SSA Form Qld

Project ID 89809
SSA/2022/QNW/89809 (Oct ver 2)

Instructions & DORA consent

- *This form must be completed by a local site Principal Investigator (PI) or delegate where the research is being conducted. Not all sections of the form will be relevant.*
- ***Applicants should begin negotiations with relevant Hospital and Health Service (HHS) personnel responsible for resources that will be required for the study, e.g. Heads of Departments or delegate/s and Director of Finance or delegate, as early as possible. Negotiations pertaining to the research governance processes should commence and run parallel to the Human Research Ethics Committee (HREC) approval cycle. If the Site Specific Assessment (SSA) form is signed and submitted prior to ethics approval, and then documents are changed, the SSA form must be updated and re-signed. Research Governance Authorisation is not given until there is evidence of ethics approval.***
- *The SSA form must be forwarded to the HHS/site research governance personnel at the site of the research for consideration and checking prior to final Authorisation by the HHS Chief Executive Officer (CEO) or delegate*
- *All aspects of this SSA form are to be completed where relevant and the required associated documents attached.*
- *Further Information for example CV's may be requested in order for the institution to appropriately assess your study*
- ***CONTRACT TEMPLATES: The Medicines Australia and Medical Technology Association of Australia (MTAA) Contract Templates are accepted for Clinical Trials and the Queensland Public Sector Health System Multi-Site Research collaboration agreement schedule is an approved template for non clinical trials research only involving Qld Health partners. The Brisbane Diamantina Health Partners (BDHP) Research Passport Agreement is an approved template for collaborative non clinical trials research for BDHP partners - check with your local Research Governance Officer (RGO). see link for further information https://www.health.qld.gov.au/hiiro/html/regu/for_researcher***

For further information on how to complete this application please refer to https://www.health.qld.gov.au/hiiro/html/regu/for_researcher.

Queensland Health Database of Research Activity DORA 2.0

http://dora.health.qld.gov.au

Ethical Review Manager (ERM) is the online system used for the management and administration of all human research ethics and governance applications submitted to a Human Research Ethics Committee and/or Research Governance Office for studies conducted within Queensland Health and the Hospital and Health Services.

The Database of Research Activity (DORA) is a publicly accessible, searchable internet web site which takes meta-data from the ERM system (e.g. title, summary, sponsor, investigator, contact, site names and emails and start and stop dates).

The searchable database covers all Queensland Health and the Hospital and Health Services human research (not just clinical trials) and is designed to facilitate greater collaboration and communication between researchers, improve patients' access to research information and raise awareness about the benefits of health and medical research.

I, the local site Principal Investigator, have the authority to give consent for the above details to be uploaded onto the Queensland Health Database of Research Activity.

- (•) Yes
- ( ) No

I, the local site Principal Investigator, give consent for the above details for this site to be uploaded onto the Queensland Health Database of Research Activity.

- (•) Yes
- ( ) No

I agree to any published papers and other research output being deposited in DoRA 2.0 in line with applicable publisher copyright and open access archiving policies.

- (•) Yes
- ( ) No

Privacy notice

Privacy notice Personal information collected by Ethical Review Manager (ERM) is handled in accordance with the Information Privacy Act 2009. ERM is collecting research application information. All personal information will be securely stored and accessible by authorised staff. High level application details regarding your authorised application (including the project title and contact you nominate) will be made available on the Database of Research Activity (DoRA 2.0). http://dora.health.qld.gov.au/

Your personal information will not be disclosed to other third parties without consent, unless the disclosure is authorised or required by or under law. For information about how Queensland Health protects your personal information, or to learn about your right to access your own personal information, please see our website at www.health.qld.gov.au.

Purpose of this Form

What is the purpose of this form?

