Policy Title	**NOCA Access to Data for Service Evaluation and Quality Initiatives**		
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Approved by	**NOCA Governance Board**		
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Changes	Section 1.0 – Policy Statement Section 2; Scope of Policy – Inclusion and exclusion from this policy clearly outlined. Section 4; Glossary of Terms and Definitions – New Section Section 6; NOCA Procedure for Access to Data for Service Evaluation and Quality Initiatives - Process updated Appendix 1: Process flow - Process updated Appendix 2: National Office of Clinical Audit (NOCA) Data Access Request Form Appendix 4. HSE Risk Matrix Appendix 5: Release of Aggregate Data by NOCA		

NOCA Policy on Access to Data for Service Evaluation and Quality Initiatives

1.0 Policy Statement

The role of the National Office of Clinical Audit is to promote sustainable clinical audit and support informed decisions on how services are delivered and clinical care improved. NOCA is responsible to evaluate audit data and publishing findings arising from national clinical audits.

Information is a valuable resource and as such, wherever possible, it should be collected once and used many times, with appropriate safeguards in place (HIQA, 2013). NOCA will authorise access to clinical audit data for service evaluation and quality purposes in a timely manner. This may be done by NOCA alone or in collaboration with audit processors, whom NOCA work with to provide national clinical audit. In supplying data, NOCA complies with its obligations under the Data Protection Acts (1988 /2003) and with HSE National Consent Policy (HSE, 2013).

2.0 Scope of this Policy

This policy refers only to the secondary use of clinical audit data for service provision and quality purposes. Some examples may include;

- Health service quality assurance and quality improvement purposes,
- Performance monitoring E.g. assess if national targets are being met and to identify areas where improvements are required.
- Planning of services E.g. planning, provision and measurement of acute hospital services and also for the allocation of resources.
- Other purposes deemed appropriate by Audit Clinical Governance Committee

This only refers to anonymous and de-identified aggregate audit data. Access to these audit findings will be made available to audit stakeholders as deemed appropriate by the specific Audit Governance Committee.

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 research purposes
- Industry requests for post market surveillance information.,

Distinct policies will be developed to manage such requests.

3.0 Purpose

This policy document defines the process by which access will be granted to aggregate clinical audit data for service evaluation and quality purposes managed by NOCA.

Requests will only be considered from Stakeholders within a Hospital Group or National remit of service evaluation and quality purposes.

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). Data release for this purpose will be aggregated. .
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).
Service evaluation	Service/practice evaluation evaluates the *effectiveness* or efficiency of an existing or new service/practice that is evidence based, with the intention of generating information to inform local decision-making. This type of activity is sometimes referred to as a clinical effectiveness study, baseline audit, activity analysis, organisational audit and benchmarking (HQIP, 2011)

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 to ensure

- Implementation of policies relating to data access; and for staff compliance with these policies.
- Maintenance of register of requests for access to data for purpose of service provision and quality purposes.

5.2 NOCA Audit Clinical Governance Committees

Each Individual Audit Clinical Governance Committee is responsible to evaluate requests for data access. This may result in approval of requests, rejection of requests or request for further information or clarification.

5.3 NOCA Governance Board

The NOCA Governance Board is responsible to review a request for access to data, which has been refused by the Audit Governance Committee.

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 Administrator, NOCA Audit Co-Ordinator and Audit Clinical Lead

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

The NOCA Administrator, Audit Coordinator and Clinical Lead are initially responsible to initially review and process requests expeditiously.

The NOCA Administrator and Audit Coordinator will compile the data for the Applicant.

The NOCA Administrator will maintain the Data Request Log.

5.5 The Applicant

The applicant is responsible to ensure

- The NOCA Data Access Request Form is fully completed.
- Adequate time has been given to request the data, particularly if the data request is complex.
- To maintain confidentiality as outlined in Section 6 of the Data Access Request Form (Appendix 2).

