

Document Number:	2.3
Document Name:	Data requests standard procedure
Version Number:	2019.1
Effective Date:	14/02/2019

1.0 Purpose

This document outlines the standard procedure for processing data requests received by ANZDATA and releasing data to third parties.

2.0 Procedure

2.2. Data requests are received and considered by the ANZDATA Executive following principles agreed by the Steering Committee (see Policy 2.2)

The implementation of this is performed by ANZDATA staff under the direction of ANZDATA Executive.

2.3. Typical procedure for data requests (See figure 1 below)

2.3.1. Approval process

- Request received through centralized email address: requests@anzdata.org.au
- Logged and assigned a tracking number by requests administrator. Details are entered into the requests log and a project folder and readme file created on the ANZDATA S:\ drive.
- Requests to be reviewed at requests meeting within 1 week of receipt. The following questions should be considered (see figure 1):
 - Is the data already published by ANZDATA?
 - Are any similar requests recorded in the request log?
 - Is the Request from an ANZDATA contributor or funder? (see Box 1)
 - Is the project clinically and scientifically valid?
 - Is identified data being requested? (see Box 2)
 - Is data linkage involved (see procedure 2.5)?
 - Is input from an existing ANZDATA working group required? (see Box 3)
 - Is the requestor asking for ANZDATA assistance with analysis?
 - Is ethics approval required prior to the release of data?
 - Has any NOMS, NZBS or Baxter Healthcare data been requested?

- Requests manager or request administrator will liaise with requestor to clarify any details required
- Request may be approved in accordance with this policy by the ANZDATA requests manager or any member of the ANZDATA executive
- Following initial review of request, an email will be sent to the requestor by either the requests administrator or the requests manager informing the requestor of the tracking ID and outcome of review (approval or the requirement of additional information). (See appendices A and B)
- Where requests are outside the scope of this document or where there is ambiguity as to whether or not the request fits standard criteria, the request will be reviewed at the monthly ANZDATA executive meeting for approval

2.3.2. Extraction Process

Once a request has been approved by the Requests Manager or a member of the ANZDATA executive:

- Extraction assigned to an ANZDATA statistician/staff member
- Request log updated with status changed to 'extract'. Approval date, assignment details, request category, and urgency category entered.
- Email sent to requestor by request administrator informing them of tracking number, approval and assignment. A data use agreement form should be attached to this email
- Project title and requestor details uploaded to the ANZDATA website by requests administrator
- Data to be extracted within the following time frame:
 - Urgent requests: 1 business day
 - Basic tabulated data: 7-10 days
 - Line data (not requiring significant data manipulation): 7-14 days
 - Complex requests/analysis: to be negotiated with requestor
- When data extraction is complete, the code will be checked by a second statistician/staff member for quality assurance
- Data transfer:
 - Simple tabular or summary data may be sent to the requestor via email
 - All identifiable, sensitive or single line data must be transferred via the secure report depot
- Data requests that require head unit, ethics or other approvals (see table 1) will not be released until these approvals are received by ANZDATA

Administration

- Following each request meeting, the requests administrator will update any status changes in the request log and online (see Box 4)
- All updates and significant correspondence should be documented in the readme file within the specific request folder on the S:\ drive



ANZDATA Registry
C/O SAHMRI, PO Box 11060
SAHMRI Building, Level 4 South, North Terrace
Adelaide, South Australia 5001
Ph: +61 8 8128 4758 Fax: +61 8 8128 4769

- All approval letters and related documents should be saved in the specific request folder on the S:\ drive
- Prior to the transfer of any data, the person transferring the data will confirm the following:
 - All required approval letters and ethics approvals have been received by ANZDATA
 - The extraction code and output has been checked by a second ANZDATA staff member
 - All identifying information has been removed from the data set unless explicitly approved for release
 - A data use agreement has been sent to the requestor if required
 - The data is being transferred through the appropriate method (see above)
- Following transfer of data the person completing the request will:
 - Email the requestor to inform them of data transfer
 - Update readme file to confirm data transfer and request completion
 - Update requests log with date of completion.