- [x] Option 1. To submit a NEW Site Specific Assessment Form
- [ ] Option 2. As directed by the RGO. For example to create a non-lead SSA for the low risk/low cost multi centre research process or otherwise when a full SSA completion is not required

Project Details

HREC Reference Number *(i.e. HREC/2019/DEF/50000)*

HREC/QTHS/89809

1.1 To which Queensland Health Research Governance Office will this SSA Form be submitted?

North West HHS RGO

1.2 What is the name of the site/s to which this SSA Form applies?

- ☐ All
- ☐ Burketown Primary Health Clinic
- ☐ Camooweal Primary Health Clinic
- ☐ Cloncurry Hospital
- ☐ Dajarra Primary Health Clinic
- ☐ Doomadgee Hospital
- ☐ Julia Creek Hospital
- ☐ Karumba Primary Health Clinic
- ☐ McKinlay Primary Health Clinic
- ☐ Mornington Island Hospital
- ☑ Mount Isa Hospital
- ☐ Normanton Hospital
- ☐ Other

1.3 Provide the anticipated start and finish dates for the research project <u>at this site.</u>

Start Date: 10/08/2022

Finish Date: 31/10/2022

1.4 Please enter the short title of this project: (must be same as on ethics approval)

8-year retrospective review of emergency laparotomy outcomes in a Queensland rural hospital

1.4a Please enter the full project title as in the HREA (maximum 2000 characters):

8-year retrospective review of emergency laparotomy outcomes in a Queensland rural hospital

1.5 Acronym if applicable

2 *Description of the Project in Plain Language:*

Give a concise and simple description in plain language, of the aims of this project, the proposal research design and the methods to be used. Please keep the total number of characters below 2000 including spaces.

Emergency laparotomy (EL) is a major operation in general surgery undertaken on often critically unwell patients for a range of underlying conditions. It is associated with high rates of mortality (1, 2). The National Emergency Laparotomy Audit (NELA), undertaken in the UK since 2013 collects prospective data on approximately 25,000 emergency laparotomies each year (3). The most common indication for EL is intestinal obstruction or perforation with a reported 30-day mortality rate of 8.7% and an average length of stay (LOS) of 15.1 days based on the 2019-2020 audit (3). The success of NELA in identifying areas requiring improvement in both management and clinical outcomes has encouraged similar studies in Australia and New Zealand reporting a 30-day mortality of between 7-9% and a LOS of 15.5 days (4, 5). These standards have been implemented in separate studies as perioperative 'bundles of care' for patients undergoing emergency abdominal surgery, with both studies reporting a reduction in post-operative mortality (6-8). There is a lack of existing surgical research in rural hospitals with only one previous relevant study (Rural Emergency Laparotomy Audit) (9). There are two objectives of this study. The first is to obtain accurate EL data to compare local outcomes and practices with national and international standards based on those reported in the reported in NELA, the Australian and New Zealand Emergency Laparotomy Audit Quality Improvement (ANZELA-QI) and the Rural Emergency Laparotomy Audit (RELA). The second is to determine if there are any significant differences between Australian rural and metropolitan locations. This is a retrospective clinical study with data which will be collected at Mount Isa Base Hospital for an 8-year period (January 2014 – December 2021) for patients undergoing an EL. The principal and the associate investigator is responsible for all data collection and entry. All patients over the age of 18 undergoing an emergency laparotomy

Research Personnel

3.1 ***Please complete the following table for the Site Principal Investigator <u>at this site</u> (If the purpose of this submission is to create a satellite site SSA, and you have ticked option 1 as the purpose of this SSA form, please enter the details of the PI at the Primary Site who is supervising the trial at your satellite site).*** *(all fields marked are mandatory):*

Title *	Dr
First Name *	Dong Tony
Surname *	CHENG
Organisation *	QLD Health
Department *	General Surgery

Address *

(If your address only has one line then use a full stop in the second line as both lines are mandatory)

	30 Camooweal Street
	Mount Isa
City *	Mount Isa
State *	QLD
Postcode *	4825
Country *	Australia

Telephone * 0411533521

Email * Tony.Cheng@health.qld.gov.au

If this researcher has an ORCID number, please include it here.

ORCiD Number 0000-0003-4884-3157

Have you been credentialed at a Queensland Health HHS ? **(Clinical Staff only)**

- (•) Yes
- ( ) No
- ( ) Not applicable

3.2 ***Is there an Associate Investigator who will be involved in the project at the site/s listed in this SSA?***

- (•) Yes
- ( ) No

3.2a ***Please complete the following table for each Associate Investigator <u>at this site</u>*** *(all fields marked are mandatory):*

Title * Dr

First Name * Nariyoshi

Surname * Miyata

Organisation * QLD Health

Department * General Surgery

Address *

(If not using two lines please enter a full-stop (i.e. '.') as both lines are mandatory)

30 Camooweal Street

Mount Isa

City * Mount Isa

State * QLD

Postcode * 4825

Telephone * 0452045224

Email * Nariyoshi.Miyata@health.qld.gov.au

Country * Australia

If this researcher has an ORCID number, please include it here.

