Information

NOTE: THIS FORM IS NOT for ETHICS or ETHICS APPROVAL

This QA form can be used for:

- clinical audit
- quality assurance
- evaluation activities
- a project that involves the potential for no more than negligible risk.

This QA form is only for:

- a project at a **Victorian** site/organisation
- a **single-site** application (if a project involves more than one site/organisation, a separate QA form must be submitted for each site/organisation).

Refer to *Ethical Considerations in Quality Assurance and Evaluation Activities* (NHMRC, 2014) and *National Statement on Ethical Conduct in Human Research* (NHMRC, 2007) for essential information.

⚠ **Before filling in the QA form, discuss the project with the research office to which you intend to submit the application.** ⚠

The research office will advise whether the QA form is the right choice for your project.

Is the Project QA?

Does the project involve:

• a vulnerable group of participants?	○ Yes ◉ No
• asking questions about sensitive topics?	○ Yes ◉ No
• more participant burden than just inconvenience?	○ Yes ◉ No
• more participant risk (physical, psychological or privacy) than routine care/business?	○ Yes ◉ No

• identifiable participant data being accessed by staff who do not have rightful clinical access?	○ Yes	◉ No
• a clinically significant departure from routine care?	○ Yes	◉ No
• randomisation, a control group or a placebo?	○ Yes	◉ No

Could the project:

• last more than two years?	○ Yes	◉ No
• infringe privacy or professional reputation of participants, healthcare providers or organisations?	○ Yes	◉ No
• determine findings that may be clinically relevant to participants (e.g. genetic test results)?	○ Yes	◉ No
• breach confidentiality of participants' personal information, beyond the risk in routine care/business?	○ Yes	◉ No

This project **may** qualify as QA.

To verify that the project is QA, discuss it with the research office to which you intend to submit the application. The research office will advise whether the QA form is the right choice for your project.

Organisation

Before filling in the QA form, discuss the project with the research office to which you intend to submit the application.

The research office will advise whether the QA form is the right choice for your project.

Select the reviewing organisation: The Royal Children's Hospital (Melbourn

This QA form relates to the above organisation only.

If the project involves participants or data from other organisations (sites), a separate QA form must be submitted to those organisations.

- (•) Acknowledged

Project Details

Project title: Validating the use of chest x-rays as measures of lung volume using computed tomography

Local reference number *(optional)*: 97964

Project category

- ( ) Clinical Audit
- ( ) Quality Assurance
- ( ) Evaluation Activity
- (•) Negligible Risk Research

Anticipated start date for the project: 01/07/2023

Anticipated finish date for the project: 30/11/2023

Reminder: A project longer than two years does not qualify as QA.

If the project may last longer than two years, contact the reviewing organisation's research office to discuss your project **before** you fill in the rest of this form.

It is mandatory to upload a project protocol.
The protocol is a detailed description of the project, and must include:

- *Background and rationale*
- *Aims and objectives*
- *Methodology for collection of data*
- *Recruitment details (if prospective data collection)*
- *Privacy, storage and disposal of data*
- *Data source, use and statistical analysis*
- *Risks and ethical issues (including mitigation and management)*
- *Dissemination of research (e.g. publication)*

Upload protocol

Documents

Type	Document Name	File Name	Version Date	Version	Size
Protocol	97964_Rib Project Protocol_23May23_V1.0	97964_Rib Project Protocol_23May23_V1.0.docx	23/05/2023	1.0	44.4 KB

Departments

Department(s) involved in the project

Department	Medical Imaging
Head of department	Dr Padma Rao
Location/campus	Royal Children's Hospital

Other Sites

Are other Victorian sites/organisations involved in this project?

- ○ Yes
- ◉ No

Principal Investigator

Principal Investigator

Title	Prof
First Name	David
Surname	Tingay
Organisation	Royal Children's Hospital/ Murdoch Children's Research Institute

Department: Neonatal Medicine/Neonatal Research

Address: 50 Flemington Rd

City: Parkville

Postcode: 3052

Telephone: 0413567295

Email: david.tingay@rch.org.au

Qualification

Senior post-doctoral researcher for >15 years, Prof Uni Melb,

Upload Principal Investigator's CV

Documents

Type	Document Name	File Name	Version Date	Version	Size
Curriculum vitae	Tingay_CV_UoM_19Nov22	Tingay_CV_UoM_19Nov22.docx	19/11/2022	1.0	224.2 KB

Associate Investigator(s)

Does the project team involve any Associate Investigators?

