Commercial or Investigator Initiated	Number of Sites	Site's Role
Investigator Initiated	***Multicentre***	***Lead Site*** *(MS HREC **IS** the reviewing HREC)*

Summary of Institutional Procedures - Guide for Researchers

Queensland Government
Metro South Health

Required:

1. All documents are to be uploaded onto ERM and all submissions are via ERM

Initial Submission

Document	Documents to be uploaded into ERM	Type of Letter from MS HREC to Lead Site	Documents to be uploaded into ERM	Type of Letter from MS RGO	Do I need to wait for the MS RGO letter?
Human Research Ethics Application (HREA)	✓	Approval Letter All documentation submitted with the initial HREC application must be noted in the Approval Letter. The project at the site cannot start until the RGO Authorisation Letter is issued.	✓	Authorisation Letter All documentation submitted with the initial application for site authorisation must be noted in the Site "Authorisation to Commence Research" letter. NOTE: No RGO approval is given for the protocol. The project at the site cannot start until the RGO Authorisation Letter is issued.	Yes
Protocol	✓		✓		
Investigator Brochure	✓		✘		
PICF/s – Master Copy (with version control)	✓		✓		
Assessment Tools	✓		✓ (Only if document/s contains site specific information or identifiers)		
Patient tools eg diary, wallet card, brochures	✓				
Advertisements	✓				
HREC Review Only Indemnity	✓ (discuss with HREC)		✘		
In addition to the items listed above, the following form part of the Site Specific Application to obtain authorisation to commence research:					
SSA Application	✘	NA	✓		
Research Contract Approval and Study Execution Form	✘		✓		
HREC Approval Letter	✘		✓		
PICF/s – Site Specific (tracked only with version control)	✘		✓		
Clinical Trial Research Agreement (CTRA)	✘		✓ (discuss with RGO)		
Insurance Certificate	✘				
Site Specific Standard Indemnity	✘				
Risk an Benefit Letter	✘		✓		
Data & Material Transfer Agreement	✘		✓ (discuss with RGO)		
eCTN (if applicable submit as soon as received)	✘		✓	Nil	No

Investigator Initiated	Multicentre	Lead Site *(MS HREC **IS** the reviewing HREC)*

After Study Authorisation

The following submissions are to be electronically uploaded into ERM.

	Document[1]	Documents to be uploaded into ERM	Type of Letter from MS HREC to Lead Site	Documents to be uploaded into ERM	Type of Letter from MS RGO	Do I need to wait for the MS RGO letter?
AMENDMENT	Protocol Amendments[2] that pose **NO CHANGE** to the institutional risk or resource requirements	✓	Approval Letter	✗	Nil	No
	Protocol Amendments[2] that **DO POSE A CHANGE** to the institutional risk or resource requirements	✓	Approval Letter	✓	Authorisation Letter The amendment can not be implemented until MS RGO approval is given. No RGO approval is given for protocol amendments	**Yes**
	Research Contract Approval and Study Execution Form to accompany a protocol change that poses a risk	✗	NA	✓		
	Risk and Benefits Letter	✗	NA	✓		
	HREC Approval letter of Protocol Amendment that **DOES POSE A CHANGE** to the institutional risk or resource requirements[2]	✗	NA	✓		
PICF	Amended Multi-Centre Master PICF (with version control)	✓	Approval Letter	✓ Submit only **if** fulfils criteria on Page 3	Authorisation Letter Site specific PICF cannot be used until RGO Authorisation Letter is received.	**Yes**
	Amended Site Specific PICFs[3] (for multi-centre studies where the Master PICF is changed resulting in a significant implication for the site) (tracked only with version control)	✗	NA			
	HREC Approved Letter of PICF Master	✗	NA			
LEGAL	CTRA - amendment	✗	NA	✓	Signed CTRA	No
	Research Contract Approval and Study Execution Form to accompany CTRA Amendment	✗	NA	✓	Signed by RGO	No
	eCTN - amendment to MSRGO approved site	✗	NA	✓	Nil	No
	HREC Review Only Indemnity – amendment	✓	Signed Indemnity	✗	NA	NA
	Site Specific Standard Indemnity - amendment	✗	NA	✓	Signed Indemnity	No
	Updated Insurance Certificate	✗	NA	✓	Nil	NA
SAFETY	Investigator Brochure - amendment	✓ **Lead CPI**	Acknowledgement Letter	✗	NA	NA
	On-Site SAEs[4]	✗ (if there is a DSMB) ✓ Lead CPI (if no DSMB)	Acknowledgement Letter	✗ Site PI to submit (USMs and USADEs only)	Acknowledgement Letter	No
	DSMB Reports / Letters (if DSMB convened)[5]	✓ **Lead CPI**	Acknowledgement Letter	✗	NA	NA
	GCP Breaches[6] (**DO NOT** send deviations)	✓ **Lead CPI**	Acknowledgement Letter	✓ **Site PI to submit**	Acknowledgement Letter	No
REPORTS	Commencement Form	✗	Nil	✗	Nil	No
	Progress Reports (or more frequently depending on HREC approval conditions)[7]	✓ **Due 30 April**	Acknowledgement Letter	✗ (Submit only if PI deems findings important)	Nil	No
	Study or Site Closure/Suspension	✓	Acknowledgement Letter	✓	Nil	No
OTHER	General correspondence (eg memos that impact on the study - eg clarification of inclusion / exclusion criteria)	✓	Nil	✗	NA	NA
	Any other documents not listed	✓	Nil	Please check with the RGO office before submission	Nil	No

