aci.health.nsw.gov.au

Neonatal Intensive and Special Care Units' Data Registry research data applications

A guide for researchers about the NICUS research data request and approval process

Integrated Digital Enablement Accelerator Stream

November 2025

Agency for Clinical Innovation

NSW GOVERNMENT

The information in this resource should not replace a clinician's professional judgement.

The Agency for Clinical Innovation (ACI) works with clinicians, consumers and system leaders to improve the health system in NSW. We design and implement new ways to deliver care for patients.

The ACI partners with the Ministry of Health, pillar organisations, local health districts, specialty networks, clinicians, patients and carers. We work together to achieve better value in healthcare by:

- improving patient and provider experience
- improving patient outcomes
- delivering efficient and sustainable healthcare services.

The ACI is part of the Clinical Innovation and Research Division and works closely with the Office for Health and Medical Research.

aci.health.nsw.gov.au

AGENCY FOR CLINICAL INNOVATION

1 Reserve Road St Leonards NSW 2065
Locked Bag 2030, St Leonards NSW 1590
Phone +61 2 9464 4666
Email **aci-info@health.nsw.gov.au** | **aci.health.nsw.gov.au**

Further copies of this publication can be obtained from the Agency for Clinical Innovation website at aci.health.nsw.gov.au

Title	Neonatal Intensive and Special Care Units' Data Registry research data applications: A guide for researchers		
Replaces	February 2025. Neonatal Intensive and Special Care Units' Data Registry research data applications: A guide for researchers		
Revised	November 2025. Updated links to data request form from NICUS to ACI form.		
Next review	2027		
Produced by	Integrated Digital Enablement Accelerator Stream		
Preferred citation	NSW Agency for Clinical Innovation. Neonatal Intensive and Special Care Units' Data Registry research data applications: A guide for researchers. Sydney: ACI; 2025.		
CM ACI/D23/3958	SHPN (ACI) 250755	ISBN 978-1-74231-229-3	ACI_12125 [10/25]

Contents

About this guide **4**
Purpose 4
Scope and applicability 4
Awareness and communication 4
Review 4
Data governance and management **5**
NICUS Data Governance and Management Framework 5
Definitions used in this document 5
NICUS data assets 5
NICUS research data application and approval process - overview 5
NICUS research data application and approval process – step by step **8**
Step 1: Develop the research question 8
Step 2: Develop the research protocol 8
Step 3: Consult with NICUS Centralised Data Steward regarding feasibility of the proposed project 8
Step 4: Submit an ethics application to a local human research ethics committee 9
Step 5: Commence application via the ACI Data Request Form 9
Step 6: Upload required documentation into the ACI Data Request Form 10
Step 7: Await review and recommendations by the NICUS Research Committee 10
Step 8: Await review and recommendations by the Centralised Data Custodian 10
Step 9: Submit any project amendments and ethics approval of amendments 10
Step 10: Await data release by the NICUS Centralised Data Steward 11
Step 11: Complete the ACI Confidentiality Undertaking 11
Step 12: Upload research manuscripts to the ACI Data Request Form prior to publication for review 11
Step 13: Upload conference presentation details to the ACI Data Request Form 12
Appendix 1: Schedule 1 - ACI conditions of data release **13**
Appendix 2: Frequently asked questions - NICUS research data application process **15**
Appendix 3: Developing the research question - question formats and tips **19**
Appendix 4: Related NSW Health policy and supporting documents **21**
Legislation 21
Policy directives and guidelines 21
Supporting documents 21

About this guide

Purpose

The purpose of this document is to provide a practical guide for researchers who are applying to use Neonatal Intensive and Special Care Units' Data Registry (NICUS) data through the application, approval and data release process, in accordance with the NICUS Data Governance and Management Framework.

Scope and applicability

The application and approval process outlined in the Neonatal Intensive and Special Care Units' Data Registry Research Data Applications: A Guide for Researchers about the NICUS Research Data Request and Approval Process (the Guide for Researchers) applies when a study Principal Investigator, clinician, manager or other applicant proposes to use NICUS data for:

- all multi-site research studies using NICUS data
- all multi-site quality improvement and multi-site audit projects using NICUS data
- single-site research studies where NICUS is requested to perform the data extraction
- all research studies involving NICUS data requiring data linkage undertaken by the Centre for Health Record Linkage (CHeReL)
- research grants, publications and conference presentations, posters using NICUS data.

