Policy Title	**NOCA Research Data Access Policy** **(Access to Anonymous and De-identified Data for Research Purposes)**		
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Approved by	**NOCA Governance Board**		
Issue Date	**December 2015**	**Review Date**	
Version	**2.14**		

Policy Title	**NOCA Policy on Access to Anonymous and De-identified Data for Research Purposes**		
Issue Date	**December 2015**	**Review Date**	
Version	**2.14**		
Changes	**Section 1: Policy Statement of Research in NOCA** **Section 2: Scope of Policy – Focus on data requests for research purposes** **Section 4: Glossary of Terms and Definitions – New Section** **Section 6: Procedures for Submitting a Request for Data – Process updated** **Appendix 1: List of Research Ethics Committees** **Appendix 2: Process flow - Process updated** **Appendix 3: National Office of Clinical Audit (NOCA) Release of Data for Research Form** **Appendix 4. Acknowledgement of the National Office of Clinical Audit** **Appendix 5. HSE Risk Matrix** **Appendix 6 – Release of data by NOCA for research**		

NOCA Policy on Access to Data for Research Purposes

1.0 Policy Statement

The National Office of Clinical Audit (NOCA) encourages high quality research within an ethical framework designed to improve clinical care provided to patients. This will encompass a wide range of activities such as

- Primary research led by the National Office of Clinical Audit
- Collaborative research with other national and International research partners
- Facilitation of access to data routinely collected for clinical audit for analysis.

NOCA will authorise access to clinical audit data for purposes of research. This may be done by NOCA alone or in collaboration with audit processors, whom NOCA work with to provide national clinical audit.

All requests for access to data for research purposes are managed equitably, through the same process, whether the request comes from NOCA internally or from an external source. Access to clinical audit data for research purposes will ***only*** be granted when audit data has been reported at a national level. All requests for data for research purposes are considered by the Individual audit governance committees and the NOCA Governance Board.

In supplying data, NOCA complies with its obligations under the Data Protection Acts (1988 /2003) and the HSE National Consent Policy (HSE, 2013). The applicant will ensure that ethical approval has been received or written confirmation from a Research Ethics Committee (REC) that approval is not required for the research proposal.

NOCA aims to be transparent in its decision-making process; details of projects for which access has been granted will be published on the NOCA website.

2.0 Scope of this Policy

This document refers only to the access to clinical audit data by researchers. Distinct policies will be developed for both primary research led by NOCA and collaborative research with NOCA.

Inclusions

This policy includes requests for access to both anonymous and de- identified data. This policy covers all NOCA audits with the exception of the National Perinatal Epidemiology Centre (NPEC). NPEC has established processes for managing access to data for research purposes (NPEC,2013).

Exclusions

This policy does not cover

- Inquiries by the press and public for general information,
- Freedom of Information requests
- Requests for access to data for service provision and quality initiatives,
- Requests for data from industry for post market surveillance.

Such requests are managed by distinct policies.

3.0 Purpose

This policy document defines the process by which access will be granted to clinical audit data managed by NOCA for research purposes.

Requests will be considered only from individuals affiliated with an education, healthcare or other research institution. A meeting or consultation with the requester may be required if there are any questions or reservations about the release of data.

4.0 Glossary of Terms and Definitions

Aggregate Data	This is data which is analysed in greater detail than available in any reports and is not routinely published by NOCA. This type of information will not routinely allow direct identification of individuals or hospitals.
Anonymous Data	Data collected without identifiers such as name, address or date of birth and that can never be linked to an individual (HSE, 2013)
Archival Data	Data that was previously accumulated for another purpose, such as clinical practice, research or clinical audit (HSE, 2013). This is also known as secondary use of information (HIQA, 2013)
Audit processor	Organisation to whom audit data is submitted and who analyses the audit data for national clinical audit.
Clinical Audit	A clinically led, quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and to act to improve care when standards are not met (DOH, 2008)
Conflict of Interest	A' set of circumstance that creates a risk that professional judgement or actions regarding a primary interest will be unduly influenced by a secondary interest' (Institute of Medicine, 2009, P. 46)
De-identified Data	Data are separated from personal identifiers, for example, through the use of a link, e.g a code. Access to the link is strictly controlled. As long as a link exists, data are considered indirectly identifiable as opposed to being anonymous (HSE, 2013)
Research	Systematic inquiry that uses disciplined methods to answer questions or solve problems. The purpose of clinical research is to develop, refine and expand the base of knowledge (Polit & Beck, 2006).
Record Level data	Record level data contain information about a unit of observation (HPO,

	2015). Where this data refers to an individual this is sensitive data and this will be anonymised prior to release. Anonymised record level data is intended for specialist users such as research.

