icnarc intensive care national audit & research centre

Napier House
24 High Holborn
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Request for patient-level data

This form is for patient-level data only, which contains sensible information about individuals and can be identifiable, pseudonymised or anonymised. Please refer to this tool for guidance about classifying patient-level data and what information to include in this form.

Please note that, as an independent research organisation and registered charity, ICNARC provides data services on a cost-recovery basis and is generally unable to support unfunded requests. Requests for patient-level data will incur a charge based on the nature and complexity of the request. All requests are passed to the Data Access Committee for approval and prioritisation.

Please note that deadlines of less than six weeks are unlikely to be met. We urge all requests to be made well in advance of personal deadlines to avoid disappointment.

Completing this form:

- All information must be added to this form and not in an accompanying document or email(s)
- Be as specific as possible; the form expands to allow more information to be entered
- Once completed, email form to **data@icnarc.org**

ICNARC Office Use Only:			
Application Date:		**Application Reference:**	
Review Date:		**Approval Date:**	

YOUR DETAILS	
Name	
Job title	
Unit / Hospital / Organisation	
Contact telephone	
Contact email	

YOUR REQUEST	
What is the purpose of the request?	

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Is this a new request or is it related to a previous request?	New ☐ Related ☐ (Ref)
What is your target date for delivery?	/ /
Any further info about your timelines	
Will you require periodic refreshes of the data? If yes, how often?	

YOUR PROJECT	
Title of the Project	
Lay Summary of the Project	
Technical Summary of the Project	
Expected Public Benefit	
Funding	

EXTRACT SPECIFICATION	
What level of identifiability are the data you are requesting?	☐ Patient identifiable data ☐ Pseudonymised patient-level data ☐ Anonymised patient-level data only
Which dataset do you require aggregate analysis of?	☐ Case Mix Programme (CMP) ☐ Irish National Intensive Care Unit Audit (INICUA) ☐ National Cardiac Arrest Audit (NCAA) ☐ Something else, e.g. a research project or clinical trial:
Which countries should be included in the aggregate data?	☐ All available Or, specific countries: ☐ England ☐ Wales ☐ Northern Ireland ☐ Scotland (NCAA only) ☐ Republic of Ireland (INICUA only)
Which sites (e.g. critical care units or hospitals) should be included?	☐ All participating sites (note: for clinical audit data, participating non-NHS sites will be excluded by default) ☐ Specific types of site (e.g. critical care units providing Level 3 care) (please specify criteria): ☐ Specific site(s) If specific sites, please list site names, ICNARC ID numbers (e.g. ICNNO for critical care units or NCAANO for hospitals), or ODS codes:
What date restriction should be applied?	/ / to / /

Which patients should be included?	☐ All patients (or admissions, team visits, etc) ☐ Specific patients (please specify inclusion/exclusion criteria):
Would you like the extract to include records that are incomplete or undergoing validation?	☐ No – validated records only ☐ Yes – include records that are incomplete or undergoing validation
What fields (variables) would you like included in your extract? (please list)	
Is any data linkage to other data sources required?	☐ Yes ☐ No
If yes, describe all data flows (or attach a detailed data flow diagram)	
If yes, who will conduct the data linkage	☐ ICNARC ☐ Another organisation (please identify):
If ICNARC will conduct data linkage, list any identifiers that will be provided	
If relevant, describe your desired linkage algorithm	

Lawful bases	
Lawful basis – common law duty of confidentiality (CLDC)	☐ Consent ☐ Section 251 ☐ Other ☐ N/A
Selected CLDC Lawful basis justifying documents	☐ HREC approval ☐ CAG approval ☐ Other ☐ N/A
Lawful basis – UK GDPR Article 6	☐ (a) Consent – The data subject has given consent to the processing for an agreed purpose ☐ (b) Contract – Processing necessary for the performance of a contract ☐ (c) Legal obligation – Processing is necessary for compliance with a legal obligation ☐ (d) Vital interests – processing is necessary to protect the vital interests of the data subject ☐ (e) Public task - processing is necessary for the performance of a task in the public interest ☐ (f) Legitimate interests – processing is necessary for the purposes of the legitimate interests pursued by the controller. ☐ N/A – request is for fully anonymised data only

