Multicentre Research Projects only - ACCEPTING SITE GUIDANCE when GC HREC is NOT the Reviewing HREC

Documents sent to the Gold Coast HREC vs. the Gold Coast RGO: Summary of Institutional Procedures - Guide for Researchers

Underlying Principle:

1. The Human Research Ethics Committee (HREC) undertakes the scientific and ethical review of a study.

2. The Research Governance Office (RGO) reviews the financial, resources, contractual and regulatory aspects of undertaking the research at the site.

3. Site specific negotiations and completion of the SSA form should commence as soon as or before the HREC Application has been submitted. Site will not receive the formal Authorisation Letter to commence the study until the HREC Approval letter is presented to the RGO.

4. Institutional/Governance authorisation or acknowledgment must be received before a study can start or an amendment to the PICF study can be implemented.

5. All documents ideally would be uploaded onto AU-RED. This ensures paper copies of documents do not need to be submitted to the RGO unless specified below.

Initial Submission - ACCEPTING SITE GUIDANCE when GC HREC is *NOT* the Reviewing HREC					
Document	**Paperwork to be sent to the GC HREC**	**Type of Letter from GC HREC to Accepting Site**	**Paperwork to be sent to the GC RGO when the Reviewing HREC is NOT at the same site as GC RGO**	**Type of Letter from GC RGO**	**Do I need to wait for the GC RGO letter?**
Ethics Application form (NEAF / LNR)	✘	NA	✓	Authorisation Letter	**Yes**
Protocol	✘		✓		
Investigator Brochure	✘		✓		
PICF – Master Copy (with version control)	✘		✓		
Assessment Tools	✘		✓ (Only if tool contains site specific information or identifiers)		
Patient tools e.g. diary, wallet card, brochures, advertising	✘		✓ (Only if tool contains site specific information or identifiers)		
Advertisements	✘		✓ (Only if advertisement contains site specific information or identifiers)		
CTN / CTX Form	✘		✓ (to be submitted on line from 01.07.2015)		
HREC Review Only Indemnity	✘		✘		
In addition to the items listed above, the following form part of the site specific application to obtain authorisation to commence research:					
SSA and cover letter/form to RGO	✘	NA	✓	All documentation submitted with the initial application for site authorisation must be noted in the Site "Authorisation to Commence Research" letter. The project at the site cannot start until the RGO Authorisation Letter is issued.	
HREC Approval Letter	✘		✓		
PICFs – Site Specific (tracked and clean with version control)	✘		✓		
Clinical Trial Research Agreement (CTRA)	✘		✓		
Insurance Certificate	✘		✓		
Site Specific Standard Indemnity	✘		✓		

After Study Authorisation - ACCEPTING SITE GUIDANCE when GC HREC is NOT the Reviewing HREC

	Document[1]	Paperwork to be sent to the GC HREC	Type of Letter from GC HREC to Accepting Site	Paperwork to be sent to the GC RGO when the Reviewing HREC is NOT at the same site as GC RGO	Type of Letter from GC RGO	Do I need to wait for the GC RGO letter?
AMENDMENT	Protocol Amendments[2] that pose **NO CHANGE** to the institutional risk or resource requirements[3]	✘	NA	✓	The amendment can be implemented at the site after HREC approval is received[2]	No
	Protocol Amendments[2] that **DO POSE A CHANGE** to the institutional risk or resource requirements[3]	✘	NA	✓	Authorisation Letter The amendment can not be implemented until GC RGO approval is given	**Yes**
	HREC Approval letter of Protocol Amendment to GC RGO	✘	NA	✓	NA	NA
PICF	Amended Multi-Centre Master PICF (with version control)	✘	NA	✓	NA	**Yes**
	Amended Site Specific PICFs (for multi-centre studies where the Master PICF is changed) – (tracked and clean with version control)	✘	NA	✓[2]	Authorisation Letter Site specific PICF cannot be used until RGO Authorisation Letter is received.	**Yes**
LEGAL	CTRA - amendment	✘	NA	✓	Signed CTRA	No
	CTN / CTX Form - amendment	✘	NA	(to be submitted on line from 01.07.2015)	NA	No
	HREC Review Only Indemnity – amendment	✘	NA	✘	NA	No
	Site Specific Standard Indemnity - amendment	✘	NA	✓	Signed Indemnity	No
	Updated Insurance Certificate	✘	NA	✓	Acknowledgement Email	No
SAFETY	Investigator Brochure - amendment	✘	NA	✘	NA	No
	SAEs - On-site[4] commercial studies	✘	NA	✓[4]	Acknowledgement Email	No
	SAEs - On-site[4] investigator initiated studies	✘	NA	✓[4]	Acknowledgement Email	No
	12 monthly line listings and Safety Reports[5]	✘	NA	✘[5]	NA	No
	DSMB Reports / Letters	✘	NA	✘	NA	No
	Protocol Deviations/Violations[6]	✘	NA	✓[6]	Acknowledgement Letter	No
REPORTS	Commencement Form	✘	NA	✓	Acknowledgement Email	No
	Annual Reports (or more frequently depending on HREC approval)[7]	✘	NA	✓[7]	Acknowledgement Email	No
	Study or Site Closure/Suspension	✘	NA	✓	Acknowledgement Letter	No
OTHER	General correspondence (e.g. memos that impact on the study - e.g. clarification of inclusion / exclusion criteria)	✘	NA	✘	NA	No
	Change of Address of Sponsor (Australia sponsor/address only requires submission)	✘	NA	✓	Acknowledgement Email	No
	Any other documents not listed	✘	NA	Please check with the RGO office before submission	Acknowledgement Letter	No