5.0 Responsibilities

5.1 NOCA Manager

The NOCA manager is represented at each individual audit Clinical Governance Committee by the identified Audit Coordinator

The NOCA Manager is responsible for the implementation of adopted policies relating to data access and for staff compliance with these policies.

5.2 NOCA Audit Clinical Governance Committees

Each Individual Audit Clinical Governance Committee is responsible to

- Evaluate requests for data access for research. This will result in a recommendation to approve or reject the request or request for further information or clarification.
    - Requests for access to data will only be considered following review by an ethics committee. Research projects will require ethical approval or written confirmation that approval is not required from a recognised research ethics committee (REC) or from an identified unrecognised REC (See Appendix 1).
    - Formulation of feedback to applicant detailing reason for rejection
- Engage with the research applicant on the progress of the research projects.

Additionally, Audit Clinical Governance Committees meet quarterly and requests for access to data for research are a standing agenda item at each meeting.

5.3 NOCA Governance Board

The NOCA Governance Board is responsible for approval or refusal of access to data for research purposes, following recommendation from the Individual NOCA Governance Committees.
Should an applicant have received approval from another REC (hospital and/or local) which is not identified in this policy, a decision on whether to accept this will only made by the Chair of the NOCA Governance Board.

Additionally, the NOCA Board meets quarterly and requests for access to data for research are a standing agenda item at each meeting. Following these NOCA Board meetings, NOCA will publish, on its website, a register of approved projects.

5.3.1 The NOCA Governance Board Data Appeals Committee

A single Ad Hoc Appeals Committee shall be established by the NOCA Governance Board to hear appeals arising from the decisions relating to requests on access to data from NOCA. The membership of the Ad Hoc Appeals Committee shall be as follows:

- Chair of the NOCA Governance Board or Nominee
- HSE Quality Improvement representative or Nominee
- Public / Patient representative.

The members of the NOCA Governance Board Data Appeals Committee cannot have adjudicated on the data request under appeal.

5.4 NOCA Audit Co-Ordinator/ NOCA Administrator

The NOCA Administrator will confirm receipt of all requests for data access, log requests, and support this process.

Each Individual Audit Co-ordinator is responsible for ensuring that all requests meet the relevant criteria, and for processing requests expeditiously. Requests which do not meet the criteria can be returned with suggestions for change.

The NOCA Administrator will maintain the Data Request Log.

5.5 The Applicant

The applicant is responsible to ensure that ethical approval has been received or written confirmation from a Research Ethics Committee (REC) that approval is not required for the research proposal. Refer to Appendix 1 to list of REC.

The applicant can submit contemporaneous applications to the REC and request for access to data the individual Audit Clinical Governance Committee for the research project. A copy of the submission to the REC is included in the application.

Data will be released to the applicant only when NOCA receives details of the decision by the REC. Research projects which have been amended after REC approval must be re-submitted to the Individual Audit Clinical Governance Committee for access to data.

The applicant is responsible to maintain confidentiality as outlined in the **Confidentiality and Data Release Agreement** (Section 7 of the **National Office of Clinical Audit (NOCA) Release of Data for Research Form** (Appendix 3).

The applicant is responsible to acknowledge the following in published or unpublished research papers;

- Hospital data coordinators / collectors in participating audits
- NOCA
- Audit processors.

Appropriate wording for this acknowledgement is provided in Appendix 4.

