
- ☐ **Clinical Trial Investigator Brochure and/or Product Information –** Version as approved by the HREC or in any subsequent amendment approval letters.

- SSA submission may be possible prior to receipt of HREC approval, please contact the relevant site's RGO/s for advice.
- Please note that there are 3 Sections to the checklist, not all sections will be relevant to all research projects.
- Application Forms, Budgets & Head of Department approvals require provision of original or scanned/emailed signatures prior to final authorisation, processes vary between PHO's, consultation is therefore recommended with the relevant RGO/s prior to submission.