ORCiD Number N/A

Have you been credentialed at a Queensland Health HHS (Clinical Staff only)?

- (•) Yes
- ( ) No
- ( ) Not applicable

3.2a ***Please complete the following table for each Associate Investigator <u>at this site</u>*** *(all fields marked are mandatory):*

Title * Dr.

First Name * Francis

Surname * Asomah

Organisation * QLD Health

Department * General Surgery

Address *

(If not using two lines please enter a full-stop (i.e. '.') as both lines are mandatory)

30 Camooweal Street

Mount Isa

City * Mount Isa

State * QLD

Postcode * 4825

Telephone * 0431731849

Email * Francis.Asomah@health.qld.gov.au

Country * Australia

If this researcher has an ORCID number, please include it here.

ORCiD Number N/A

Have you been credentialed at a Queensland Health HHS (Clinical Staff only)?

- (•) Yes
- ( ) No
- ( ) Not applicable

3.3 ***Please complete the following table for the Site Contact Person*** *(all marked fields are mandatory):*

Title *	Dr
First Name *	Dong Tony
Surname *	CHENG
Organisation *	QLD Health
Department *	General Surgery
Address *	

(If your address only has one line then use a full stop in the second line as both lines are mandatory)

	30 Camooweal Street
	Mount Isa
City *	Mount Isa
State *	QLD
Postcode *	4825
Country *	Australia
Telephone *	0411533521
Email *	Tony.Cheng@health.qld.gov.au

3.4 **Are there any additional study team members e.g. study coordinators or academic supervisors if they have not been listed as Associate Investigators or the contact?**

- ( ) Yes
- (•) No

3.5 Will any of the researchers at the site/s listed in this SSA Form require extra training to enable their participation in this project for example evidence of GCP training is required to conduct Clinical Trials?

- ( ) Yes
- (•) No

Recruitment

4.1 Does this project involve active recruitment of participants?

- ○ Yes
- ◉ No

4.2 Research involving access to coronial material

Research involving access to coronial material must be referred to the Queensland Health Forensic and Scientific Services Human Ethics Committee (FSS-HEC) for ethical and legal approvals. This also applies to clinical research projects where there is a component involving coronial material. In this context, examples of coronial material include tissues from coronial autopsies, slides and blocks, blood samples, autopsy reports and other documents and data relating to coronial autopsies

To access the web link for FSS, please click on the Information Icon at the right hand side of this question.

4.2a Does this study require access to Coronial Material?

- ○ Yes
- ◉ No

Data

5 Queensland Health policy on access to confidential information held by the Department.

For information and web links relating to Public Health approval, click on the Information Icon at the right hand side of this question.

All studies

Have you consulted with the data custodian/s regarding access to Confidential Information held by Queensland Health, to determine whether the data you require is collected and accessible?

- ◉ Yes
- ○ No

Studies requiring PHA approval

Projects that require PHA approval will not be processed through research governance until PHA approval has been granted.

5.1 Does this study require a PHA approval?

- ○ Yes
- ◉ No

Clinical Trials

6 Is this a Clinical Trial?

- ○ Yes
- ◉ No

Insurance and Indemnity

7.1 Is Insurance required for this project?

- ○ Yes
- ◉ No

7.2 Has Indemnity been provided for this project?

- ○ Yes
- ◉ No

Sponsor and Contracts

7.3 Who is the sponsor of this project?

- ○ Commercial Sponsor or Contract Research Organisation (CRO)
- ○ Collaborative Research Group
- ◉ Hospital
- ○ University
- ○ Other

7.3a What is the name of the Hospital sponsoring the project?

Mount Isa Base Hospital

7.3b ***Please enter the Sponsor's details for invoicing if applicable:***

Title

First Name

Surname

Organisation

Address

City

State

Postcode

Telephone

Fax

Email

Country

Please Select...

7.4 Are there contracts associated with the project (if this is a satellite site SSA then upload the Medicines Australia or MTAA Clinical Trial agreement AND the teletrials subcontract found at https://www.health.qld.gov.au/hiiro/html/regu/for_researcher)?

