

PART A: STUDY SUBMISSION INFORMATION (mandatory for all research – to be completed by Research Team)

Please note: Signatures are not required on the Site Specific Assessment

ERM Project ID:

Full Study Title:

Metro South Initiating Site & Department (eg PAH – ICU):

Sponsor:

Site Contact:

Metro South Site/s Approval (required when PAH is not lead site, and/or research includes multiple sites within MSHHS):

PAH (Multi site PAH not Lead - Dept Head Signs)	Name:	Signed	Date:
QEII	Name:	Signed	Date:
Redland/Wynnum	Name:	Signed	Date:
Logan/Beaudesert	Name:	Signed	Date:
Inala Indigenous	Name:	Signed	Date:
MSAMHS	Name:	Signed	Date:
Community/Oral	Name:	Signed	Date:

Principal Investigator Signature

Name: **Title:** **Dept:**

I declare that I will take responsibility for the conduct of this study according to the [Metro South Research Management Policy PL2017-55](#) and associated procedures.

I have a perceived, potential or actual conflict of interest that conflicts or may conflict with my duties.

If ticked, please refer to [PR2018-176 Research Management – Research Integrity Procedure](#).

Signed:

Date:

Metro South Initiating Department Head Signature (if investigator on study please obtain line manager's signature)

Name: **Title:** **Dept:**

My signature indicates that I agree for the use of resources under my delegated authority.

Signed:

Date:

Metro South Initiating Department Finance Manager Signature (if costs = \$10K or less, finance signature not required)

Name: **Title:** **Dept:**

My signature indicates that I have reviewed the budget and agree to cost allocations and resources under my delegated authority.

Signed:

Date:

Research Internal Order Number (mandatory):

Total Funded (cash only): \$

Total In-kind Contribution: \$

**If per participant please specify target participant number*

For funded studies, please identify the funding source

Funding Source Name 1:	Funding Source Name 2:	Funding Source Name 3:
Amount Funded: \$		
Grant Application Number:		

PART B: AMENDMENT DOCUMENTS FOR REVIEW Complete this Part B for Amendments (All amendments to be sent electronically to MSH-RGO@health.qld.gov.au)

Instructions for Submission of Amendments:

1. Fill out Study Details in PART A of this Form
2. Provide Relevant Signatures in Part A of this Form (See below point 4-6)
3. List name of document that is being amended

Signatures on this form for amendments may include :-

4. Principal Investigator Signature is required for all contract amendments & Public Health Act changes, Co-ordinator is able to sign on behalf of Principal Investigator for all other amendments
5. Department Head Approval for changes which may include use of resources staffing levels, access to information, extension of study, financial impact Less than \$10K
6. Finance Manager Approval required for anything above \$10K

Name of Document	Version number	Version Date	Tracked Version	Clean Version
HREC Approval (required for all amendments to research)				
Research Agreement Amendment				
Indemnity Amendment				
QCAT Approval				
Public Health Act Approval				
Insurance Certificate				
(Site) PICF				
Curriculum Vitae				
Update eCTN				
Other				
Amendment impact on Department			Yes	No
Amendment impacts on resources				
Amendment impacts on payments				

List what the changes are and the reason for the changes that have occurred (include changes in procedure, recruitment, number of participants, research personnel, additional sites etc.)