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

Summary of Institutional Procedures - Guide for Researchers

Required:

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

Queensland Government
Metro South Health

Initial Submission - LEAD CPI GUIDANCE

Document	Documents to be uploaded into ERM	Type of Letter from MSHREC	Documents to be uploaded into ERM	Type of Letter from MSRGO	Do I need to wait for the MSRGO 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 – Multicentre - Master Copy (with version control) Single Site - (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	✓		✘		
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	✘		✓		
PICFs – Site Specific (tracked only with version control)	✘		✓		
Clinical Trial Research Agreement (CTRA)	✘		✓		
Insurance Certificate	✘		✓		
Site Specific Standard Indemnity	✘		✓		
Indemnity Register Form	✘		✓		
eCTN (if applicable submit as soon as received)	✘		✓	Nil	No

Commercial	Multicentre or Single	Lead Site (MSHREC **IS** the reviewing HREC)

After Study Authorisation - LEAD CPI GUIDANCE

The following documents are to be electronically uploaded into ERM.

	Document[1]	Documents to be uploaded into ERM	Type of Letter from MSHREC	Documents to be uploaded into ERM	Type of Letter from MSRGO	Do I need to wait for the MSRGO letter?
AMENDMENT	Protocol Amendments[2] that pose **NO CHANGE** to the institutional risk or resource requirements	✓	Approval Letter	✘	NA No RGO approval is given for protocol amendments	NA
	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	✓		
	HREC Approval letter of Protocol Amendment[2] that **DOES POSE A CHANGE** to the institutional risk or resource requirements	✘	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 Approval letter for Master PICF	✘	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/s	✘	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 - update[4]	**Sponsor**	Acknowledgement Letter	✘	NA	NA
	On-Site SAEs[4, 5]	**Sponsor (USMs and USADE)**	Acknowledgement Letter	✘Site PI to submit (USMs and USADEs only)	Acknowledgement Letter	No
	Annual Line Listing Reports and Safety Reports[4, 6]	**Sponsor**	Acknowledgement Letter	✘	NA	NA
	DSMB Reports / Letters[4]	**Sponsor**	Acknowledgement Letter	✘	NA	NA
	GCP Breaches[7] (**DO NOT** send deviations)	✓	Acknowledgement Letter	✓	Acknowledgement Letter	No
REPORTS	Commencement Form	✘	NA	✘	Nil	NA
	Progress Reports (or more frequently depending on HREC approval conditions)[8]	✓ Due 30 April	Acknowledgement Letter	✘ (Submit only if PI deems findings important)	Acknowledgement Letter	No
	Study or Site Closure/Suspension	✓	Acknowledgement Letter	✓	Nil	NA
OTHER	General correspondence (eg memos that impact on the study - eg clarification of inclusion / exclusion criteria)	✓	Nil	✘	NA	NA
	Change of Address of Sponsor (Australia sponsor/address only requires submission)	✓	Nil	✓	Nil	No
	Any other documents not listed	✓	Nil	Please check with the RGO office before submission	Nil	No

Commercial	Multicentre or Single	Lead Site (MSHREC IS the reviewing HREC)

NOTATIONS - LEAD CPI GUIDANCE

NOTATIONS

[1] **Please note this document only applies to MS HREC 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** for a MS site can be implemented once the reviewing MSHREC provides the CPI with the approval letter for that 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] **IBD** updates, **DSMB** reports, and **Annual Line Listings** are to be submitted directly to MSHREC by the sponsor. Do not submit to MSRGO.
The sponsor is to advise the CPI of submission, MSHREC will reply to the CPI, and the CPI will notify all Accepting Sites with submission and HREC reply documents. A copy of any submission should be sent to the CPI and PI for their records.

[5] **On-Site SAEs** ***are not to be submitted*** to MSHREC. USM or an USADE reports are to be submitted to MSHREC by the sponsor.
On-Site SAEs ***are not to be submitted*** to MSRGO, except if the MS PI deems the SAE as a Significant Safety Issue requiring an USM or an USADE report.

[6] **Individual Safety Reports/Letters, Quarterly and 6-Monthly Line Listing** ***are not to be submitted*** to the MSHREC or MSRGO.

[7] **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.

[8] **Multi-Centre Research –**The Progress Report will be collated by CPI. Individual Progress Reports from sites will not be accepted.
MS site/s Progress Reports are to be submitted to the MS RGO 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 Research Manager
iEMR: Electronic Medical Record
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
Integrated Addendum to ICH E6(R1): Guidelines for Good Clinical Practice Guidelines E6(R2) *Annotated with TGA comments