- ○ Yes
- ◉ No

Regulatory and Safety

7.5 Biosafety, chemical and radiation safety. Complete this section only if relevant to the site/s.

It may be necessary for research organisations to complete notification, registration or licence requirements for research involving biosafety, regulatory issues and/or radiation. If so, evidence of this is required.

Please indicate if any of the items below are required for this project at this site.

- ☐ ARPANSA certificate
- ☐ Institutional Biosafety Committee (IBC) notification
- ☐ Licence application to the Office of the Gene Technology Regulator (OGTR) for approval of genetically modified organisms
- ☐ NHMRC Gene and Related Therapies Research Advisory Panel (GTRAP) assessment
- ☐ Application for a licence to the NHMRC Licensing Committee to conduct embryo research
- ☐ Other
- ☑ Not applicable.

Resources

8. Does this project require input or support from internal departments or services at the site/s?

- ○ Yes
- ◉ No

Budget

9.1 How is this project funded?

Other

9.1a You have selected "Other" as the funding source for this project. Please provide more information.

No funding source is required

9.2 Has funding been confirmed?

- ○ Yes
- ◉ No

9.3 Upload funding agreement here, if not already provided as a Schedule in the contract. ***CONTRACT TEMPLATES: The Medicines Australia and MTAA Contract Templates are accepted for Clinical Trials and the Queensland Public Sector Health System Multi-site Research collaboration agreement schedule is an approved template for non clinical trials research only involving Qld Health partners and the BDHP Research Passport Agreement is an approved template for collaborative non clinical trials research for BDHP partners - check with your local RGO. see link https://www.health.qld.gov.au/hiiro/html/regu/for_researcher***

9.4 Is the local Hospital and Health Service the Administering Institution?

- ○ Yes
- ◉ No

9.4a Identify the external administering organisation that will receive and manage the funding. Costs incurred by the HHS will be recovered. Please provide the details required to generate invoicing

Not applicable

9.5 For all research, the Principal Investigator must provide information on the resource implications for the site/s. Budget breakdown must be provided with evidence that the Business Manager has reviewed the budget for the project. Contact the local RGO if uncertain.

Has the study budget been completed and uploaded?

- ○ Yes
- ◉ No

9.6 Why has the detailed study budget not been completed and uploaded for this project?

No costs are associated with running this project as the principal and associate investigator will be reviewing clinical data electronically using existing site-based infrastructure in their own time.

9.7 Expected income generated by this project:

- ○ There is a set "dollar value" of funding paid to conduct this project
- ○ Funding for this project is paid on a "per participant" (capitation) basis
- ○ Income for this project is a combination of set amounts and "per participant" payments
- ◉ No income is expected

9.8a What is the dollar value of funding confirmed/awarded/contracted for this project overall?

N/A

9.8b What is the dollar value of funding given to this project at this site?

N/A

9.8d What is the dollar value of in-kind support the HHS will give to support this project (i.e the funding shortfall).

N/A

9.9 Please explain how any funding shortfall will be managed.

N/A

Intellectual Property

10 Is there a possibility of new Intellectual Property to be developed from this project?

- ○ Yes
- ◉ No

10.1 Has a search of patent databases been undertaken?

For information on searching patent databases, please click on the Information Icon on the right hand side of this question.

- ○ Yes
- ◉ No

10.2 Does the contract state arrangements for the use of existing intellectual property and the parties' rights in relation to ownership?

- ○ Yes
- ◉ No

10.3 Does the contract state arrangements for the use of all new intellectual property developed through the research project?

- ○ Yes
- ◉ No

If there is a possibility of Intellectual Property being created from this project, Queensland Health is able to provide assistance in this area if required. Please contact the local RGO for further information.

Outcomes

11.1 How will the participants, local community, organisation or institution benefit from the results of this project?

The local community, organization and institution will benefit from the knowledge derived from this clinical audit. No previous audit has ever been for emergency laparotomy performed in Mount Isa and local standards can be compared to national and international standards with appropriate recommendations for improvement if required.

11.2 How do you plan to ensure this occurs?

For example, will you report the outcomes of this project to the Head of Department at this site, will it contribute to process re-design or is there potential for intellectual property commercialisation?

Local EL outcomes will be statistically compared to national and international standards. Whereby certain areas require improvement in clinical, subsequent recommendations can be made appropriately to the Health Service and to the Director of Surgery Dr. Francis Asomah as appropriate.