Figure 1:

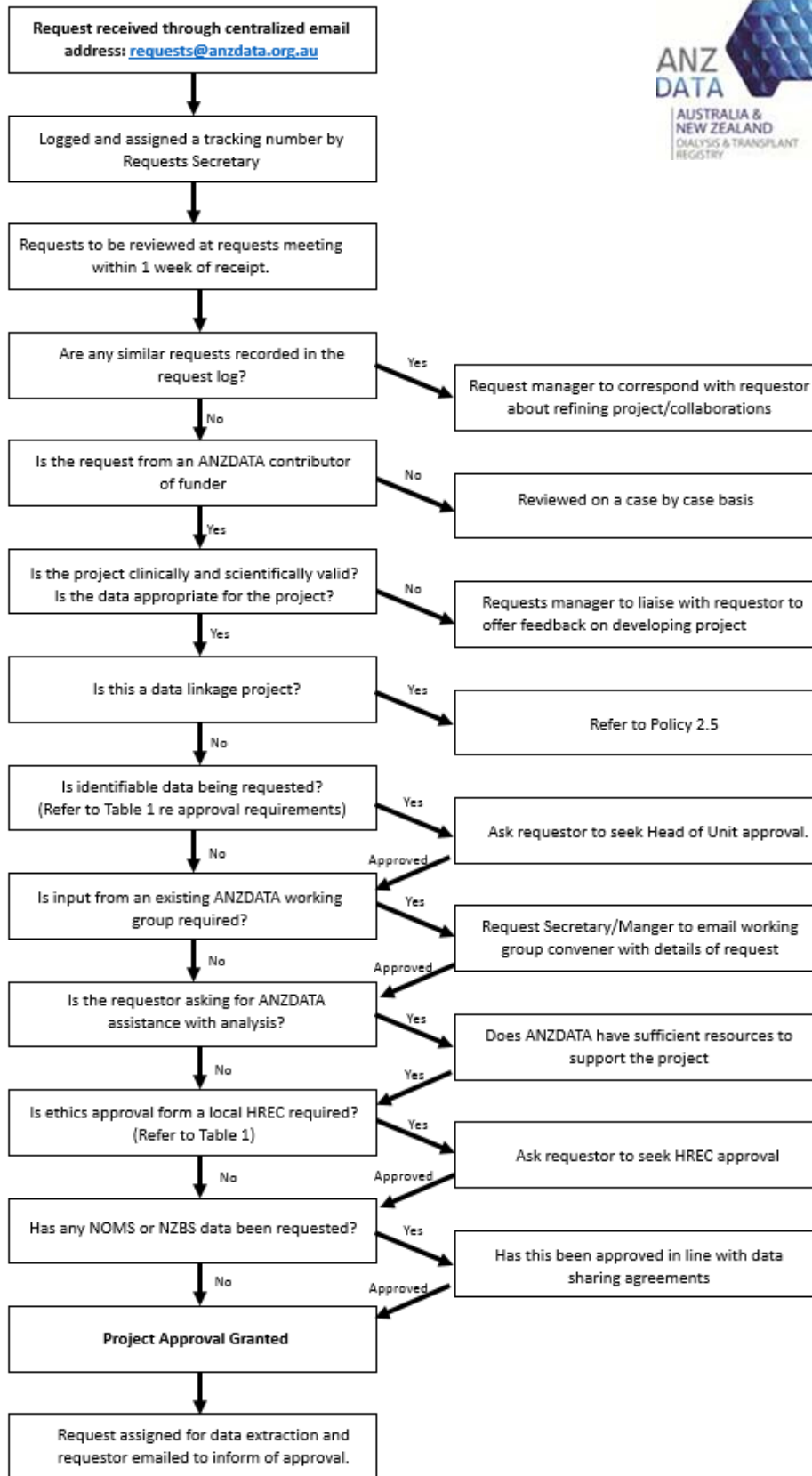


Table 1: Table 1: Approvals required by request type

	Head of Unit Approval	Local HREC Approval	NOMS / NZTLT / Baxter Approval	Executive Approval⁺
<u>Publicly available data</u>				
<i>Data already published by ANZDATA</i>	No	No	No	No
<u>De-identified data</u>				
<i>Tabular summary data (to State level)</i>	No	No	No	Yes
<i>Single line data</i>	No	No	No	Yes
<u>Identifiable data</u>				
<i>Tabular summary data (centre identified)</i>	Yes - if sensitive	No	No	Yes
<i>Single line data (centre identified)</i>	Yes - if sensitive	Yes - if research	No	Yes
<i>Single line data (patient identified)</i>	Yes	Yes - if research	No	Yes
<u>NOMS/NZBS/Baxter Healthcare data</u>				
<i>Tabular summary data</i>	No	No	Yes*	Yes
<i>Single line (de-identified)</i>	No	Yes	Yes*	Yes
<i>Single line data (identified)</i>	Yes	Yes	Yes	Yes
<u>Data Linkage</u>				
<i>Research Project</i>	No	Yes	No	Yes –Full