- (•) Yes
- ( ) No

Associate Investigator

Title: Dr

First Name: Sophia

Surname: Dahm

Organisation: Royal Children's Hospital

Department: Junior resident medical officer

Telephone: 0430002064

Email: sophia.dahm@mcri.edu.au

Role in project: Co-Principal Investigator (supervised by D Tingay)

Associate Investigator

Title	Dr
First Name	Arun
Surname	Sett
Organisation	Royal Children's Hospital
Department	PIPER
Telephone	0405491595
Email	Arun.Sett@thewomens.org.au
Role in project	Investigator leading statistical analysis

Associate Investigator

Title	Dr
First Name	David
Surname	Stewart
Organisation	Royal Children's Hospital
Department	Neonatal Medicine
Telephone	0432080536
Email	david.stewart@rch.org.au
Role in project	Investigator

Associate Investigator

Title	Dr
First Name	Fiona
Surname	Ramanauskas
Organisation	Royal Children's Hospital
Department	Medical Imaging department
Telephone	93453432
Email	fiona.ramanauskas@rch.org.au
Role in project	CT image segmentation and image quality assessment

Associate Investigator

Title	Dr
First Name	Padma
Surname	Rao
Organisation	Royal Children's Hospital
Department	Medical Imaging department
Telephone	93455847
Email	padma.rao@rch.org.au
Role in project	Supervise Investigators in medical imaging aspects of project

Associate Investigator

Title	Dr
First Name	Rebecca
Surname	Gardiner
Organisation	Royal Children's Hospital
Department	Medical Imaging department
Telephone	93455255
Email	rebecca.gardiner@rch.org.au
Role in project	Investigator (assessing CXR ribs counting)

Upload Associate Investigator's CV

Student(s)

Does the project team involve any students?

- (•) Yes
- ( ) No

Contact the reviewing organisation's research office regarding student policies and requirements.

Student

Title	Ms
First Name	Emma
Surname	Gunn
Organisation	University of Melbourne
Department	Department of Paediatric
Telephone	0411984370
Email	e.gunn1@student.unimelb.edu.au

Describe the supervisory arrangements, support and training.

Supervisor is Professor David Tingay. There is 1.5 days a week dedicated time to this project for Emma Gunn and supervision.

Role in project: Will assist Dr S Dahm in CY segmentation and data entry

Contact

Contact Person

Title	Prof
First Name	David
Surname	Tingay
Organisation	Royal Chidlren's Hospital
Telephone	0413567295
Email	david.tingay@rch.org.au

Data Collection and Use

Type(s) of data to be collected

- ☐ Prospective collection of data
- ☑ Existing records or data

Specify the type(s) of **existing** data

- ☑ Clinical data
- ☐ Research data

Type(s) of information to be collected and/or used

- [x] Personal information
- [x] Health information
- [ ] Sensitive information

Describe the data that will be collected and/or used.

CT images will be analysed as per protocol. Analysis will occur within the RCH Medical Imaging Dept (due to software licences only being held on these computers). Final CT images used for analysis will have identifying information (DOB, URN, Name) redacted and DICOM image stored in study database.
Baseline health data (including age) will be extracted from the RCH EMR As per protocol and entered into the study RedCap. These data will not include standard identifying features (such as name, address, URN).
A screening log storing RCH URN and study identification number will be created in a password protected excel sheet held within the RCH Medical Imaging Dept. The screening log will be deleted once the main study dataset is finalised. No identifiable data will be stored in the main study database at the MCRI (RedCap).

Will data be sought from a third party?

- ○ Yes
- ◉ No

Will data be provided to a third party?

- ◉ Yes
- ○ No

Describe the data to be provided.

The main study database will be built in RedCap and held at the MCRI. As detailed above the main study database will not include identifiable data and infants will be recorded using the unique study identification number. Data that will be stored include reason for CT scan, relevant past and current medical history, age/weight at CT study, gestational age and weight at birth, gender, primary diagnosis, anaesthetic support at CT scan (if any), de-identified scout tomogram and segmented CT images (DICOM) and teh study results (number of ribs, lung volumes in cm3 calculated from CT and hounsfeld unit count for each lung).