6.0 Procedures for Submitting a Request for Data

Who	Procedure	Output
Research Applicant	Request approval for access to data from NOCA by completing the "National Office of Clinical Audit (NOCA) Release of Data for Research Form"	"National Office of Clinical Audit (NOCA) Release of Data for Research Form" received by NOCA
Audit Co-ordinator / NOCA Administrator	Review the "National Office of Clinical Audit (NOCA) Release of Data for Research Form" to ensure all required data included. • All required fields relating to research request completed (Section 1-4). Research projects will require ethical approval (or written confirmation from a REC that approval is not required prior to release of Data from NOCA. • All required fields relating to Conflict of Interest (Section 5) must be completed. • All required fields relating to NOCA Data Access Policy)and the "Confidentiality Agreement for Data provided by the National Office of Clinical Audit" must be completed (Section 6) • The "National Office of Clinical Audit (NOCA) Release of Data for Research Form" must be dated and signed by the Applicant. The NOCA Administrator registers the request in the Data Request Log .	Completed "National Office of Clinical Audit (NOCA) Release of Data for Research Form" are compiled for the Individual Audit Clinical Governance Committee

Who	Procedure	Output
Audit Co-ordinator	The Audit Co-ordinator will contact the Applicant • Where there is incomplete or inconclusive information, • Where NOCA does not hold the requested information.	Further information received.
Individual Audit Clinical Governance Committee	The assessment criteria outlined below provide a framework for the assessment of requests for access to Individual Audit Clinical Governance Committee. The criteria will be used to inform the decision making process: Research projects will require ethical approval (or written confirmation for a REC that approval is not required (NOCA will process request forms with ethical review in progress. Data will only be released when confirmation of the REC decision is received by NOCA) • The individual/organisation can prove their ability to maintain the confidentiality and integrity of the data. • In the view of the Individual Clinical Governance Committee the benefits to accrue from the data use outweigh any potential risks. In the event of the identification of a risk each clinical governance committee will use a risk matrix (Appendix 5) to assess the risk • The extent to which the individual or organisation for which the individual works has a track record in the research field or experience in the analysis of large data files will be considered during the assessment process • The proposed usage of the outputs • The extent to which the outputs will serve the public good • The extent to which the proposed work/outputs supports/contributes to evidence-based policy-making	Data released to Applicant Data not released to applicant Request for further information from Applicant

Who	Procedure	Output
	Review of Applications for release of data can result in a recommendation to the NOCA Governance Board to • Release of data by NOCA • Release of data by Audit Processor • Request further information pending decision • Decline to release data.	
NOCA Governance Board	Approve the decision taken by the individual Audit Clinical Governance Committee Disapprove the decision taken by the individual audit clinical governance committee	Feedback to the individual audit clinical governance committee as required
Applicant	Should the receipt of data or analyses cause the Applicant to request further data or analyses, this will be processed as a new request. Applicants are therefore urged to consider listing all their data/analyses request needs at the start of the process and to ensure these are all included on the "National Office of Clinical Audit (NOCA) Release of Data for Research Form"	Further request to the individual Audit Clinical Governance Committee
Applicant	Should the individual Audit Clinical Governance Committee refuse to release data, the Applicant can seek to appeal this decision. NOCA provides a mechanism for appeal of data access decisions. Appeals must be made in writing to the NOCA Board Appeals Committee within 12 weeks of the date of the NOCA decision letter. The reasons for the appeal must be clearly stated. A copy of the original request for data access should also be attached. All decisions of the NOCA Governance Board Data Appeals Committee (i.e. uphold or reject the appeal) are final. Decisions of the NOCA Governance Board Data Appeals Committee hall be communicated in	Appeals process with input from NOCA Governance Board Data Appeals Committee

Who	Procedure	Output
	writing to the applicant and reported to the NOCA Governance Board.	
NOCA/ Audit Processor	Data will be released in electronic format. The file will be encrypted (See Appendix 6 – Release of data by NOCA) In certain circumstances, it will be necessary to charge a fee for the release of data in order to cover the costs to NOCA of preparing the data: such circumstances include when the amount of data processing is extensive NOCA will update the Data Request Log when data is released. This will be published on the NOCA website.	Applicant receive file.
Applicant	The applicant should provide a written summary / progress report of the work performed on data supplied by NOCA at regular 6 monthly intervals following receipt of the data. Each update should be received and reviewed by the individual audit co-ordinator no longer than 30 days after the period end. The audit coordinator will liaise with the Clinical lead and the individual Clinical Governance Committee if any further clarification is required. The purpose of this is to ensure appropriate interpretation of the data. All reports should be electronically submitted. Should the reports not be forthcoming or deemed unsatisfactory NOCA retains the right to allow applicants who have requested the same data, access to it for their own research purposes On completion of the project, a final written report will be sent to the NOCA Governance Committee within 3 months of the end date. NOCA reserves the right to request an update at any stage throughout the duration of the project where it is felt there is grounds and reason to do so. This final research report should include appropriate acknowledgements to include;	NOCA will receive progress and final report