The application and approval process outlined in the Guide for Researchers **is not** applicable for:

- all non-research related NICUS data requests and activities related to NICUS, for example, for the purpose of health service planning and management within NSW Health. Access to NICUS data for non-research activities are approved by the Centralised Data Custodian and do not need to follow the steps outlined in this Guide for Researchers
- data used for local, single unit level quality improvement
- data used for local, single unit level clinical audit.

Awareness and communication

This document is available to download from the **NICUS web page** on the Agency for Clinical Innovation (ACI) website, along with related documents and links to the ACI Data Request Form.

Review

This document will be reviewed within the first 2 years of operation. It will then remain in effect until reviewed at least every 2 years or as deemed appropriate based on changes to data and information, technology, data management and transfer or regulatory requirements.

Data governance and management

The ACI is committed to establishing and maintaining good governance, data management practices and business processes that meet the needs of clinicians, researchers as well as regular reporting requirements, while complying with legislative requirements and stakeholder expectations.

NICUS Data Governance and Management Framework

The key roles and responsibilities for governing the collection, use, sharing, security and maintenance of data held within NICUS are outlined in the NICUS Data Governance and Management Framework and reflected in the Guide for Researchers. The roles and responsibilities have been established in alignment with the NSW Health Data Governance Framework.

The NICUS Data Governance and Management Framework is available via the **NICUS web page**.

Definitions used in this document

The terms '**research data**' and '**research project**' are used to describe data for research studies, multi-site quality improvement projects and multi-site audit purposes.

The terms '**Researcher**' and '**Principal Investigator**' are used to refer to person applying to use NICUS data for research, multi-site improvement studies and multi-site audit purposes on behalf their research team or hospital.

NICUS data assets

NICUS has four core data sets available for research studies, multi-site quality improvement projects and multi-site audit purposes:

- NICUS Clinical Dataset, which collects maternal and infant data on all newborn patients admitted to an intensive or special care unit in NSW and/or the ACT to document and follow up a newborn patient's clinical progress.
- NICUS Surgical Dataset, which collects clinical data on eligible infants who undergo surgery in the first 28 days after livebirth.
- NICUS 2-3 year Follow-up Dataset, which collects prospective neurodevelopmental assessment data from eligible surviving children at 2-3 years of corrected age and a medical assessment of eligible survivors.

  NICUS 5-year Follow-up Dataset, which collects prospective neurodevelopmental assessment data from eligible surviving children at 5 years of corrected age and a medical assessment of eligible survivors.