Ensure there is an appropriate agreement in place regarding transfer of data.

In what form will data be accessed or collected?

- [ ] Identifiable (or potentially identifiable)
- [x] Re-identifiable
- [ ] Non-identifiable/anonymous

In what form will data be used and stored?

- [ ] Identifiable (or potentially identifiable)
- [x] Re-identifiable
- [ ] Non-identifiable/anonymous

Provide justification for data needing to be identifiable or re-identifiable.

In case there is a need to re-analyse the original CT images or scout tomograms or perform data quality checking on EMR collected data.

Who will be able to identify or re-identify data?

Only the listed Investigators with RCH appointments and rightful clinical access

If project team members will be accessing or using identifiable health information, do they have rightful clinical access to the data?

- (•) Yes
- ( ) No

Data Storage

Ensure compliance with the *Health Records Act* (Vic) (2001) and the *Australian Code for the Responsible Conduct of Research* (NHMRC, 2018) as applicable.

How will data be stored?

The study screening log will be stored at the RCH Medical Imaging Dept (password protected excel file managed by Dr Ramanauskas). De-identified (but re-identifable) study data will be held in a dedicated RedCap database at MCRI. Any further study documents will be scanned and stored at teh Neonatal Research Server managed by the MCRI IT department in a dedicated folder. This server iis a closed server with access only to MCRI and RCH staff approved by MCRI IT and Prof Tingay (Group Leader)

Location of data storage

As detailed above within the RCH and MCRI IT networks

Duration of data storage

7 years

What will happen to the data at the end of the retention period (e.g. how will it be destroyed)?

All electronic and paper based data will be destroyed as per RCH and MCRI policy. The screening log will be deleted once the main study dataset is finalised.

Participants

What does the project involve?

- [ ] Recruitment of participants
- [x] Access to records
- [ ] None of the above

Target number of records *(maximum)*: 300

Consent

What type of consent will be sought?

- ○ Consent from participant (or parent/guardian or person responsible)
- ◉ No consent required
- ○ Impracticable to obtain consent
- ○ Other

Benefit, Risk and Ethical Issues

What are the public benefits of this project and relevance to clinical care?

Prompt: Will this project generate new information that will have direct implications for patient clinical management?

This project aims to determine the utility of a commonly used bedside assessment (counting number of ribs to location of diaphragm) to direct clinical decisions regarding respiratory support settings for babies in the NICU.

What possible risks, burdens or inconveniences may participants experience?

None as this is will use existing CT images held within the RCH Medical Imaging database.

Describe any foreseeable ethical issues and how they will be addressed, including any risk to privacy.

The only foreseeable risk is to privacy. As detailed in the Protocol and previous sections of this application all subjects (CT images) will be allocated a unique identification number that will be used throughout the study database. The only potential risk to privacy is within the screening log that will be held within the RCH Medical Imaging Dept (until destroyed once final study dataset finalised). Important identifiable data will not need to be collected into the main database (this includes not collecting URN, name, address or DOB into main study database).

Supporting Documents

Are there any other supporting documents for the project?

- ◉ Yes
- ○ No

Select the documents

- ☐ Advertising material
- ☐ Case report form
- ☐ Copy of other approval
- ☐ Data management plan
- ☐ GP/consultant information
- ☐ Interview schedule
- ☐ Invitation to participant
- ☑ Letter of support
- ☐ Participant information and consent form (PICF) (tracked)
- ☐ Peer review
- ☑ Protocol (tracked)
- ☐ Questionnaire
- ☐ Research agreement
- ☐ Statistician comments
- ☐ Other

Upload letter of support

Documents

Type	Document Name	File Name	Version Date	Version	Size
Letter of support	MedicalImagingSDDSignOff_2023-05-16_1115	MedicalImagingSDDSignOff_2023-05-16_1115.pdf	16/05/2023	1.0	50.8 KB

Upload protocol (tracked)

Documents

Type	Document Name	File Name	Version Date	Version	Size
PROTOCOL (TRACKED)	99967_Rib Project Protocol_5July23_V2.0_TRACKED	99967_Rib Project Protocol_5July23_V2.0_TRACKED.docx	05/07/2023	2.0	44.5 KB

Signature of Head of Department

• A Head of Department may delegate responsibility to an appropriate staff member.