Selected Article 6 Lawful basis justification	
Lawful basis – UK GDPR Article 9	☐ (a) Consent- the data subject has given explicit consent to the processing of those personal data for one or more specified purposes, ☐ (b) Legal obligation - processing is necessary for the purposes of carrying out the obligations and exercising specific rights of the controller ☐ (c) Vital interests -processing is necessary to protect the vital interests of the data subject or of another natural person where the data subject is physically or legally incapable of giving consent; ☐ (d) Legitimate activities - processing is carried out in the course of its legitimate activities with appropriate safeguards by a foundation, association or any other not-for-profit body with a political, philosophical, religious or trade union aim and ☐ (e) Manifestly public - processing relates to personal data which are manifestly made public by the data subject; ☐ (f) Legal claims - processing is necessary for the establishment, exercise or defence of legal claims or whenever courts are acting in their judicial capacity; ☐ (g) Substantial public interest - processing is necessary for reasons of substantial public interest, ☐ (h) Preventive or occupational medicine - processing is necessary for the purposes of preventive or occupational medicine ☐ (i) Public health - processing is necessary for reasons of public interest in the area of public health ☐ (j) Scientific research - processing is necessary for archiving purposes in the public interest, scientific, statistical or historical research purposes ☐ N/A – request is for fully anonymised data only
Selected Article 9 Lawful basis justification	

YOUR SETTINGS	
What method of transfer of information is proposed?	
What measures are in place to protect and use the information securely and confidentially?	
What type of security assurance does your organisation have in place?	
Details of your organisation as data controller?	
Who else will have access to this information?	

YOUR OUTPUTS	
Will the information be used in a publication?	Yes ☐ No ☐
Will the information be used in a presentation?	Yes ☐ No ☐
Please state the date until which the data will be retained	
Date information to be destroyed	

Guidance for completing the form

YOUR DETAILS	
Name	Please insert your full name
Job title	Job title is the name of the position the applicant holds within their organisation
Unit / Hospital / Organisation	Please give the full name of the organisation on whose behalf you are making the application or within which you work in your professional capacity as an applicant. This should include a parent organisation, and sub-division or department if appropriate (for example University of Edinburgh, Department of Informatics)
Contact telephone	Please include a contact telephone number that the applicant can be contacted on
Contact email	Please include a work email address that the applicant can receive communications through. Personal email is not valid.

YOUR REQUEST	
What is the purpose of the request?	Please provide any background information explaining the reason for this request and how the information will be used to support local quality improvement.
Is this a new request or is it related to a previous request?	The application can be a completely new application, an extension, a renewal or amendment. For extensions, renewals or amendments, please provide an original application reference number.
What is your target date for delivery?	Please provide the date by which you would like to receive the data. Please provide the date in the format dd/mm/yyyy.
Any further info about your timelines	Please add more information explaining the date provided above.
Will you require periodic refreshes of the data? If yes, how often?	Please indicate if data refreshers will be required. Please indicate how often data refreshes will be needed (i.e. every 6 months)

YOUR PROJECT	
Title of the Project	Please insert the title of your project
Lay Summary of the Project	Please provide a concise and clear description of the project, (e.g., as required by URKI in funding applications). It should outline the problem, objectives and expected outcomes in language that is understandable to the general public
Technical Summary of the Project	Please provide a summary of the proposed research, in a manner that is suitable for a specialist reader
Expected Public Benefit	Please provide a description in plain English of the anticipated outcomes, or impact of project on the general public
Funding	Please give details about the funding to carry out the analyses requested