NICUS research data application and approval process - overview

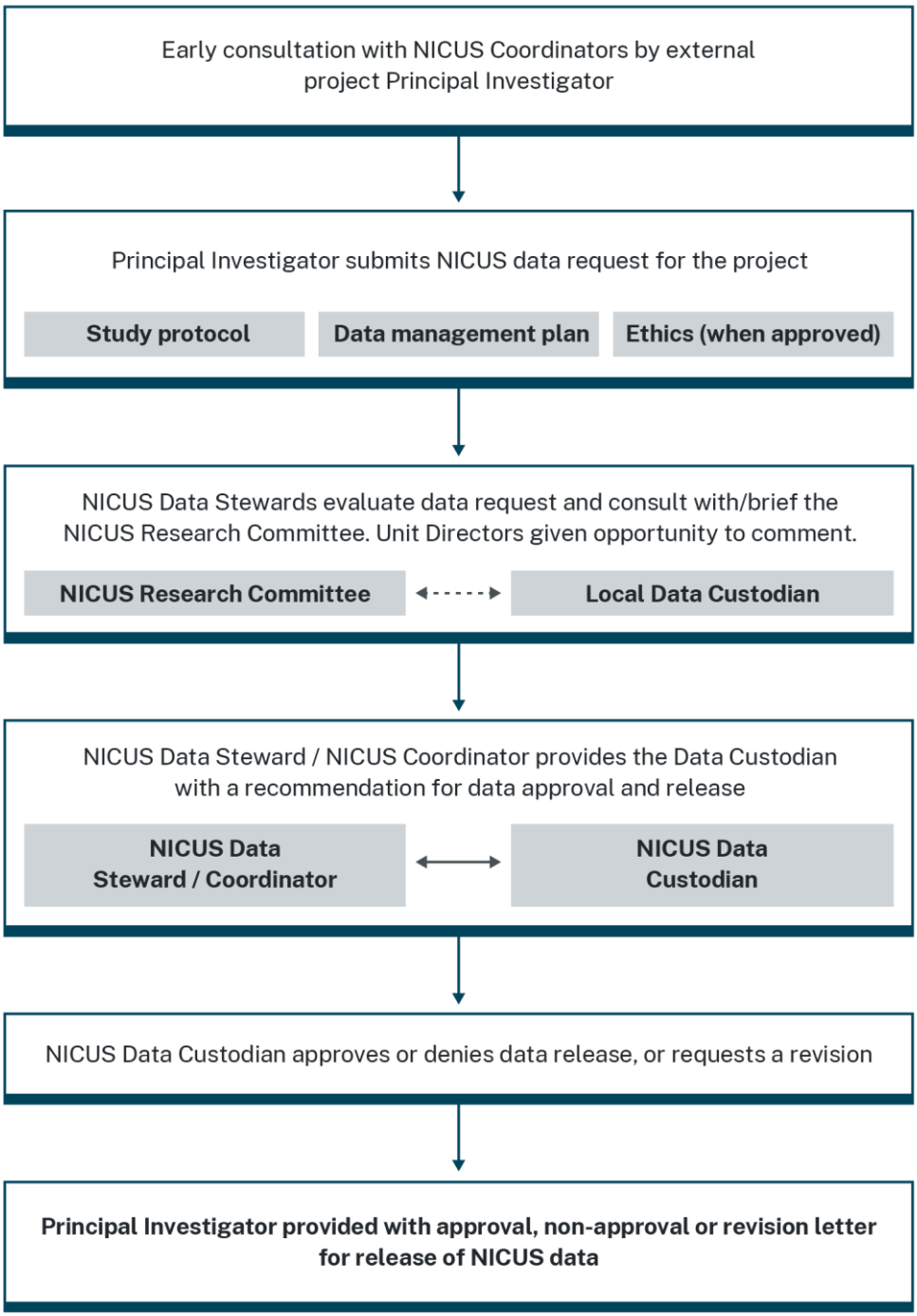
An overview of the process from application through to approval for release of NICUS data for research studies, and for multi-site quality improvement projects and multi-site audit purposes is outlined in Figure 1.

All applications for NICUS research data requests, including required supportive documentation of ethics approval, are to be made via the **ACI Data Request Form**.

Each sequential step in the application, approval and data release process is explained in more detail on the following pages.

For specific guidance on the process for research data requests, approvals and data release, please refer to the NICUS Data Governance and Management Framework and the NICUS Research Data Requests: Guide for Researchers.

Figure 1: NICUS research data application and approval process



NICUS research data application and approval process – step by step

Prior to an initial consultation with the NICUS Centralised Data Steward complete Steps 1 and 2.

Step 1: Develop the research question

The research question should be clear, specific, measurable, to the point and lead to new information. Spending time to develop a good research question is fundamental to the success of the project. The format of the research question will be determined by the type of project being conducted. See Appendix 3 for examples of how to frame a research question, or seek relevant guidance from your local organisation.

Step 2: Develop the research protocol

The research protocol (at minimum in draft form) needs to be developed prior to the initial consultation with the NICUS Centralised Data Steward and before submitting an application via the **ACI Data Request Form**. There are many standard templates for developing a research protocol. Your local Human Research and Ethics Committee (HREC) at your university, research institute or hospital will be able to assist you. Alternately, the National Health and Medical Research Council (NHMRC) provide resources and FAQs for developing an ethics application.

The final research protocol approved by your local HREC will need to be uploaded into the **ACI Data Request Form** before your application can progress to formal review by the NICUS Research Committee and NICUS Data Custodian.

Step 3: Consult with NICUS Centralised Data Steward regarding feasibility of the proposed project

It is strongly recommended that you consult with the NICUS Centralised Data Steward about the feasibility of the project, including the variables you propose to collect, prior to submitting an ethics application to your local HREC.

Researchers can contact the NICUS Centralised Data Steward via email at **ACI-NICUSRegistry@health.nsw.gov.au**. We will try to respond within 5 business days. We can arrange to speak with you virtually about your research proposal at a mutually agreeable time. Please note, during periods of peak demand, there may be a delay in our ability to provide a consultation.