Investigator Initiated	*Multicentre*	*Lead Site (MS HREC **IS** the reviewing HREC)*

Notations

NOTATIONS

[1]**Please note this document only applies to MSHREC as the Reviewing HREC and MSRGO as the Reviewing Institution.**
This **Summary of Procedures document can be applied retrospectively to the 1 January 2012** to all items listed above unless the PI deems it important to notify institution (eg patient safety would be or has been compromised if institution not notified).

[2]**Protocol Amendments** can be implemented once the reviewing MSHREC provides the CPI with the approval letter for that amendment. However if the amendment poses a change in institutional risk or increased resources then the site **MUST** obtain MSRGO approval prior to implementing the amendment. Examples 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 or extra procedures or involvement of other departments not previously approved (eg Radiology). These examples are not an exhaustive list.
MSRGO does not approve or acknowledge protocols or protocol amendments. If the amendment requires a change to the Master PICF see '3' below as to whether it requires MSRGO approval.

[3]Examples of **A Significant Implication for Site** at MS are protocol requirements that require a change to the CTA.

[4]**If there is** an established DSMB then **On-Site SAEs *are not to be submitted*** to MSHREC or the MSRGO, except if the CPI deems the SAE is a Significant Safety Issue requiring an USM or USADE report.
If there is NO established DSMB then **ALL** On-Site SAEs are to be submitted to MSHREC.

[5]For multi-centre investigator-initiated studies where a **DSMB** has been convened the DSMB report is required to be submitted to MSHREC. No submission to MSRGO.

[6]**GCP Breaches only *are to be submitted*** to both the MSHREC and MSRGO**. Definition of a GCP Breach at Metro South** is where patient safety is compromised (eg 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 *are not to be submitted* to either MSHREC or MSRGO (eg late study visits or medical or clinical assessment is missed unless patient safety is compromised, deviation that affects the ethical acceptability of the study). These examples are not an exhaustive list.

[7]**Multi-centre research –** Individual Progress Reports are to be collated by CPI. Individual Progress Reports from sites will not be accepted.
MS site/s Progress Reports are to be submitted to the MSRGO only if the PI deems the findings important.

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 the CPI has CPI responsibilities.
CPI: Coordinating Principal Investigator
CTRA: Clinical Trial Research Agreement
CTX: Clinical Trial Exemption
DSMB: Data Safety Monitoring Board
eCTN: Electronic Clinical Trial Notification
ERM: Ethics Review Manager
HREA: Human Research Ethics Application
HREC: Human Research Ethics Committee
Lead Site: A site that is participating in a multi-centre research project and has taken on CPI responsibility.
MS: Metro South
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.
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 monitoring the conduct of the research being conducted at one or more sites within and/or across Australian jurisdictions. Additionally the reviewing HREC will apply the ethical review and approval process to Single-Site research at MS sites.
RGO: Research Governance Office
SAE: Serious Adverse Event
Single-Site Research: A research project undertaken at only one site.
TGA: Therapeutic Goods Administration
USADE: Unanticipated Serious Adverse Device Effect
USM: Urgent Safety Measure

REFERENCE

National Statement on Ethical Conduct in Human Research (2007) (updated 2018)
Guidance on safety monitoring and reporting in clinical trials involving therapeutic goods, November 2016
Australian Code for the Responsible Conduct of Research 2018
Framework for Monitoring: Guidance for the National Approach to Single Ethical Review of Multi-Centre Research, Jan 2012
Research Governance Handbook: Guidance for the national approach to single ethical review. December 2011
Risk-based Management and Monitoring of Clinical Trials Involving Therapeutic Goods
Integrated Addendum to ICH E6(R1): Guidelines for Good Clinical Practice Guidelines E6(R2) *Annotated with TGA comments