EXTRACT SPECIFICATION

What level of identifiability are the data you are requesting?	Please confirm what type of data you require – identifiable, pseudonymised or anonymised. Please refer to our guide to applying for data for more information.
Which dataset do you require aggregate analysis of?	Please tick all datasets that apply and/or provide the specific project(s) or trial(s) required if necessary
Which countries should be included in the aggregate data?	Please tick countries that apply and/or select all available data if necessary
Which sites (e.g. critical care units or hospitals) should be included?	Please tick the relevant level of information required and indicate the types of care units or specific sites required if necessary
Date range of required analyses / data?	Please include dates of the period of the datasets you propose to access. Please provide the dates in the format dd/mm/yyyy
Which patients should be included?	Please provide a description of precisely the criteria which define the patients to be included and to be excluded from the data extract you are requesting
Would you like the extract to include records that are incomplete or undergoing validation?	Records that are incomplete or undergoing validation may be suitable for some purposes, for example early reporting of outcomes for clinical trials.
What fields (variables) would you like included in your extract?	Please provide a detailed list of all the fields (variables) that you require
Is any data linkage to other data sources required?	Please confirm whether or not you require a linkage to other data sources by ticking the relevant box.
If yes, describe all data flows (or attach a detailed data flow diagram)	Please provide a description of all the data flows as detailed as possible, and/or provide a detailed data flow diagram as an attachment
If yes, who will conduct the data linkage	Please indicate which organisation will produce the linkage
If ICNARC will conduct data linkage, list any identifiers that will be provided	Please provide a detailed list of all the identifiers that you will provide us for the linkage production
If relevant, describe your desired linkage algorithm	Please provide a description of the algorithm you would like to be used for the linkage production
Lawful bases	
Lawful basis – common law duty of confidentiality (CLDC)	At least one legal basis must apply whenever you process personal data. Please select the appropriate CLDC lawful basis. Processing shall be lawful only if, and to the extent, that at least one of the following applies. Further information regarding the common law duty of confidentiality can be found on the NHS England webpage
Selected CLDC Lawful basis justifying documents	Please indicate what evidence you will provide to support your stated legal basis for processing data under CLDC

Lawful basis – UK GDPR Article 6	At least one legal basis must apply whenever you process personal data. Please select the appropriate Article 6 lawful basis. Processing shall be lawful only if, and to the extent, that at least one of the following applies. More information for identifying a suitable lawful basis may be found on the HRA Website Further details regarding the lawful basis can be found on the ICO website
Selected Article 6 Lawful basis justification	Please detail your justification for the selected lawful basis
Lawful basis – UK GDPR Article 9	At least one legal basis must apply whenever you process personal data. Please select the appropriate CLDC lawful basis. Processing shall be lawful only if, and to the extent, that at least one of the following applies. 'Special category' personal data is: ● data which reveals racial or ethnic origin, political opinions, religious or philosophical beliefs, trade union membership ● data concerning health (the physical or mental health of a person, including the provision of health care services) ● data concerning sex life or sexual orientation ● genetic or biometric data processed to uniquely identify a natural person. Further information regarding the legal basis for processing special category data can be found on the ICO website
Selected Article 9 Lawful basis justification	Please detail your justification for the selected lawful basis

YOUR SETTINGS	
What method of transfer of information is proposed?	Please indicate the method of data transfer which you would like to use for sending and receiving data files
What measures are in place to protect and use the information securely and confidentially?	Please, provide the information on how the received data will be protected and used securely. Examples of information that may help you answer this question, include information on relevant policies/procedures relating to information security, staff training, and information regarding the computing and physical environment that the shared data will be stored/accessed in
What type of security assurance does your organisation have in place?	Please provide the following details about your organisation security assurance: - For Data Security and Protection Toolkit – organisation code, score, version completed - For ISO 27001 – certificate
Details of your organisation as data controller?	Please provide the following details about your organisation as data controller: - ICO registration number - Registration expiration date - Registered address
Who else will have access to this information?	Please list all people who will have access to the data

YOUR OUTPUTS

Will the information be used in a publication?	Please tick your answer and include details and dates of any planned publication
Will the information be used in a presentation?	Please tick your answer and include details and dates of any planned presentation
Please state the date until which the data will be retained	Please confirm how long you intend to retain the data relating to your proposal.
Date information to be destroyed	Please provide a date when the data will be destroyed. A written declaration confirming data destruction must be provided to ICNARC upon reaching this date.

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24 High Holborn
London WC1V 6AZ
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email icnarc@icnarc.org

ICNARC INFORMATION SHARING AGREEMENT

This Agreement is between the

1. Intensive Care National Audit & Research Centre (ICNARC) whose registered address is Napier House, 24 High Holborn, London WC1V 6AZ;

AND

(1) Applicant Name: Organisation Name, Function/Role of Organisation of Registered Address of Organisation;

AND

(2) Applicant Name: Organisation Name, Function/Role of Organisation of Registered Address of Organisation

Which collectively hereafter referred to as "Parties" and Party/Parties 2 and 3 collectively referred to as "Applicant(s)"

RECITALS:

A. WHEREAS ICNARC is a non-profit organisation, an independent registered charity (charity number: 1039417) and a Company limited by Guarantee, without shareholders, established to provide a national audit of patient outcome from critical care.