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NOTATIONS

1Please note this document only applies to GC RGO procedures when the Reviewing HREC is NOT the GC HREC. Therefore if the Reviewing HREC is in Victoria and if GC is an Accepting Site then this document pertains to GC it is an Accepting Site within GC RGO jurisdiction.

2Protocol Amendment approvals will be sent to you from the study's CPI. A copy of the Protocol Amendment and Reviewing HREC approval letter must be sent to the GC RGO. The amendment can be implemented once the CPI provides the GC PI with the Reviewing HRECs approval letter for that amendment, however if the amendment poses a change in institutional risk or increased resources then the site MUST obtain GC RGO approval prior to implementing the amendment.

If the amendment requires a change to the Master PICF then GC RGO approval for the Site-Specific PICF must be received before the patient specific changes can be implemented.

3Examples of Risk to the Institution are new unapproved data is to be collected and/or sent off site; or collection of extra tissue samples. Examples of Resource Implications are protocol requirements for extra visits, extra procedures or involvement of other departments not previously approved (e.g. Radiology). These examples are not an exhaustive list.

4 Per NHMRC Safety monitoring and Reporting in clinical trials involving therapeutic goods.

The On-Site SAEs that must be submitted to the GC RGO are – Signifigant Safety Issues (SSIs); Unexpected & Related Serious Adverse Event (URSAEs) occurring at the site

For investigator-initiated studies submission of ALL On-Site SAEs to GC RGO is required.

5At an Accepting Site no submissions of any safety reports are required to GC RGO. PI to initial, dates and file in site folder.

6Violations and/or deviations must be submitted to the Reviewing HREC as per their guidelines. Violations need to be submitted to GC RGO as outlined in the table. Definition of a violation at Gold Coast is where patient safety is compromised (e.g. signing an unapproved PICF, enrolment of an inappropriate patient into the trial; a dosing, timing or delivery error in the study intervention attributable to members of the research team; the research team failed to comply with pre-specific trial guidelines for data collection and/or outcome evaluation due to avoidable reasons). Deviations do not require to be submitted (e.g. late study visits unless patient safety is compromised, deviation affects the ethical acceptability of the study, medical or clinical assessment is missed) to either GC HREC or GC RGO.

7In accordance with the Reviewing HREC requirements the CPI will advise re the requirements for submission Annual Reports.

Annual reports to be submitted 1 May every year.

GLOSSARY

Accepting PI: A Principal Investigator from an Accepting Site who is participating in the study but does not have the CPI responsibilities.
Accepting Site: A site that is participating in a multi-centre research project, but which has not taken on CPI responsibility.
Coordinating Principal Investigator (CPI): The CPI Team from the Lead Site is responsible for coordinating all HREC processes throughout the study, on behalf of the Accepting PI's over which
CTN: Clinical Trial Notification
CTRA: Clinical Trial Research Agreement
CTX: Clinical Trial Exemption
DSMB: Data Safety Monitoring Board
HREC: Human Research Ethics Committee
Lead Site: A site that is participating in a multi-centre research project and has taken on CPI responsibility.
Multi-Centre Research: A research project undertaken by a group of institutions (or individuals) at one or more sites within and/or across Australian jurisdictions.
GC: Gold Coast
NEAF: National Ethics Application Form
PI: Principal Investigator = PI for an Accepting Site in Multi-Centre Research; PI for Single-Site Research
PICF: Participant Informed Consent Form
Reviewing HREC: For multi-centre research, the reviewing HREC is NHMRC certified which, under the single ethical review process, has reviewed and ethically approved the study and has assumed responsibility for
RGO: Research Governance Office
SAE: Serious Adverse Event
Single-Site Research: A research project undertaken at only one site.