*De-identified NZBS data relating to fact and date of wait-listing for transplantation does not require NZTLT approval prior to data release

+Except in the case of data-linkage requests, executive approval may be delegate to the requests manager

3.0 Definitions

Box 1: List of ANZDATA contributors and funders

Contributors:

- Nephrologists caring for patients within the registry
- Transplant surgeons caring for patients within the registry
- Renal and transplant nurses caring for patients within the registry

Funders

- Kidney Health Australia
- Australian and New Zealand Society of Nephrology
- Organ and Tissue Authority, Australia
- New Zealand Ministry of Health.

Indirect funders

- State and Federal departments of health

Box 2: Identifiable variables

Variables considered identifiable data

- Hospital name/code
- Surname
- Given name
- Date of birth
- ANZDATA ID number
- Hospital Medical Record Number

Variables consider potentially identifiable data (avoid release unless essential for project, does not require head of unit approval)

- Postcode

Box 3: List of current ANZDATA working groups

- Indigenous Health Working Group
- Paediatric Working Group
- Peritoneal Dialysis Working Group
- Haemodialysis Working Group
- Transplantation Working Group
- Patient Reported Outcomes Measures (PROMs) Working Group
- New Zealand Working Group

Box 4: Request statuses to be updated in log file and online:

- Received
- For Approval
- Awaiting Response from Requestor
- Awaiting Working Group Review
- Awaiting Executive Review
- Awaiting local HREC Approval
- Awaiting NOMS Approval
- Awaiting NRTL Approval
- Awaiting Baxter Healthcare Approval
- Awaiting Other External Approval
- On Hold
- Extract
- Identity Variables Extract
- Clinical Variables Extract
- Completed

4.0 Exhibits / Appendices / Forms

Appendix A: Request approval letter template

Appendix B: Confirmation of request receipt template



ANZDATA Registry
C/O SAHMRI, PO Box 11060
SAHMRI Building, Level 4 South, North Terrace
Adelaide, South Australia 5001
Ph: +61 8 8128 4758 | Fax: +61 8 8128 4769

5.0 Document History

Revision	Date	Description
2017.1	21/09/2017	Creation
2019.1	14/02/2019	Updated the 'approval process' section, Table 1 and Box 4 to reflect the linkage of Baxter Healthcare data



ANZDATA Registry
C/O SAHMRI, PO Box 11060
SAHMRI Building, Level 4 South, North Terrace
Adelaide, South Australia 5001
Ph: +61 8 8128 4758 | Fax: +61 8 8128 4769

Appendix A: Request approval letter template

Dear {Requestor},

Thank you for your data request to ANZDATA for your project {Project Title}.

Your request has been given the Request ID {ID number}, please note this number and quote it in any correspondence with ANZDATA for tracking purposes.

This request was reviewed on {Date} and has been approved for data release.

The extraction of your data has been assigned to {ANZDATA staff member}. Simple data requests will usually be completed within 7-14 days, however, more complex request may have a longer turnaround time.

Please find attached a data usage agreement that outlines the terms of use for {ANZDATA/ANZOD} data. We would appreciate if you could read sign and return this form via email.

Please do not hesitate to contact us at requests@anzdata.org.au if you have any questions or require further information.

Kind regards,



ANZDATA Registry
C/O SAHMRI, PO Box 11060
SAHMRI Building, Level 4 South, North Terrace
Adelaide, South Australia 5001
Ph: +61 8 8128 4758 | Fax: +61 8 8128 4769

Appendix A: Request approval letter template

Dear {Requestor},

Thank you for your data request to ANZDATA for your project {Project Title}.

Your request has been given the Request ID {ID number}, please note this number and quote it in any correspondence with ANZDATA for tracking purposes.

This request was reviewed on {Date},

{the request has been forwarded to our *** working group for comment and to ensure there is no overlap with current ANZDATA projects}

or

{Some additional information is required before the data can be approved for release ...}

or

{This project will require local HREC approval prior to data release ...}

or

{... etc.}

Please do not hesitate to contact us at requests@anzdata.org.au if you have any questions or require further information.

Kind regards,