Who	Procedure	Output
	• Hospital data coordinators / collectors in participating audits, • NOCA • Audit processor.	
Applicant	Destruction of Data • As recommended by the RCSI REC, Applicant destroys the data file within 5 years of receipt of the data OR • By the agreed timeframe arising from REC approval All versions of the data from NOCA or subsets thereof must be deleted/destroyed by the applicant and a confirmation email sent or returned to NOCA. After this point, access to the same data may be granted to others.	Destruction of data by the applicant.

References

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Data Protection Commissioner (2007) Data Protection Guidelines on research in the Health Sector,(Data Protection Commissioner: Mr. Billy Hawkes). Available at: http://www.dataprotection.ie/documents/guidance/Health_research.pdf (Accessed on: 17/06/2013).

Department of Health and Children. (2008) *Building a Culture of Patient Safety. Report of the Commission on Patient Safety and Quality Assurance.* Available at: http://www.cpsqa.ie/publications/ (Accessed on: 17/06/2015).

Healthcare Pricing Office (2015) Draft HPO Data Access Policy.(Personal Communication).

Health Services Executive (2011) Risk Assessment Tool and Guidance (Including guidance on application). Available at: http://www.hse.ie/eng/about/Who/qualityandpatientsafety/resourcesintelligence/Quality_and_Patient_Safety_Documents/riskmgmt.html (Accessed on 15/07/2015)

Health Services Executive (2013) National Consent Policy QPSD-D-026-1. V.1 (Chair: Dr Deirdre Madden), Available at: http://www.hse.ie/eng/about/Who/qualityandpatientsafety/Advocacy/National_Consent_Advisory_Group/consent.html (Accessed on; 17/06/2015)

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National Perinatal Epidemiology Centre (2013) Policy on Access to anonymised data for research purposes. (Personal Communication)

Polit, D. Beck, C. (2006) Essentials of Nursing Research, Methods, Appraisal and Utilisation (Sixth Edition). Philadelphia, USA: Lipincott, Williams and Wilkins.

Legislation

Data Protection Act, 1988, Act No.25 of 1988, Available at: http://www.irishstatutebook.ie/1988/en/act/pub/0025/index.html (Accessed on: 10/04/2015)

Data protection (Amendment) Act 2003 Act number 6 of 2003, Available at:

http://www.irishstatutebook.ie/2003/en/act/pub/0006/index.html (Accessed on: 10/04/2015)

S.I. No. 190/2004 - European Communities (Clinical Trials on Medicinal Products For Human Use) Regulations, 2004 Available at; http://www.irishstatutebook.ie/2004/en/si/0190.html (Accessed on: 16/07/2015).

Appendix 1: Research Ethics Committees

NOCA Audit Governance Committees will accept approval for research from the 12 currently recognised RECS (Recognised under Regulation 7 of European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004)