Other documents

Advertisements and Flyers

Please upload any HREC Approved Advertisements and/or Flyers if site specific changes have been made.

Other HREC Approved study related documents including those requiring site specific amendments which have not been uploaded elsewhere in this form. You may include the ethics approval letter if available. Please contact your local RGO for advice.

Please upload here.

Documents

Type	Document Name	File Name	Version Date	Version	Size
Other project-related documentation	89809_Approved	89809_Approved.pdf	04/10/2022	1.0	122.9 KB

Please upload all other supporting documents related to the Site Specific Assessment. Including any declarations of support and the initially authorised SSA as directed by the RGO if option 2 has been chosen as the purpose of this form.

Documents

Type	Document Name	File Name	Version Date	Version	Size
Other project-related documentation	RESEARCH PROTOCOL ver. 2.0	RESEARCH PROTOCOL ver. 2.0.docx	04/10/2022	2.0	42.3 KB

Head of Department signature page

Declaration by delegated Department Head/s

Declaration by delegated Department Head/s at the site where the Principal Investigator/Site Coordinator will conduct the research for the purpose of resourcing the research project.

- I certify that I have read the project details in this SSA for the research project application named above.
- I certify that I have discussed this research project and the resource implications for this Department, with the Principal Investigator/Site Coordinator.
- I certify that there are suitable and adequate facilities and resources for the research project to be conducted at this site. This is for 'Actual costs' and 'In kind' contribution.
- My signature indicates that I support this research project being carried out using such resources.

Will the Head of Department sign this document electronically through this website, provide an email or letter of support specifically referencing this correspondence, or with a "wet-ink" signature?

For instructions on how to obtain a wet ink signature on this form, please click on the Information Icon in the right hand side of this question.

- ○ Electronic signature
- ◉ Upload document
- ○ Wet-ink sign after printing

PI Signature page

Declaration by the Principal Investigator.

- I declare the information in this form is truthful and accurate to the best of my knowledge and belief and I take full responsibility for the sites for which I have responsibility
- I declare I am signing this form on behalf of the research team including Associate Investigators and I confirm any named person on this application is aware of and agree to their involvement in the research.
- I will only start this research project after obtaining authorisation from the site/s and approval from the responsible Human Research Ethics Committee (HREC)
- I accept responsibility for the conduct of this research project according to the principles of the NHMRC National Statement on the Ethical Conduct in Human Research 2007 (Updated 2018) and the Australian Code for the Responsible Conduct of Research (2018) and Note for Guidance on Good Clinical Practice E6 (R2)
- I undertake to conduct this research project in accordance with the protocols and procedures as approved by the HREC and the ethical and research arrangements of the organisation(s) involved
- I undertake to conduct this research in accordance with relevant legislation and regulations
- I agree to comply with the requirements of adverse or unexpected event reporting as stipulated by the HREC and NHMRC
- I will adhere to the conditions of approval stipulated by the HREC and will cooperate with HREC monitoring requirements
- I will inform the HREC and the delegated department or Divisional Head if the research project ceases before the expected date. I will discontinue the research if the HREC withdraws ethical approval
- I will adhere to the conditions of authorisation stipulated by the authorising authority at the site/s where I am Principal Investigator. I will discontinue the research if the authorising authority withdraws authorisation at the site/s where I am Principal Investigator
- I understand and agree that study files and documents and research records and data may be subject to inspection by the HREC, the sponsor or an independent body for audit and monitoring purposes
- I understand that information relating to this research, and about me as a researcher, will be held by the Queensland Health or Hospital and Health Services Research Governance Officer and on the Research Ethics Management Database. This information will be used for reporting purposes and managed according to the principles established in the Privacy Act 1988 (Cth) and relevant laws in the States and Territories of Australia.

Will the Principal Investigator sign this document electronically through this website, provide an email or letter of support specifically referencing this correspondence, or with a "wet-ink" signature?

For instructions on how to obtain a wet ink signature on this form, please click on the Information Icon in the right hand side of this question.

- (•) Electronic signature
- ( ) Upload document
- ( ) Wet-ink sign after printing

Electronic signature

Request Signature Sign

Signed: This form was signed by Dr Dong Tony Cheng (Tony.Cheng@health.qld.gov.au) on 05/10/2022 15:47

Once you have received all requested signatures you can submit the form (action on the left panel).