6.0 NOCA Procedure for Access to Data for Service Evaluation and Quality Initiatives (Appendix 1)

Who	Procedure	Output
Applicant	Request for aggregate data by completing the "National Office of Clinical Audit Data Access Request Form"	"National Office of Clinical Audit (NOCA) Data Access Request Form" received by NOCA
NOCA Administrator, Audit Co-ordinator	Review the "National Office of Clinical Audit (NOCA) Data Access Request Form" to ensure all required data is included. • All required fields relating to data request are completed (Section 1-4). • 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) Data Access Request Form" must be dated and signed by the Applicant. The NOCA Administrator will contact the Applicant • Where clarification is required for incomplete or inconclusive data request, • Where NOCA does not hold the requested information. The NOCA Administrator registers the request in the Data Request Log .	Completed "National Office of Clinical Audit (NOCA) Data Access Request Form" are compiled for the Individual Audit Clinical Governance Committee
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. • 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	Data released to Applicant Data not released to applicant Request for further information from Applicant

Who	Procedure	Output
	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 4) to assess the risk • 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 Review of Applications for release of data can result in • Release of data by NOCA / Audit Processor • Request for further information pending decision • Refusal to release data. Should the data request be unclear, the Audit Clinical Governance Committee can request clarification from the applicant. All decisions are reported to the NOCA governance Board.	
NOCA Audit Coordinator & Clinical Lead	Where there is not a pending Audit Clinical Governance Committee meeting, review of the request will be facilitated by email communication	Audit Clinical Governance Committee
NOCA/ Audit Processor	Aggregate data will be released in electronic format by NOCA. (See Appendix 4 – 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.	Applicant receive file.
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	Appeals process with input from NOCA Governance Board Data Appeals Committee

Who	Procedure	Output
	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 writing to the applicant and reported to the NOCA Governance Board.	

References

Committee on Conflict of Interest in Medical Research, Education, and Practice; Institute of Medicine (2009) Conflict of Interest in Medical Research, Education, and Practice. Editors; Bernard Lo and Marilyn J. Field. Available at: http://www.research.uky.edu/ospa/info/docs/IOMCOIinMedResearch2009.pdf [Accessed on: 01/11/2015].

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: 17/06/2013).

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; 17/06/2013)

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

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Healthcare Quality improvement Partnership (2011) A guide for clinical audit, research and service review – An educational toolkit designed to help staff differentiate between clinical audit, research and service review activities. Available at: http://www.hqip.org.uk/resources/hqip-guide-for-clinical-audit-research-and-service-review/ [Accessed on: 01/11/2015]

National Cancer Registry (2014)Data confidentiality in the National Cancer Registry, General policy, procedures for release of data and staff guidelines. Available at: http://www.ncri.ie/sites/ncri/files/documents/NCRI-data-confidentiality.pdf [Accessed on: 01/11/2015].