Step 4: Submit an ethics application to a local human research ethics committee

NICUS data for research purposes cannot be approved or released without approval of a research project by a HREC. Please consult with your local HREC regarding the type of ethics your project will require.

Ethics does not need to have been approved at the time of initial application. However, approval of a HREC must always be valid at the time of the provision of the data and while the data are used for the project. The approval letter from a HREC and the project protocol approved by HREC must be uploaded into the **ACI Data Request Form** before the project can be assessed and approved by the NICUS Research Committee and NICUS Data Custodian.

Additional information

HREC approval or advice will help inform the decision to support disclosure of the information. Approval by a HREC of an application to use NICUS data does not by itself constitute authority for disclosure of the data requested but is a prerequisite for an authorisation to occur.

Additional requirements for research studies involving Aboriginal people and Aboriginal communities

If the request is for Aboriginal health information, consideration should be given as to whether the project should be submitted to the Aboriginal Health and Medical Research Council (AH&MRC) Human Research Ethics Committee.

The Principal Investigator must promptly notify ACI of any change to the approval given by the AH&MRC HREC and must provide copies of correspondence from such committees to ACI for its information. The Principal Investigator must conduct the project in accordance with the approval from the AH&MRC HREC.

Step 5: Commence application via the ACI Data Request Form

All applications for NICUS research data requests, including required supportive documentation of ethics approval are made via the **ACI Data Request Form**.

An initial application with a draft protocol can be submitted. Following approval of the project, including the project protocol, the final version of the project protocol listing the version number and date must be uploaded into the ACI Data Request Form.

Step 6: Upload required documentation into the ACI Data Request Form

The following documents must be uploaded into the **ACI Data Request Form** before a project can be reviewed and approved by the NICUS Research Committee and the Centralised Data Custodian:

- Project protocol, including protocol version number and date. The version number and date must be the same as that listed on the ethics approval letter.
- Ethics approval letter from a HREC.

All fields completed in the NICUS research data request application by the Principal Investigator.

Step 7: Await review and recommendations by the NICUS Research Committee

Where appropriate, research projects using NICUS data are reviewed by the NICUS Research Committee. Members of the Research Committee make recommendations regarding approval of the data release and/or any suggested amendments to the project.

The NICUS Research Committee meets every two months. Scheduled meeting dates of the NICUS Research Committee are available via the NICUS website on the Research Portal page.

Following review of a research request by the NICUS Research Committee, the NICUS Centralised Data Steward will inform the Centralised Data Custodian of the recommendations of the Research Committee.

Step 8: Await review and recommendations by the Centralised Data Custodian

The Centralised Data Custodian will review the recommendations of the NICUS Research Committee within 10 working days. The Centralised Data Custodian will inform the NICUS Centralised Data Steward of the final decision to approve or not approve the data release, or to request an amendment to the project.

Step 9: Submit any project amendments and ethics approval of amendments

In the event the Centralised Data Custodian requests an amendment for a project, or if a Principal Investigator determines that an amendment to the project is required, for example, to request additional variables, the amendment, revised project protocol and list of new variables must be approved by a HREC.

Following approval of the amendment to a project by a HREC, the ethics approval letter and revised project protocol listing the revised version number and date must be uploaded into the **ACI Data Request Form**.

The project will then by reassessed by the NICUS Research Committee and a recommendation made to the Centralised Data Custodian as per Step 7. The Centralised Data Custodian will then make a final decision to approve the project and release the data as per Step 8.

Step 10: Await data release by the NICUS Centralised Data Steward

Following the approval of a research project by the Centralised Data Custodian, the NICUS Centralised Data Steward and the NICUS Business Analyst will prepare the data for the project.

The time frame between approval of a project by the Centralised Data Custodian and extraction of the data is dependent on the complexity of the data request, the number of requests in progress or awaiting extraction and the availability of NICUS staff to undertake the extraction.

The NICUS Centralised Data Steward will provide the Principal Investigator with an estimated time frame for data extraction following approval of the data release by the Centralised Data Custodian. In the event of any delays to that time frame, the NICUS Centralised Data Steward will inform the Principal Investigator of the revised time frame in writing via email.