Recognised REC

Name of Ethics Committee	Address for correspondence
SJH/AMNCH Research Ethics Committee	Tallaght Hospital ,Dublin 24 – (01) 4142860
St Vincent's Healthcare Group Ethics and Medical Research Committee	Administrator, St Vincent's Healthcare Group Ethics and Medical Research Committee, Education and Research Centre, Elm Park, Dublin 4. – (01) 2774117
Clinical Research Ethics Committee of the Cork Teaching Hospitals	Secretariat, Clinical Research Ethics Committee of The Cork Teaching Hospitals, 1st Floor, Lancaster Hall, 6 Little Hanover Street, Cork – (021) 4901901
HSE North East Area Research Ethics Committee	Secretary, HSE North East Area Research Ethics Committee, Dublin Rd, Kells, Co. Meath – (046) 9280521/564
Research Ethics Committee, Mater Misericordiae University Hospital and Mater Private Hospital	Administrator, Research Ethics Committee, Mater Misericordiae University Hospital, Eccles Street, Dublin 7 – (01) 8032971
Beaumont Hospital Ethics Committee	Gillian Vale, Administrator, Ethics Committee, Beaumont Hospital, Beaumont Road, Dublin 9 – (01) 8092680
Galway Regional Hospitals Research Ethics Committee	Secretary Research Ethics Committee, Unit 4, Merlin Park Hospital, Galway. - (091) 775022
Research Ethics Committee, Our Lady's Children's Hospital, Crumlin.	Secretary Research Ethics Committee, Our Lady's Children's Hospital Crumlin, Dublin 12. – (01) 4096243/6307
Irish College of General Practitioners Research Ethics Committee	Administrator, ICGP Research Committee, 4/5 Lincoln Place, Dublin 2 – (01) 6763705
Ethics Research Committee, National Maternity Hospital	Ms Denise O'Brien, Secretary, Ethics Research Committee, Masters / CEO Office, National Maternity Hospital, Holles Street, Dublin 2 – (01) 6373100
HSE South-Eastern Area Research Ethics Committee	Secretary, Research Ethics Committee Office, Old School Of Nursing, Waterford Regional Hospital, Dunmore Road, Waterford – (051) 842391
Ethics Research Committee HSE Mid-Western Area	Secretary, Ethics Committee, Mid-Western Regional Hospital, Dooradoyle, Limerick – (061) 482482

Unrecognised REC

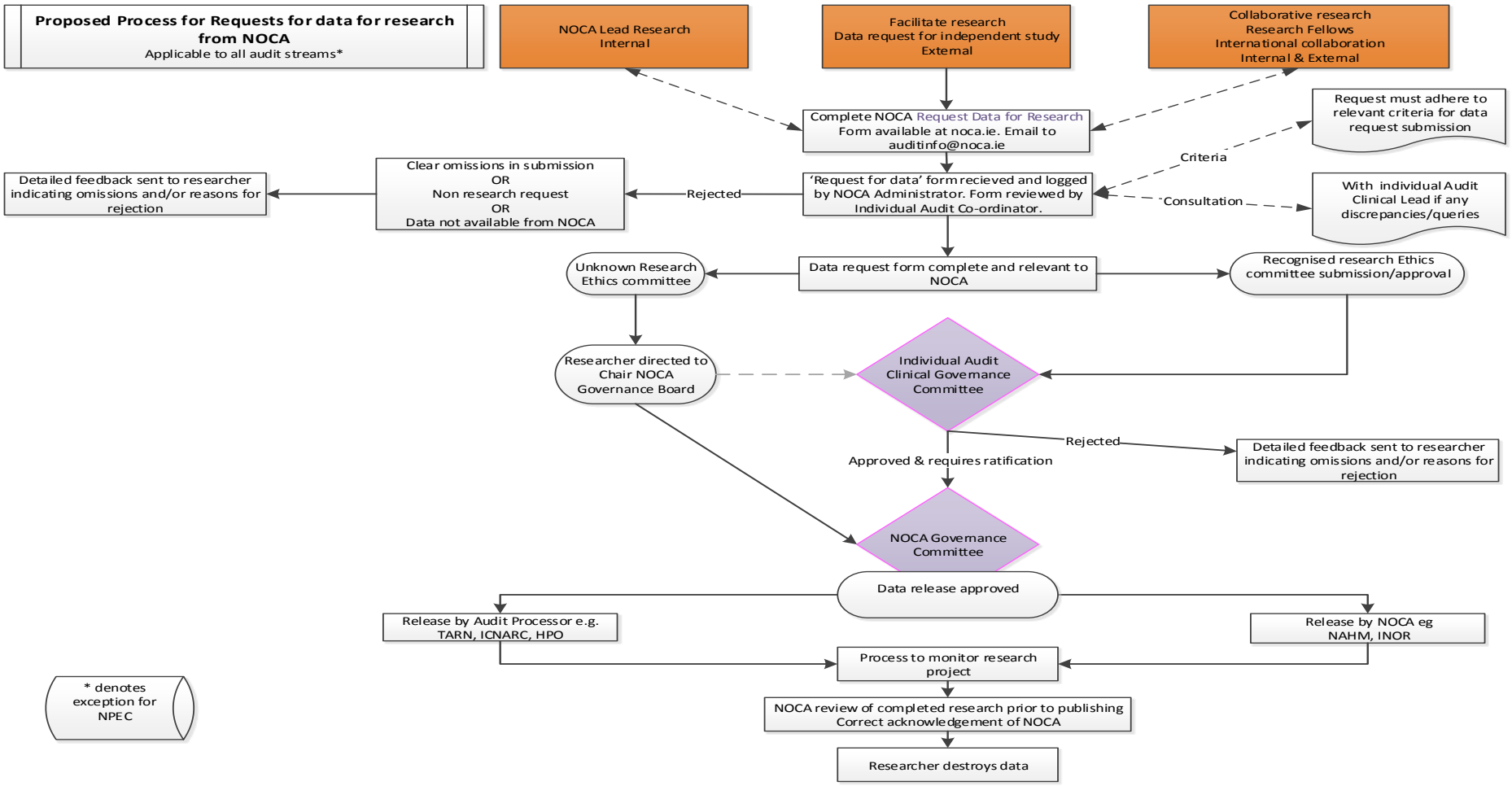
NOCA Audit Governance Committees will accept approval for research from the following un-recognised RECS.