*• An investigator must **not** approve their own research on behalf of their department. If an investigator is also Head of Department, certification must be sought from the person to whom the Head of Department is responsible.*

Who is providing signature?

- ☑ Head of Department
- ☐ Head of Department's Delegate

Declaration by Head of Department

- I have read this project application.
- I have discussed this project, and the resource implications for this department, with the Principal Investigator.
- I undertake to be the contact point for escalation of any issues (e.g. audit findings, ethical concerns, complaints) that cannot be resolved with the Principal Investigator, and will oversee the resolution of such issues.
- This project can be conducted under the auspices of this organisation utilising the resources outlined in this form and the protocol.

How will the Head of Department agree to these terms?

- You can use the ERM 'request/sign' function to electronically sign this application.
- Select 'Upload other evidence' to upload and attach other evidence, such as an email.
- Select 'Wet ink sign after printing' if you intend to sign the QA form after it is printed (i.e. 'wet ink' signature). Upload the saved Declaration page in the Supporting Documents section of the QA form.

○ Electronic signature

○ Upload other evidence

◉ Wet ink sign after printing

Sign here: .....

Date: .....

.

Signature of Principal Investigator

Declaration by Principal Investigator

- I acknowledge that this project must comply with the *National Statement on Ethical Conduct in Human Research* and the *Australia Code for Responsible Conduct of Research*.
- I undertake to conduct this project in accordance with relevant legislation and regulations.
- I confirm that, to the best of my knowledge, this project meets the criteria for quality assurance.
- I agree to the access and use of data exclusively for the purpose(s) described in this form, and will not pass the data onto a third party without prior approval and a fully executed Material Data Transfer Agreement.
- I certify that all project team members and other personnel involved in this project are appropriately qualified and experienced or will undergo appropriate training to fulfil their role in this project.
- I have consulted with other departments should they be impacted by this project.
- The information in this form is truthful and accurate to the best of my knowledge and belief, and I take full responsibility at this site.

How will the Principal Investigator agree to these terms?

- You can use the ERM 'request/sign' function to electronically sign this application.
- Select 'Upload other evidence' to upload and attach other evidence, such as an email.
- Select 'Wet ink sign after printing' if you intend to sign the QA form after it is printed (i.e. 'wet ink' signature). Upload the saved Declaration page in the Supporting Documents section of the QA form.

(•) Electronic signature

( ) Upload other evidence

( ) Wet ink sign after printing

Electronic signature

Signed: This form was signed by A/Prof David Tingay (david.tingay@rch.org.au) on 10/07/2023 2:49 PM

Signature of Associate Investigator

Declaration by Associate Investigator

- I will access and use data exclusively for the purpose(s) described in this form and the protocol.
- I acknowledge that this project must comply with the *National Statement on Ethical Conduct in Human Research* and the *Australia Code for Responsible Conduct of Research*.

Declaration by Associate Investigator

- I will access and use data exclusively for the purpose(s) described in this form and the protocol.
- I acknowledge that this project must comply with the *National Statement on Ethical Conduct in Human Research* and the *Australia Code for Responsible Conduct of Research*.

Declaration by Associate Investigator

- I will access and use data exclusively for the purpose(s) described in this form and the protocol.
- I acknowledge that this project must comply with the *National Statement on Ethical Conduct in Human Research* and the *Australia Code for Responsible Conduct of Research*.

Declaration by Associate Investigator

- I will access and use data exclusively for the purpose(s) described in this form and the protocol.
- I acknowledge that this project must comply with the *National Statement on Ethical Conduct in Human Research* and the *Australia Code for Responsible Conduct of Research*.

Signature of Student

Declaration by Student

- I will access and use data exclusively for the purpose(s) described in this form and the protocol.
- I will operate under the direct supervision of the Principal Investigator.
- I acknowledge that this project must comply with the *National Statement on Ethical Conduct in Human Research* and the *Australia Code for Responsible Conduct of Research*.