Step 11: Complete the ACI Confidentiality Undertaking

Following formal approval of the project by the Centralised Data Custodian, the NICUS Centralised Data Steward will send the Principal Investigator the following documents:

- NICUS Research Data Request Approval Letter.
- Schedule 1: ACI Conditions of data release.
- ACI Confidentiality Undertaking letter to be signed by the Principal Investigator, witnessed and emailed to the NICUS Centralised Data Steward at **ACI-NICUSRegistry@health.nsw.gov.au**. This document will be held in the ACI records management system.

Upon receipt of the signed ACI Confidentiality Undertaking letter from the Principal Investigator, the data will be released to the Principal Investigator by the NICUS Centralised Data Steward. This should occur within 3 business days of receiving the signed and witnessed ACI Confidentiality Undertaking letter.

Step 12: Upload research manuscripts to the ACI Data Request Form prior to publication for review

Any publication or report dissemination of the work arising from the project must be submitted to NICUS for review by the NICUS Research Committee and for approval by the Centralised Data Custodian prior to dissemination or publication. Publications must comply with any conditions imposed by ACI regarding the statistical interpretation or presentation of the data.

A copy of the final publication or report is to be emailed to **ACI-NICUSRegistry@health.nsw.gov.au** at least 2 weeks prior to public release.

In addition, a copy of the final publication must be uploaded into the **ACI Data Request Form** by the Principal Investigator when the paper is published.

Step 13: Upload conference presentation details to the ACI Data Request Form

Conference and symposium presentations must comply with any conditions imposed by ACI regarding the statistical interpretation or presentation of the data.

Details of conference and symposium presentations must be uploaded into the **ACI Data Request Form** by the Principal Investigator no later than 2 weeks prior to the presentation.

If a conference abstract is published in a peer reviewed journal, a copy of the abstract must be uploaded into the **ACI Data Request Form** by the Principal Investigator no later than 2 weeks prior to the conference abstract publication.

Appendix 1: Schedule 1 - ACI conditions of data release

Following approval of release of NICUS data for research purposes by the Centralised Data Custodian, the Principal Investigator will be sent a copy of Schedule 1: ACI Conditions of data release and the ACI Confidentiality Undertaking form to sign. A copy of the signed and witnessed ACI Confidentiality Undertaking will be maintained by the NICUS Centralised Data Steward.

NICUS data for research purposes are released subject to the following terms:

1. The data will only be used for the purpose(s) outlined in the research protocol and approved by the Centralised Data Custodian. Only the approved variables are provided for the purpose of this research project. No further research can be conducted using these data.
2. Any subsequent request for additional variables will require an ethics amendment and approval by the Centralised Data Custodian before any additional data will be released.
3. An ACI Confidentiality Undertaking must be signed and returned to the NICUS Centralised Data Steward prior to the data being released.
4. The data must not be used, published or disseminated in a way that might enable identification of an individual patient (mother and/or baby/babies) or an individual neonatal service, hospital or healthcare practitioner.
5. Statistical tables with data between one (1) and four (4) cases (mothers and/or babies) in any one category must not be published.
6. Data must not be linked (electronically or by personal inspection) with patient records or patient level data or personal information. No attempts to re-identify patients, health services or healthcare practitioners from the data are permitted.
7. The data are provided solely to the Principal Investigator and cannot be shared with other persons or organisations without prior consent from the Centralised Data Custodian.
8. The Principal Investigator must comply with all relevant NSW Health privacy laws in dealing with the data, as per the NSW Health Records and Information Privacy Act (2002) and the Privacy and Personal Information Protection Act (1998).
9. Data must be stored in a secure physical and electronic environment that is accessible only by persons directly involved in the project. Reasonable steps must be taken to ensure the data are not misused, lost, accessed by unauthorised persons, modified or disclosed.
10. In the event of an actual or potential data breach, or in circumstances of misfortune related to the provided data, investigators must inform the Centralised Data Custodian immediately in writing.
11. At the conclusion of the research project, data will be stored, retained and disposed of according to the NHMRC Management of Data and Information in Research: A guide supporting the Australian Code for the Responsible Conduct of Research (2019).
12. Approval of a HREC must always be valid at the time of the provision of the data and while the data are used for the project. The Principal Investigator must promptly notify NICUS of any change to the approval given by the HREC and must provide copies of correspondence from such committee(s) to

ACI for its information. The Principal Investigator must conduct the project in accordance with the approval from the HREC.

