Research Office Electronic Submission Process

SharePoint Record No:	
Endorsed by: **Approved by:** **Signature:**	**Sarah Amos – Research Governance Manager** **Rodney Green – Chief Financial Officer**
Date:	**26th November 2019**
Other related documents:	**Research Governance in NSW Public Health Organisations [(GL2011_001), publication date 25 January 2011]** **NSW Ministry of Health Policy Directive 'Clinical Trial Research Agreements for Public Health Organisations (Commercial Entities).'** **SLHD Research Governance Requirements for LH Human Research (Version 8)**

Overview of Research Office

The Research Governance Office is the first point of contact for researchers wishing to conduct research involving patients at Chris O'Brien Lifehouse.

The office will provide guidance the following:

- Site Specific Assessment submission
- Clinical Trials Research Agreements
- Insurance
- Post site authorisation requirements

Purpose and Scope

Research governance can be defined as a framework for effective oversight of research, such that it meets appropriate standards of quality, safety, privacy, risk management, financial management and ethical acceptability at Lifehouse.

It provides a framework for the organisation, hospital/facilities, managers and researchers in a shared responsibility and accountability on the conduct of the research. More information on the role of Research Governance can be found in NSW Health policy directive PD2010_056 Research - Authorisation to Commence Human Research in NSW Public Health Organisations

The purpose of this guide is to outline the submission and authorisation procedure to the Lifehouse Research Governance Office. It is designed to assist investigators with the completion of site specific (SSA), access request and ongoing site authorisation applications. The Lifehouse Research Governance office is responsible for the review of site applications (SSA's) associated with a research project that may be conducted at any of the sites within the Lifehouse.

Completing the SSA Application:

The Lifehouse SSA form and submission checklists can be found on the below links:

Internet: https://www.mylifehouse.org.au/doing-research/
Intranet:
https://myportal.lifehouserpa.org.au/clinicaltrials/SitePages/Research%20and%20Governance.aspx

SSA Submission:

SSA Form - Research Personnel:

All associate investigators and research personnel are to be listed on the SSA. All external researchers must include a CV at time of SSA submission and undergo the formal Lifehouse HR Process.

Where the research to be conducted is a Clinical Trial, all associated investigators and research personnel are to submit a valid Good Clinical Practice (GCP) Certificate at time of SSA submission.

Where associate investigator and research personnel time is voluntary please annotate on the SSA time within section 6 under hours per week *Time donated 'in kind'.*

SSA Form - Head of Department:

All Head of Department (HoD) signatures are to be wet ink. Where there is a conflict of interest e.g. the Principal Investigator is also the HoD the deputy or equivalent is to sign as HoD. For further clarification, please contact the Research Governance Manager.

SSA Form - Data Custodian:

Please note, the ***data custodian signatory*** should be signed when more than 50 medical records are to be accessed. The data custodian for all medical records including Radiation Oncology's electronic medical record is the Health Information Services Manager.

SSA Form - Signature requirements:

All signatures required for the SSA must be of wet ink. Please note that all heads of department must tick: "*Able to perform the investigations/services indicated, within the present resources of the department".* The SSA will not be able to progress without this indication and all required signatures.

Other Submission Documentation:

All other documentation is to be included as per the a HREC approval and Lifehouse Governance checklist located:

Internet: https://www.mylifehouse.org.au/doing-research/
Intranet:
https://myportal.lifehouserpa.org.au/clinicaltrials/SitePages/Research%20and%20Governance.aspx

Contract and Indemnity

All contracts and indemnities are to be submitted to the Research Governance Manager in hard copy with wet ink signatures.

All contracts and indemnities should be scanned and included within the electronic submission.

Please note, only 1 contract and 1 indemnity is to be submitted for LH CEO signing. The sponsor will be provided with a scanned copy of the original fully executed document. All originals will remain within the Research Governance Office.

Contract Amendments:
All amendments to contracts are to be submitted to the Research Governance Manager in hard copy with wet ink signatures.
All amendments to contracts are to be scanned and electronically submitted to the research Governance Manager.