Name of Ethics Committee
Connolly Hospital REC (RCSI Hospital Group)
Dublin City University Research Ethics Committee
Health Research Board Research Ethics Committee
NUI Maynooth Research Ethics Committee
NUI Galway Research Ethics Committee
Royal College of Surgeons Ireland Research Ethics Committee
Royal College of Physicians Ireland Research Ethics Committee
Trinity College Research Ethics Committee
University College Dublin Research Ethics Committee
University of Limerick Research Ethics Committee
Waterford Institute of Technology Research Ethics Committee

Should an applicant have received approval from any other REC (hospital and/or local) which is not identified in this policy, a decision on whether to accept this is only made by the Chair of the NOCA Governance Board.

This will be reviewed on implementation of the forthcoming Patient Safety and Health Information Bill.

Appendix 2: Process flow for release of data for research to external bodies



Appendix 3: National Office of Clinical Audit (NOCA) Release of Data for Research Form

National Office of Clinical Audit (NOCA)

Section 1: Applicants Details

Date of Application	
Applicants Name	
Affiliation	
Address	
Telephone	
Email	
Project Lead, Investigator or Project Supervisor name	
Affiliation	
Address	
Telephone	
Email	
Is the research project being undertaken in fulfilment of an academic course? Yes □ No □ If Yes, indicate the qualification: □ Undergraduate degree □ Masters degree □ PhD	

Section 2: Proposed Research Plan

Title of Research Proposal:
Research Project plan: Please attach a description of your research project. Project plan must include: • Background (Lit review etc.) • Rationale for research • Primary hypothesis/Research question • Aims • Methodology (Research approach) • Methods (Interviews/RCT's/Surveys etc.) • Inclusion/Exclusion criteria • Data analysis plan • Person responsible for data analysis • Presentation of findings • Proposed output from the project: include scientific journal/s to which the completed manuscript will be submitted, detail of conference/forum where data will be discussed. • References Attach additional pages as required
Outline of proposed study timing (Gantt Chart) a. Duration (months) : b. Anticipated commencement date: c. Anticipated completion date:
How is this research project resourced?

Section 3: Data Requirements

What data fields are you requesting from NOCA? Please review each audit streams individual Data Dictionary and include data fields. Attach additional pages as required
Data period Start date: Finish date:
Other specific requests (e.g. geographical area, organisation etc.)

Section 4: Data Management

Please state how the data will be stored and accessed?

Please outline the period of retention.

Section 5: Ethical approval

Has your research project been approved by a Research Ethics Committee? Yes ☐ Provide details of the Ethics Committee(s) that have reviewed or will review the protocol. Please attach a copy of the ethics application and approval certificate from the relevant Ethics Committee(s). *Please attach a copy of the study ethics approval certificate from the relevant REC(s)*
No ☐ If not, why not?