Legislation

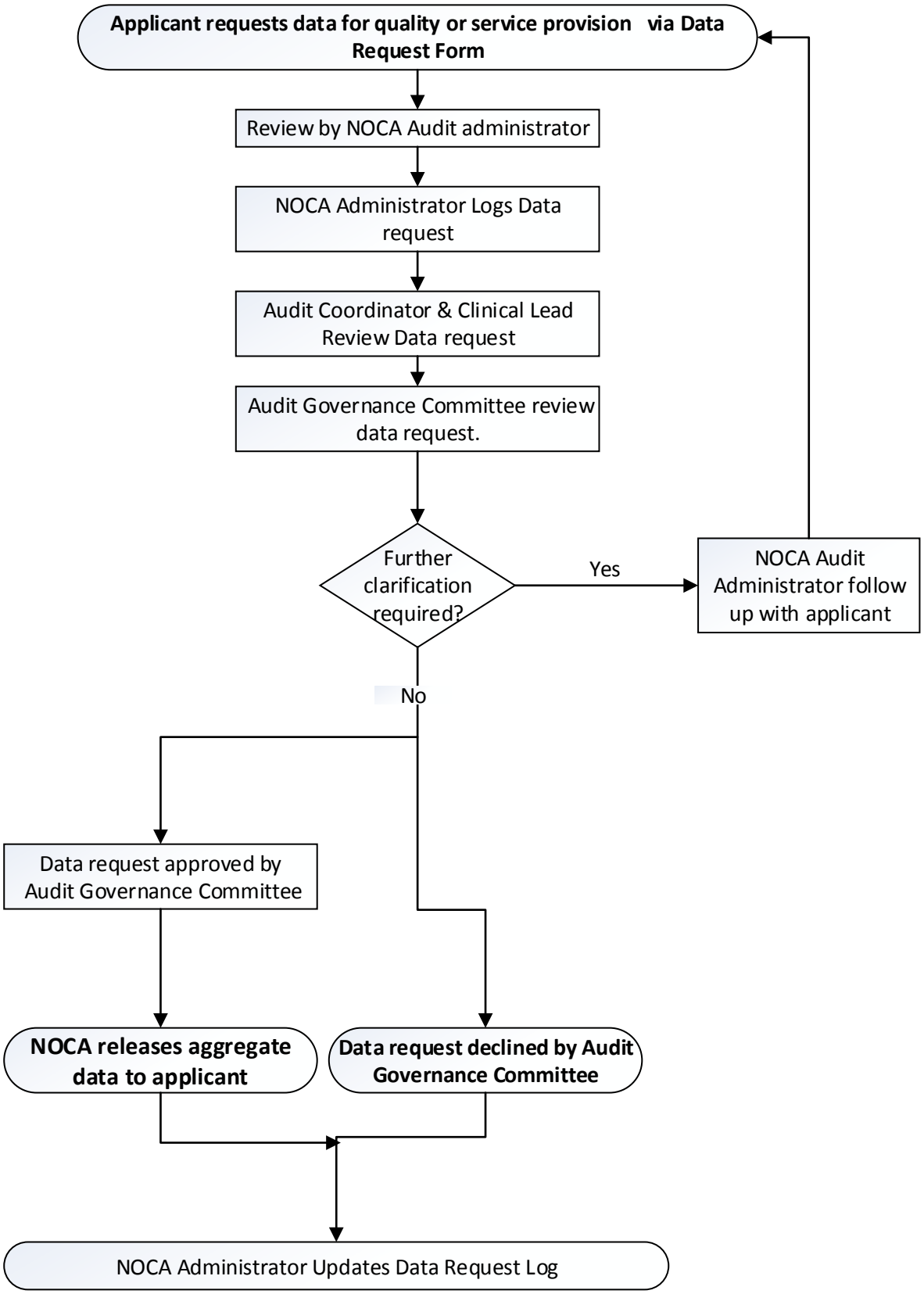
Data Protection Act, 1988, Act No.25 of 1988, Available at: http://www.irishstatutebook.ie/1988/en/act/pub/0025/index.html (Accessed on: 10/04/2015)

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: NOCA Procedure for Access to Data for Service Evaluation and Quality Initiatives


Applicant requests data for quality or service provision via Data Request Form
Review by NOCA Audit administrator
NOCA Administrator Logs Data request
Audit Coordinator & Clinical Lead Review Data request
Audit Governance Committee review data request.
Further clarification required?
Yes
NOCA Audit Administrator follow up with applicant
No
Data request approved by Audit Governance Committee
NOCA releases aggregate data to applicant
Data request declined by Audit Governance Committee
NOCA Administrator Updates Data Request Log

Appendix 2: National Office of Clinical Audit (NOCA) Data Access Request Form

Section 1: Applicants Details

Date of Application	
Applicants Name	
Organisation Name	
Address	
Telephone	
Email	

Section 2: Purpose of the Data request

Please provide a brief summary of up to 200 words describing the aims of the proposed project and how does this relate to request for this data?
Please describe how the data will be used and its intended purpose?
Please indicate the target audience for this data?

Section 3: Data Requirements

Define the data extract requirement (as appropriate) Specify Audit, data queries. (Define data fields required if known)	
Data parameter – data entry period/ form restriction.	
Geographic area.	
Organisation restriction.	
How is the data to be presented?	
Please confirm the date this data is required by?.	

Section 4: Data Management

Please state how the data will be stored and accessed?
Please outline the period of retention.

Section 5: Conflicts of Interest

Does the Applicant have any conflict of interest in this specific data request, or any relevant affiliations? Yes ☐ No ☐ If *Yes,* give details:

Section 6: Data Access 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 / We certify that I have read the NOCA Data Access Policy and agree to the terms outlined in the Policy	
Applicants Signature	
Date	

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 declared all potential conflicts of interest?	
Have you singed the confidentiality agreement	

Office use only

_____

	Comment	Signature	Date
Date received			
Documentation checked			
Applicant contacted			
Outcome provided to Applicant			

Appendix 3. 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 4: Release of Aggregate Data by NOCA

NOCA adheres to the following principles when releasing aggregated data.

1. NOCA will not release small numbers i.e not present data where variables are reported between 1-5.
2. NOCA aims to ensure secure release of data to third party.

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.

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 will be transmitted via a secure transmission mechanism.