The study coordinator is to notify the Research Governance Manager via email of the hardcopy submission.

Submission Email Subject Title: CTRA/Indemnity Amendment, LH Reference Number, delivered in hardcopy to RGM.

New SSA Electronic Submission:

The Principal Investigator (PI) is to electronically submit the SSA unless they have delegated submission responsibility. In the event where this occurs, the PI must be included – carbon copied (cc) in the email submission. Essential details to be included within the submission email include the below.

Submission Email Subject Title: NEW SSA Submission, Principal Investigator Name, Short Title of Study, Email x of x

Submission Email Attachments: All documents are to be submitted in a zip file attachment to the Research Governance Manager. All documents submitted should reflect the SSA submission checklist and HREC approved documents. Zip File documents should be labelled in order as per the Research Governance cover letter with appropriate numbering.

Submission Email Body: The body of the email should act as a cover letter outlining the study title and documents submitted. The Cover letter should be signed by the PI in Wet Ink in the event where the submission email is delegated.

Note: The cover letter written in the body of the email should mirror the cover letter submitted with the hardcopy SSA, Contract and Indemnity.

Request for further information Response Submission:
Where the Research Governance Manager has requested further information, the above process will apply when responding. However, the ***submission Email Subject Title*** will change to: LH Reference Number, RESPONSE to request for further information,

All hard copy documents required are to be submitted in parallel to the Research Governance Manager's in tray.

Notification of Amendment Electronic Submission:

The Principal Investigator (PI) is to electronically submit the amendment unless they have delegated submission responsibility. In the event where this occurs, the PI must be included – carbon copied (cc) in the email submission. Essential details to be included within the submission email include the below.

Submission Email Subject Title: Amendment, LH Reference number, Principal Investigator. In the event where an amendment if a priority review please use:
Amendment, LH Reference Number, PRIORITY, Month Submitted, Email x of x.

Submission Email Attachments: All documents are to be submitted in a zip file attachment to the Research Governance Manager. All documents submitted should reflect the HREC approved documents listed on HREC approval letter. Zip File documents should be labelled in order as per the HREC approval letter and Governance cover letter. The amendment submission should include the Lifehouse Research Governance Amendment Form.

Submission Email Body: The body of the email should act as a cover letter outlining the study title and documents submitted. Wet Ink signatures are required on the Lifehouse Amendment form when the Principal Investigator has not sent the amendment notification email. *Note: The cover letter written in the body of the email should mirror the cover letter submitted with hardcopy documents.*

Request for further information Response Submission:
Where the Research Governance Manager has requested further information, the above process will apply when responding. However, the ***submission Email Subject Title*** will change to: *Amendment, LH Reference Number, Response to RGM Queries, Email x of x*

All hard copy documents required are to be submitted to the Research Governance Manager in tray.

Safety Reporting and Annual Reporting

All Safety reporting requirements are to be reported electronically within the required time frames as per NSW Health Policy Directive PD2017_039.

Significant Safety Issue (SSI) Email Submission Title: ACTION REQUIRED, SSI, LH reference number.

Suspected Unexpected Serious Adverse Event (SUSAR) Email Submission Title: ACTION REQUIRED, SUSAR, LH Reference Number.

Unanticipated Serious Adverse Device Effects (USADES) Email Submission Title: ACTION REQUIRED, USADES, LH Reference Number.

Annual Safety Reporting Email Submission Title:[Year]Annual Report, LH Reference Number.

Submission Email Body: The body of the email should act as a cover letter outlining the study title and documents submitted. The Cover letter should be signed on behalf of the PI if applicable.
Note: The cover letter written in the body of the email should mirror the cover letter submitted with hardcopy documents

Changes to Research Personnel

All changes to research personnel must be acknowledged by the Research Governance Manager before the personnel can participate in research activities outlined in NSW Health Policy Directive PD2010_056.

Submission Email Subject Title: Change in Research Personnel, LH Reference Number, Month Submitted.

Submission Email Body: The body of the email should act as a cover letter outlining the study title and documents submitted. Wet ink signatures will be required on the Lifehouse Research Governance Change in Personnel Form.