B. WHEREAS [Name of Applicant 1] is the [role on project which application is for] for the study entitled " ".

C. WHEREAS [Name of Applicant 2] is the [role on project which application is for] for the study entitled " ".

D. WHEREAS the Applicants wish to request Data ("Data" as defined in the Request for analyses / data form) from ICNARC for data extract/analysis of the Trial/Study/CMP audit (the "Purpose")

E. ICNARC will grant controlled access to data and information to the Applicant(s) on the terms set out in this Information Sharing Agreement.

IT IS AGREED between ICNARC and the Applicant(s) that the information provided in the Form will form part of this Agreement, and:

1. The Applicant(s) agree to the following:

a) to process the Shared Data only for the purposes outlined in the Form;
b) that use of the Shared Data is limited only to what is necessary for the completion of the project as described in the Form;
c) that at the expiration of this agreement, all Shared Data and any copies made thereof will be irreversibly destroyed from all devices where the data were stored and shall declare such destruction in writing to ICNARC;
d) to abide by the Caldicott Principles and all the requirements of Data Protection Laws with respect to the Shared Data as necessary.

2. The Applicant(s) shall ensure that a data protection impact assessment (DPIA) has been conducted for the data requested.

3. The Applicant(s) shall ensure that appropriate technical and organisational measures are taken against unauthorised or unlawful processing of all Shared Data and against deliberate or accidental loss or destruction of, or damage to, Shared Data and in keeping the Shared Data secure and confidential. Such measures include appropriate controls on access and training for anyone who has access to the Shared Data. The Applicant(s) will immediately notify ICNARC of any such unauthorised or unlawful processing, or deliberate or accidental loss or destruction of, or damage to the Shared Data.

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4. Where ICNARC agrees to share Shared Data with the Applicant(s), the parties acknowledge that they be separate Controllers, i.e. not Joint Controllers with ICNARC, with respect to any Shared Personal Data. The Applicant(s) shall comply with their obligations under the Data Protection Laws, as Controllers, in respect of Processing of the Shared Personal Data, including compliance with any individual rights' received.

5. Any material breach of the Data Protection Laws by the Applicant(s) shall give grounds to ICNARC to terminate this Agreement on notice. The Applicant(s) shall indemnify ICNARC against all liabilities, costs, expenses, damages and losses suffered or incurred by ICNARC arising out of or in connection with the breach of the Data Protection Laws by the Applicant(s), its employees or agents.

6. For the purposes of this Agreement:

a) "Controller", "Joint Controller", "Personal Data" and "Processing" have the same meaning as described in the Data Protection Laws;
b) "Data Protection Laws" means all legislation and regulatory requirements in force from time to time relating to the use of personal data and the privacy of electronic communications, including, without limitation (i) any data protection legislation from time to time in force in the UK including the Data Protection Act 2018 or any successor legislation, as well as (ii) UK GDPR as amended by The Data Protection, Privacy and Electronic Communications (Amendments etc) (EU Exit) Regulations 2019 and (iii) the Common Law Duty of Confidentiality;
c) "Shared Data" means the data set out in the Data Request Specification section of the Request for Analyses/Data Form;
d) "Shared Personal Data" means any "Personal Data" found in the "Shared Personal Data";
e) "Form" the Request for Analyses / Data form above.

7. The Applicant(s) shall preserve the confidentiality of information and Shared Data pertaining to study/audit participants, and in particular:

a) not use, or attempt to use, the Shared Data to compromise or otherwise infringe the confidentiality of information on participants or their right to privacy;
b) not attempt to identify any individual (living or dead) from the data, or attempt to make any such identification; and
c) match or link the data to any other source of information, unless agreed by ICNARC beforehand in writing.

8. The Applicant(s) will not attempt to establish the identity of, or communicate with, any of the study/audit participants or any individual derived from the Shared Data. You agree not to attempt to link the Shared Data provided under this agreement to other information, even if access to that Shared Data has been formally granted to you, without specific permission being sought from ICNARC.

9. The Applicant(s) shall not transfer or disclose the Shared Data, in whole or part, to any third party outside the team listed in the attached form. The Applicant(s) will require anyone listed in the team who utilises these Shared Data to comply with the terms of this agreement.

