

Dr Cameron Lutman
 Research Ethics & Governance Manager
 South Western Sydney Local Health District

Dear Cameron,

Project Title (full):	<i>Please ensure you include the FULL research title as it appears on the application</i>
External HREC Reference:	<i>e.g. HREC/14/HNE/111 or 20XX/ETHXXXXX</i>
SWSLHD SSA Reference:	<i>e.g. SSA/14/LPOOL/200 or 20XX/STEXXXXXX</i>
Local Project Number (SWSLHD) (if applicable - projects submitted only in REGIS will not have this number:	<i>e.g. HE14/284 or 20XX/PIDXXXXX</i>

Contact Details (must be completed for all submissions):

Principal Investigator Name:	<i>Dr John Smith</i>
Principal Investigator e-mail:	<i>John.smith@health.nsw.gov.au</i>
Contact Person Name:	<i>Ms Jane Doe</i>
Contact Person e-mail:	<i>Jane.doe@health.nsw.gov.au</i>

For any amendments to the protocol, do supporting departments within SWSLHD need to be notified?
Yes **No**

(for example if an amendment requires:
 • access to retrospective data, a signature from medical records will be required
 • drawing bloods, a signature from pathology will be required)
 If yes, please contact the office on SWSLHD-ethics@health.nsw.gov.au to determine the next steps.
 Please find attached documentation for review and noting.

Please answer the following questions in relation to this amendment:

1. Is this amendment submission due to COVID-19? *Yes/No – if no please stop here.*
 2. Does this amendment include adding a SARS-COV-2 COVID test? *Yes/No*
 3. Is this amendment to add a new COVID-19 related element to the current project? *Yes/No*
 4. Is this amendment in response to the wider COVID-19 situation? *Yes/No*
 5. Is the study suspended due to COVID-19? *Yes/No*
 6. Is the study terminated due to COVID-19? *Yes/No*
 7. Terminated Decision: *(please circle)* SPONSOR – CPI – Regulatory body
 8. Reason for termination: *(please state)*
-
9. Serious Breach due to COVID-19? *Yes/No*
 10. SSI due to COVID-19? *Yes/No*
 11. USM due to COVID-19? *Yes/No*

While attaching your electronic documents please ensure to use the numbering in your document file name as per below:

PLEASE NUMBER YOUR ATTACHMENTS	Document	Version/Edition	Date
1)	<i>e.g Approval letter from the Royal Prince Alfred Hospital Human Research Ethics Committee</i>	<i>Nil</i>	<i>20/02/2015</i>
2)	<i>e.g. Participant Information Sheet</i>	<i>5.0</i>	<i>20/05/2014</i>
3)			

While attaching your electronic documents please ensure to use the numbering in your document file name as per below:

SITE SPECIFIC DOCUMENTATION <i>(this section can be deleted if there are no Site Specific documents):</i>						
Please find attached documentation for review and authorisation for use at the following Hospital(s):						
Master				Site Specific		
PLEASE NUMBER YOUR ATTACHMENTS	Document	Version	Date	Version	Date	Site Name

Please ensure that all documentation is clearly outlined on the above form. Failure to include all documentation (including correct version numbers and dates) will result in the request not being noted or authorised. Please contact the office on 8738 8304 if you are unsure of what information to include

1)	e.g. Participant Information Sheet and Consent Form (Optional Tissue Study)	5.0	20/05/2014	1.0	01/01/2015	Campbelltown Hospital
2)	Delete lines that are not relevant					
3)						
4)						
5)						
6)						
7)						
8)						

Office Use Only:




Name of RGO: Dr Cameron Lutman,
Research Ethics and Governance Manager

Action: Noted and Approved

Signature: _____
Date: _____

All documents listed above should be attached as separate files (PDF copies are preferred) and emailed to SWSLHD-ethics@health.nsw.gov.au with **Subject line:**
MC AMENDMENT SUBMISSION – [INSERT LOCAL PROJECT NUMBER or REGIS NUMBER]

PLEASE NOTE ANY SUBMISSIONS EMAILED TO THE OFFICE WITHOUT NUMBERED ATTACHMENTS WILL NOT BE ACCEPTED
E.g.

-  1. Cover Letter
-  2. HREC Approval Letter
-  3. Annual Report