Commercial or Investigator Initiated	Multi-centre or Single Site	Site's Role
Commercial	***Multicentre***	***Accepting Site (MSHREC 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.

2. Lead CPI to send this document to the Accepting Sites for MSHREC procedure guidance.

Initial Submission - ACCEPTING SITE GUIDANCE

Document	Documents to be uploaded into ERM	Type of Letter from MSHREC	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)	✘	NA	Follow Site's institutional procedures	NA	**NA**
Protocol	✘				
Investigator Brochure	✘				
PICF/s – Master Copy (with version control)	✘				
Assessment Tools	✘				
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	Follow Site's institutional procedures	NA	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)	✘				
Insurance Certificate	✘				
Site Specific Standard Indemnity	✘				
eCTN (if applicable submit as soon as received)	✘				

Commercial	Multicentre	Accepting Site *(MSHREC **IS** the reviewing HREC)*

After Study Authorisation - ACCEPTING SITE GUIDANCE

The following documents 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]	✘	NA	**Follow Site's institutional procedures**	NA	NA
PICF	Amended Multi-Centre Master PICF (with version control)	✘	NA			
	Amended Site Specific PICFs (for multi-centre studies where the Master PICF is changed) – (tracked and clean with version control)					
LEGAL	CTRA - amendment	✘	NA			
	eCTN - amendment to MSRGO approved site/s					
	HREC Review Only Indemnity – amendment					
	Site Specific Standard Indemnity - amendment					
	Updated Insurance Certificate					
SAFETY	Investigator Brochure - update[3]	✓ **Sponsor**	Acknowledgement Letter			
	On-Site SAEs[4]	✓ Sponsor (USMs and USADE)	Acknowledgement Letter			
	Annual Line Listings and Safety Reports[3]	✓ Sponsor	Acknowledgement Letter			
	DSMB Reports / Letters[3]	✓ Sponsor	Acknowledgement Letter			
	GCP Breaches[5] (**DO NOT** send deviations)	✓ via Lead CPI	Acknowledgement Letter			
REPORTS	Commencement Form	✘	NA			
	Progress Reports (or more frequently depending on HREC approval conditions)[5]					
	Study or Site Closure/Suspension					
OTHER	General correspondence (eg memos that impact on the study - eg clarification of inclusion / exclusion criteria)	✘	NA			
	Change of Address of Sponsor (Australia sponsor/address only requires submission)					
	Any other documents not listed					

Commercial	Multicentre	Accepting Site *(MSHREC **IS** the reviewing HREC)*

After Study Authorisation - ACCEPTING SITE GUIDANCE

NOTATIONS

[1]**Please note this document only applies to MS HREC as the Reviewing HREC**.
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 Amendment** approvals will be sent to you by the study's CPI. Follow your institution's procedures for protocol amendments and changes to the Master PICF.

[3]**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.

[4]**On-Site SAEs *are not to be submitted*** to MSHREC. USMs and USADE reports are to be submitted directly to MSHREC by the sponsor.

[5]**GCP Breaches only *are to be submitted*** to the MSHREC**. Definition of a GCP Breach at MS 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 MSHREC (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.

[5]The **Progress Report** will be collated by CPI. Individual Progress Reports from sites will not be accepted.

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.
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.
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 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