Section 6: Conflicts of Interest

Do any researchers have any conflict of interest in this research or its outcomes, or any relevant affiliations? Yes ☐ No ☐ If *Yes,* give details:

Section 7: Confidentiality and Data Release Agreement

Declaration by Applicant

We/ I have read and understand the conditions under which this data is being provided by the National Office of Clinical Audit.

I undertake that the data supplied will:

1. be used only for the purposes specified in "Section 2 – Purpose of the Data Request " ;
2. not be made available to anyone not named in Section 1 above;
3. not be linked to any data not specified in Section 3 above and will not be used to identify individuals;
4. not to present in the results of analyses or other reports, or in releases of information concerning such reports, any information that might identify an individual,
5. not be used to publish information which identifies a named hospital or hospital group unless prior permission has been received from that entity,
6. be stored on computers owned by the responsible agency. No data are to be held on or stored on computers or devices owned by individuals for personal use.
7. without exception, data will not be transferred to a cloud computing device.

I / We will

1. Comply with the provisions of the Data Protection Acts 1998 (Amended 2003)

2. Acknowledge the National Office of Clinical Audit (and relevant Audit Processor) as the source of the data.

Section 7: Certification

I certify that I have read the NOCA Data Access Policy and agree to the terms outlined in the Policy	
Applicants Signature	
Lead Investigator/ Supervisor Signature	

Section 8: Application Checklist

Please satisfy each of the following before submitting the application. Failure to do so will delay review of the application. Include a copy of this checklist with the application.

Have you answered all the relevant questions in the application?	☐
Have you attached a detailed research proposal?	☐
Have you attached REC approvals plus the approved submission?	☐
Have you declared all potential conflicts of interest?	☐
Have you singed the confidentiality agreement	☐

Office use only

_____

Date received	
Documentation checked	
Researcher contacted	
Outcome provided to Researcher	
NOCA Responsible person	

Appendix 4. Acknowledgement of the National Office of Clinical Audit

Standard acknowledgement:

We thank the patients and staff of all the hospitals in Ireland who have contributed data to the NAME OF AUDIT. We are grateful to the National Office of Clinical Audit Governance Board, the NAME OF AUDIT GOVERNANCE COMMITTEE, AUDIT PROCESSOR (WHERE APPROPRIATE) for facilitating this work. {Additional Contributors to be added where necessary}.

Appendix 5. HSE Risk Matrix (Combining Impact and Likelihood)

3. RISK MATRIX	Negligible (1)	Minor (2)	Moderate (3)	Major (4)	Extreme (5)
Almost Certain (5)	5	10	15	20	25
Likely (4)	4	8	12	16	20
Possible (3)	3	6	9	12	15
Unlikely (2)	2	4	6	8	10
Rare/Remote (1)	1	2	3	4	5

Guidance on the Initial Risk Rating

For further information on applying a risk rating, refer to the Risk Assessment Tool and Guidance (HSE, 2011)

Appendix 6: Release of Data by NOCA for research purposes

Generally, data for research purposes will be record level data, but in some cases this may be aggregate data. NOCA adheres to the following principles when releasing data for research purposes.

1. NOCA will ensure all record level data is either anonymised or de-identified.
2. NOCA will not release small numbers i.e not present data where variables are reported between 1-5.
3. NOCA aims to ensure secure release of data to third party.

1. Techniques used by NOCA to de-identify record level data.

- Identification numbers e.g. specific medical record numbers, audit record identification numbers, will be removed.
- Precise dates will not be released; day of week, month and year and measures for example will be released.
- Variables where appropriate will be recorded into less distinct categories.
- Ages may be aggregated into age bands.

2. Managing small numbers

NOCA will not release critical variables reported between 1 -5. This may involve

- Signifying between 1-5 variables ~
- * Further suppression is necessary to ensure that cells between 1 and 5 critical variables are not disclosed.
- Row and Colum Totals may not be reported.
- Data is aggregated to ensure that less than 5 critical variables is suppressed.

3. Secure release of data

- Data will be released in electronic format. A full description of the data file may be supplied to the user prior to a formal request.
- Aggregated data files may be encrypted.
- Data files with record level files will be transmitted via a secure transmission mechanism.