10. The Applicant(s) will acknowledge ICNARC in any publication arising from the use of these data using the following wording:

    "This publication is based on data derived from the Intensive Care National Audit & Research Centre (ICNARC) Case Mix Programme Database. The Case Mix Programme is the national, comparative audit of patient outcomes from adult critical care coordinated by ICNARC. We thank all the staff in the critical care units participating in the Case Mix Programme. For more information on the representativeness and quality of these data, please contact ICNARC. Disclaimer: The views and opinions expressed therein are those of the authors and do not necessarily reflect those of ICNARC"

11. The Applicant(s) will contact ICNARC if any safety concerns are identified during the project.

12. The Applicant(s) accept that, if the conditions relating to the release of Shared Data as per the terms specified by ICNARC are knowingly disregarded, that this will be considered a serious offence and could result in further action being taken by ICNARC.

13. The Applicant(s) warrant and represent to ICNARC that they have full authority, power and capacity to enter into this Agreement.

14. The Applicant(s) understand that research using the Shared Data should be published according to the publication plan described in the data access request form.
15. The Applicant(s) do not require ICNARC review or approval for publication of research outputs, provided that outputs do not identify individual patients or healthcare service providers (identification of individual patients in research outputs is generally prohibited by information governance regulations; identification of healthcare service providers may be permitted subject to specific approval by ICNARC). The Applicant(s) will send one draft copy of any proposed publication or presentation arising from the Shared Data to ICNARC at the same time as submission for publication or at least 28 days before the date intended for publication/presentation, whichever is earlier. Upon acceptance for publication, the Applicant(s) will send one copy of the accepted version and, upon publication, one copy of the final published version and DOI.

16. Both parties acknowledge their respective lawful bases for processing the Shared Data: for ICNARC, these are set out in its privacy notice: www.icnarc.org/About/Information-Standards/Information-Security/Privacy-Policy; for the Applicant(s), these are set out in the respective section of the Request for Analyses / Data form.

17. The Applicant(s) acknowledge that all matters concerning the interpretation of this form and the resolution of any dispute arising from it will be determined by ICNARC.

18. The Applicant(s) confirm that the information provided in this form is accurate, correct and complete at the time of submission and any documents provided with this application form are genuine. The Applicant(s) agree to inform ICNARC of any changes to the information provided in this form immediately and respond to any requests for clarification from ICNARC, including any reviews of this agreement, in a timely fashion.

Signatories and Sign-Off:

Information Sharing Agreement Applicant Signatures			
Applicant Name (1):	Click or tap here to enter text.	**Applicant Role:**	Click or tap here to enter text.
Applicant Organisation:	Click or tap here to enter text.		
Applicant Signature:	Click or tap here to enter text.	**Date:**	Click or tap to enter a date.
Applicant Name (2):	Click or tap here to enter text.	**Applicant Role:**	Click or tap here to enter text.
Applicant Organisation:	Click or tap here to enter text.		
Applicant Signature:	Click or tap here to enter text.	**Date:**	Click or tap to enter a date.

ICNARC Office Use Only:			
Initial Information Sharing Agreement Sign-Off			
Application Reference:	Click or tap here to enter text.		
Information Sharing Agreement Start Date:	Click or tap to enter a date.	**Information Sharing Agreement End Date:**	Click or tap to enter a date.
ICNARC Representative Name:	Click or tap here to enter text.	**ICNARC Representative Role:**	Click or tap here to enter text.
ICNARC Representative		**Signature Date:**	

Signature:			

Amendment to Information Sharing Agreement Sign-Off			
Application Reference:	Click or tap here to enter text.		
Amendment Number:	Click or tap here to enter text.	**Amendment Request Date:**	Click or tap to enter a date.
Amendment Reason: (also specify the relevance to and impact on the data you have requested)	Click or tap here to enter text.		
Applicant Name (1):	Click or tap here to enter text.	**Applicant Role:**	Click or tap here to enter text.
Applicant Organisation:	Click or tap here to enter text.		
Applicant Signature:	Click or tap here to enter text.	**Date:**	Click or tap here to enter text.
Applicant Name (2):	Click or tap here to enter text.	**Applicant Role:**	Click or tap here to enter text.
Applicant Organisation:	Click or tap here to enter text.		
Applicant Signature:	Click or tap here to enter text.	**Date:**	Click or tap here to enter text.
Once complete, please email this form to data@icnarc.org			

ICNARC Office Use Only:			
Information Sharing Agreement Amendment Approval Date:		**New Information Sharing Agreement End Date:**	
ICNARC Representative Name:		**ICNARC Representative Role:**	
ICNARC Representative Signature:		**Signature Date:**	