13. Any intended presentation, publication, report or other dissemination of the work arising from the project must be submitted to NICUS for review by the NICUS Research Committee and for approval by the Centralised Data Custodian prior to dissemination or publication. Publications must comply with any conditions imposed by ACI regarding the statistical interpretation or presentation of the data. A copy of the final publication or report is to be provided to NICUS at least two weeks prior to public release, emailed to **ACI-NICUSRegistry@health.nsw.gov.au**
14. NICUS must be appropriately acknowledged in any publications or presentation with the following acknowledgement and disclaimer:

    > 'We are grateful to the Neonatal Intensive and Special Care Units' Data Registry (NICUS) at the Agency for Clinical Innovation (ACI) for providing access to the data used for this project and to the staff at NICUS for their assistance. The findings, conclusions, opinions, views or recommendations expressed in this paper are strictly those of the author(s). They do not necessarily represent or reflect the views of the ACI.
    >
    > The authors thank the Directors, NICUS members and NICUS Audit Officers of all neonatal units supporting this collaborative project. We also thank the babies and their families, and the nursing, midwifery, obstetric and medical record staff of the obstetric and children's hospitals in NSW and the ACT.'

15. Additional conditions for use of linked data. Where record linkage was carried out by the Centre for Health Record Linkage (CHeReL), the Centre for Health Record Linkage should be acknowledged in any publication, report or presentation that arises from the use of the data.
16. Additional conditions for use of information about Aboriginal people. The use of the Aboriginal and Torres Strait Islander status is subject to the approval of the AH&MRC Human Research Ethics Committee if one or more of the following apply:

    - Aboriginality is a key determinant
    - Data collection is explicitly directed at Aboriginal peoples
    - Aboriginal peoples, as a group, are to be examined in the results
    - The information may have an impact on one or more Aboriginal communities
    - Aboriginal health funds are a source of funding.

Appendix 2: Frequently asked questions - NICUS research data application process

Consultation with the NICUS Centralised Data Steward about a research project

Who can I speak to at NICUS about the feasibility of a proposed research project?

Researchers can contact the NICUS Centralised Data Steward (NICUS Coordinator) via email at **ACI-NICUSRegistry@health.nsw.gov.au**. We can reply via email or contact you by phone or via Microsoft Teams about your research proposal at a mutually agreeable time.

Please note, during periods of peak demand, there may be a delay in our ability to speak with you via phone and Microsoft Teams, but we will aim to do so as soon as possible. Enquiries are usually answered within 5 business days.

Expected time frames for NICUS research data requests

How long will it take to have a research data application reviewed by a NICUS Centralised Data Steward following initial application via the ACI Data Request Form?

As soon as a research data request is submitted via the ACI Data Request Form, the Centralised Data Steward is notified by email. The NICUS Centralised Data Steward will aim to undertake an initial review of a new application within 5 working days of receiving the application. Applications will be reviewed during business hours, Monday to Thursday inclusive.

During periods of peak demand, there may be a delay in our ability to undertake the initial review of an application within this time frame, but we will aim to do so as soon as possible.

How long will it take to have a research data application reviewed by the NICUS Research Committee?

The NICUS Research Committee meets every two months. Scheduled meeting dates of the NICUS Research Committee will be available on the NICUS website, on the Research Portal page.

How long will it take to have a research data application reviewed and a decision made by the Centralised Data Custodian?

Following review and approval of a research request by the NICUS Research Committee, the NICUS Centralised Data Steward will inform the Centralised Data Custodian of the decision and recommendation of the Research Committee. The Centralised Data Custodian will review the recommendations within 10 working days. The Centralised Data Custodian will inform the NICUS Centralised Data Steward of the final decision to approve or not approve the data release or to request an amendment.

What is the time frame between approval by the Centralised Data Custodian to data extraction?

The time frame between approval of a project by the Centralised Data Custodian and extraction of the data is dependent on the complexity of the data request, the number of requests in progress or awaiting extraction, and the availability of NICUS staff to undertake the extraction.

The NICUS Centralised Data Steward will provide the Principal Investigator with an estimated time frame for data extraction following approval of the data release by the Centralised Data Custodian. In the event of any delays to that time frame, the NICUS Centralised Data Steward will inform the Principal Investigator of the revised time frame in writing, via email.

