



Checklist for new submissions

Ethics Application

Requirements for all submissions	Yes	No	
Completed and authorised WA Health Ethics Application Form? If NO	<input type="checkbox"/>	<input type="checkbox"/>	
Has the HREA been uploaded and the WA Specific Module completed? The NSW Privacy Form and/or the Victorian Module will be needed for national projects utilising the National Mutual Acceptance Scheme if there will be sites in those jurisdictions.	<input type="checkbox"/>	<input type="checkbox"/>	
Protocol (clinical trial / non-clinical trial)	<input type="checkbox"/>	<input type="checkbox"/>	
Version number and date	<input type="checkbox"/>	<input type="checkbox"/>	
Other Documentation (if relevant)	Yes	No	N/A
Radiation Safety Officer Report (Dosimetry report)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Copy of Radiological Council (WA) approval	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Participant Information sheet / Consent forms (pharmacogenetic consent / sample consent)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Version number and date	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Recruitment documents (invitation letters, telephone scripts, posters, advertisements etc)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Version number and date	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Scales / Assessment forms	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Questionnaires, surveys, interview outlines etc	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Version number and date	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other participant documentations (identification card, diaries)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Version number and date	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Investigator's Brochure (Edition no. or version)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Study sponsors details provided? (for invoicing)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Site Authorisation

Requirements for all submissions	Yes	No	
Site Specific Assessment form completed and authorised by PI	<input type="checkbox"/>	<input type="checkbox"/>	
Business Manager sign off	<input type="checkbox"/>	<input type="checkbox"/>	
Divisional Co-Director sign off	<input type="checkbox"/>	<input type="checkbox"/>	
Budget Form	<input type="checkbox"/>	<input type="checkbox"/>	
Head of Department sign off for the Research Department AND all Supporting Departments	<input type="checkbox"/>	<input type="checkbox"/>	
Ethics and Governance fees recorded	<input type="checkbox"/>	<input type="checkbox"/>	
Budget must be zero balanced	<input type="checkbox"/>	<input type="checkbox"/>	
If an SSA is not required, has an Access Request Form been completed?	<input type="checkbox"/>	<input type="checkbox"/>	
Other Documentation (if relevant)	Yes	No	N/A
Clinical Trial Agreement (draft and unsigned)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Copy of any funding agreement (grant)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Indemnity Form (draft)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Insurance certificate of currency (policy wording may be requested)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Public liability insurance (Sponsored, CRO or CRG studies with monitors coming on-site)			
Clinical Trial Notification (eCTN) (draft online form)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
TGA ARTG number if drug/device registered	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Project registered on a clinical trials registry? (include number)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Conflict of Interest form	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Student Research and Confidentiality Declaration (for students)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Any additional approval letters (eg WAAHEC, DoH HREC ethics)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If NOT reviewed by SMHS HREC			
Site Specific Participant Information and Consent Form (based on master approved by HREC)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Copy of advertising to be used	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>