What is the time frame between data extraction and receiving the data?

After the data extraction has been completed by the NICUS Centralised Data Steward and the NICUS Business Analyst, the NICUS Centralised Data Steward will send the Principal Investigator the following documents:

- NICUS Research Data request approval letter.
- Schedule 1: ACI Conditions of data release.
- ACI Confidentiality Undertaking. To be signed by the Principal Investigator, witnessed and sent to the NICUS Centralised Data Steward at **ACI-NICUSRegistry@health.nsw.gov.au** This document will be held in the records management system at ACI.

Upon receipt of the signed ACI Confidentiality Undertaking form from the Principal Investigator, the data will be released to the Principal Investigator by the NICUS Centralised Data Steward. This should occur within 3 business days of receiving the signed and witnessed ACI Confidentiality Undertaking form.

Ethics

Can a draft protocol be submitted in the initial application via the ACI Data Request Form?

A draft protocol for a project can be submitted with the initial application by uploading it to the **ACI Data Request Form**. As soon as the project has ethical approval, the final protocol approved by HREC must be uploaded to the ACI Data Request Form. The final protocol must include a protocol version number and date, which should be the same as that listed in the ethics approval letter.

The final protocol and the ethics approval letter must be uploaded the ACI Data Request Form prior to data release.

Does ethics need to have been approved at the time of initial application?

Ethics do not need to have been approved at the time of initial application. However, all NICUS research data requests require HREC approval prior to data release. Ethical approval is required for all research projects requesting NICUS data.

Can NICUS data be released prior to ethics approval?

NICUS data will not be released without ethics approval. The final protocol and the HREC approval letter must be uploaded into the **ACI Data Request Form** prior to data release.

Can an amendment be made to a research project after the initial application for data release has been approved by the Centralised Data Custodian?

Yes, however, all amendments for research studies must be approved by a HREC. The revised protocol and ethics approval for the amendments must be submitted via the ACI Data Request Form. The amended data request will undergo a review by the NICUS Research Committee and then be reviewed and approved by the Centralised Data Custodian.

Does ethics approval need to be re-submitted to the ACI Data Request Form if an amendment is needed?

Yes, all amendments for research studies must be approved by a HREC. The revised protocol and ethics approval for the amendments must be submitted via the ACI Data Request Form. The revised protocol must include a version number and date, which should be the same as the listed in the revised HREC approval.

Costs for NICUS data requests

Is there a cost involved for applying for and obtaining NICUS data?

Currently there is no cost to apply for or obtain NICUS data.

Is there an additional cost involved for reapplying for and obtaining NICUS data following an amendment to the project protocol?

Currently there is no cost to reapply or obtain NICUS data following an ethics amendment.

Right of appeal if a release of NICUS data for a research project is not approved

Can I appeal the decision for non-approval of a NICUS research data request?

NICUS data requests undergo a rigorous review process, undertaken by the Centralised Data Custodian, NICUS Centralised Data Steward and the NICUS Research Committee. If data release for a project is not approved, the Principal Investigator will receive a letter outlining why the data were not approved for release. For example, if there was actual or perceived risk of identification of an individual infant, family or health service.

The Principal Investigator can submit an ethics amendment for the project that addresses the reasons outlined in the non-approval letter, and then reapply for NICUS data. The project will then be reassessed as per the NICUS Research Data Governance Framework for approval of projects. The Centralised Data Custodian will determine if the project will be approved following review of the amended protocol.

Conditions of release of NICUS data

Does the Principal Investigator need to sign an ACI Confidentiality Undertaking form and agree to conditions prior to data release?

Yes. It is a requirement that the Principal Investigators sign an ACI Confidentiality Undertaking form and agree to the conditions of data release outlined in Schedule 1, prior to release of NICUS data.

Is the Principal Investigator required to submit a copy of all manuscripts arising from the research project to NICUS prior to publication?

Yes. Any intended publication, report or other written dissemination of the work arising from the project must be submitted to NICUS for review by the NICUS Research Committee and for approval by the Centralised Data Custodian prior to dissemination or publication. Publications must comply with any conditions imposed by ACI regarding the statistical interpretation or presentation of the data. A copy of the final publication or report is to be emailed to **ACI-NICUSRegistry@health.nsw.gov.au** at least two weeks prior to public release.

It is also an ACI requirement that the Principal Investigator submits a copy of all published manuscripts via the ACI Data Request Form for review by the NICUS Research Committee.

Is the Principal Investigator required to inform NICUS about conference and symposium presentations arising from the research project?

Conference and symposium presentations must comply with any conditions imposed by ACI regarding the statistical interpretation or presentation of the data.

Details of conference and symposium presentations must be uploaded into the **ACI Data Request Form** by the Principal Investigator no later than two weeks prior to the presentation.

If a conference abstract is published in a peer reviewed journal, a copy of the abstract must be uploaded into the **ACI Data Request Form** by the Principal Investigator no later than two weeks prior to the conference abstract publication.

Can NICUS data be used for another research project other than the one approved by NICUS?

No. Data can only be used for the purpose outlined in the research project protocol and ethics and approved for release by the Centralised Data Custodian. Use of NICUS data without prior approval by the Centralised Data Custodian is in breach of the ACI Conditions of Data Release and may result in approval for a research project being withdrawn by the Centralised Data Custodian.

Appendix 3: Developing the research question - question formats and tips

The research question should be clear, specific, measurable, to the point and lead to new information. Spending time to develop a good research question is fundamental to the success of the project. The format of the research question will be determined by the type of project being conducted.

PICOT

For example, in a randomised controlled trial, or a project comparing a new therapy with an existing therapy, or one group of patients with another group, a **PICOT** format is used, where:

P = Population: the patients being studied

I = Intervention: the new therapy or treatment being trialled

C = Control group: the current therapy and/or treatment or existing population sub-group

O = Outcome: difference between the intervention and control groups – measures the effectiveness of the intervention compared with current and/or standard treatment

T = Time: the duration of the project, or the years of inclusion.

PICOT in a clinical example

In extremely preterm infants born <25 weeks' gestation (P), is early tropic feeding on day 1 (I) compared with standard feeds of 30ml/kg commenced on day 3 (C) associated with lower rates of necrotizing enterocolitis NEC (O) in the first 21 days after birth? (T)

PEO or PIO

The **PEO** or **PIO** question format is useful for qualitative research questions.

PEO questions identify three concepts: (1) Population, (2) Exposure and (3) Outcome(s).

In_____ (P) exposed to _____ (E) what are the outcomes____ (O)?

PEO in a clinical example

In extremely preterm infants (P), does exposure to excessive noise in NICU (E) lead to hearing loss? (O)

PIO questions also identify three concepts: (1) Population/Problem/Patient, (2) Intervention/Issue and (3) Outcome(s)

How/when do _____ (P) with _____ (I) develop _____ (O)?

In _____ (P), what is the effect of _____(I), on rates/incidence/prevalence of _____ (O)

PIO in a clinical example

In term infants with chronic heart disease (P), who require surgery >8 hours (I), what are the rates of major disability at 2 years of corrected age (O)?

Appendix 4: Related NSW Health policy and supporting documents

Legislation

- **Government Information (Public Access) Act 2009 (NSW)**
- **Health Administration Act 1982 (NSW)**
- **Health Records and Information Privacy Act 2002 (NSW)**
- **National Health and Medical Research Council Act 1992**
- **Privacy Act 1988** (Commonwealth)
- **Privacy and Personal Information Protection Act 1998 (NSW)**
- **State Records Act 1988 (NSW)**

Policy directives and guidelines

- **Guideline GL2019_002 NSW Health Data Governance Framework**
- **NSW Health Combined Delegations Manual**
- **Policy Directive PD2015_037 Data Collections – Disclosure of Unit Record Data for Research or Management of Health Services**
- **Policy Directive PD2018_001 Disclosure of unit record data by Local Health Districts for research or contractor services**
- **Policy Directive PD2023_040 Data Breaches Involving Personal or Health Information**
- **Statutory Guidelines on Research, Health Records and Information Privacy Act 2002 (NSW)**

Supporting documents

- **Guideline GL2022_002 Maternity and Neonatal Service Capability**
- **Health Stats NSW - Privacy Issues and the Reporting of Small Numbers 2015**
- **Management of Data and Information in Research: a guide supporting the Australian code for the Responsible Conduct of Research 2019**
- **National Statement on Ethical Conduct in Human Research 2023**
- **The Australian Code for the Responsible Conduct of Research, 2018**