

Policy Type: Information Governance Management
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Owner Group: Perinatal Institute

Confidentiality and Consent Policy

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Communication Method : Line Managers, Email
Consequence of Non-adherence: Serious information risk

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1 Introduction

This policy sets out the approach that the Perinatal Institute adopts in the maintenance and achievement of the highest standards of confidentiality in its activities. As a data handling organisation, confidentiality of data is central to the conduct of the Institute's activities and behaviour. In particular the Institute will ensure that it meets the following standards:

- That it has appropriate consent from data subjects for the gathering, holding and use of information about them.
- That the information it holds about individuals is held securely and confidentially until such times as it is no longer required.
- That the Institute operates both within the requirements of UK legislation and NHS guidelines relating to security and confidentiality of information.
- That any approved release or disclosure of information held is done in such a manner that confidentiality is maintained.

2 Background of the Perinatal Institute

The Perinatal Institute is an NHS organisation core funded by the West Midlands PCTs. Its principal remit is to address the high rate of perinatal mortality and morbidity in the region, and to aid improvements in perinatal care.

This is addressed through:

- Audit of perinatal deaths
- Collection of denominator data (all maternities and births in the region)
- Targeted research
- Collaborative projects to assess service developments
- Dissemination of evidence
- Education and training

Other functions of the Perinatal Institute include data collection to support:

- Confidential Enquiries
- Epidemiology
- Disease Surveillance
- Commissioning of services
- Audit of equity of service provision
- Audit of levels of patient choice
- Audit of patient safety
- Clinical Governance

3 Application of this Policy

This confidentiality policy is applied to

- All staff employed by or contracted with the Perinatal Institute including seconded staff, temporary staff and attached staff (e.g. research associates).
- All data held and used at the Perinatal Institute whether at home or within the work place.
- All work files and confidential information used by or about employees' and contractors.

Additional information and guidance relating to IT security is held in the 'Information and IT Security Policy' which sets out:

- How the Institute will manage its electronic data systems and resources.
- Responsibilities of Institute Staff in relation to Security and Confidentiality.

4 Details of this Policy

4.1 Consent

The use of person identifiable data within the Perinatal Institute is governed by the requirements under the Data Protection Act and the Health and Social Care Act to ensure that consistent use of informed consent should be the usual basis for handling confidential patient information.

The Institute has procedures and arrangements in place to ensure that the data it collects and holds has been collected within the guidelines of obtaining informed consent as applied within the NHS.

In particular, data collection documentation used by the Institute explains the purposes for which the information will be used and make clear the processes for opting out. Guidance for front line staff through training and in the standardised maternity / perinatal records contain details of the information which should be imparted to all patients, and how they can opt out. Appendix B contains the consent protocols for the collection of perinatal and neonatal data.

Procedures exist within the Institute to ensure that details of patients who withhold consent are excluded. Upon receipt of a request to the PI for information to be withheld from further analysis the following procedure will be followed:

- The NHS number of the individual in question will be used to identify any data that might already be contained in the relevant database(s);
- All data for that NHS number in the database(s) will be removed so that it cannot accidentally be included in any individual or aggregated analysis.

Confirmation has been obtained from the Information Commissioner and from Connecting for Health to affirm that these procedures are appropriate and valid:

'From the information provided to us so far, it appears that the processing is fair and lawful (as long as the fair processing information is adequate and as long as you comply with the common law duty of confidence). You outlined to me in your note that you felt this processing to be essential for both clinical audit and administrative audit. As such, it seems that it would be adequate to obtain implied consent when you collect the information (our understanding of the common law duty of confidence is that implied consent is valid in certain situations). Providing adequate fair processing information about what will happen to the data, who it will be disclosed to and whether or not it is optional is essential. You should remember that an individual has a right to object to any processing which is likely to cause damage or distress (S10 of the Act) so should consider whether or not you will actually retain some form of signature box from the care provider, even though you don't need to retain it for consent purposes. In our opinion it would not be necessary to go to PIAG as you are still obtaining implied consent.'

LOUISA STILWELL
Senior Guidance and Promotion Manager
Information Commissioners Office

'I am satisfied that you are providing clear information and a clear route to opt out for patients in your area, as such your processes don't cause any concern from my end.'

DAVID MARTIN
Digital Information Policy
Digital & Health Information Policy Directorate
NHS Connecting for Health

4.2 Secure and Confidential Holding of Data

The Perinatal Institute will ensure that all identifiable data is held in a secure and confidential manner. In particular, the following arrangements will be followed:

- There will be an identified internal 'owner' for each data set within the Institute. The responsibilities of each owner are as follows:
 - To grant authorisation to only the staff within the Institute who need to have access to the particular data set in order to do their job;
 - To approve or refuse requests for disclosure of identifiable information from the particular data set for which they have responsibility;
 - To determine when any identifiable information is no longer required and to authorise its secure removal and destruction in such circumstances.
- Data will be held within the Institute in such ways as to facilitate a separation between identifiable data and non-identifiable data. The majority of work will be carried out on the non-identifiable portions of the data sets.

- Procedures to ensure the flagging of any records where consent has not been given will be in place to ensure that such records may be either deleted or excluded from analysis.
- All identifiable electronic data will be held on servers which are securely housed and protected. Additional details of IT security and confidentiality arrangements may be found in the Institute's Information and IT Security Policy.

4.3 Legal Framework

The Perinatal Institute is governed by all the relevant legislation in the UK relating to data confidentiality and security. In addition, as an NHS organisation, the Institute will implement the relevant NHS guidelines.

4.4 Disclosure and Release

Where possible any release of information will contain only non identifiable data. Release of identifiable information must also be approved by the Institute's Caldicott Guardian in addition to the relevant data 'owner'

Secure mechanisms for release must be used and are detailed in the Information and IT Security Policy.

The PI protocol for the release of non-identifiable data is described in a separate document, 'Perinatal Institute Protocol for the Release of Non-Identifiable Data'. (see Appendix A)

The PI protocol for supply of identifiable information is as follows:

- a formal written request on the approved data request form is submitted to describe the data required;
- the request must be authorised within the requesting organisation by a manager of sufficient seniority and authority to confirm the legitimacy of the request being made. Ideally this manager should already be known to the PI;
- the request must be approved for despatch by the PI Caldicott Guardian prior to being send to the requester;
- identifiable records will only normally be sent to the hospital from which the data originated, the PCT to which the records relate; or the clinical network from which the data originates;
- identifiable data must only be supplied in an encrypted format as described in the PI Information and Information and IT Security Policy;
- the data request form will be kept by the PI for future reference.

5 Policy Review

The policy will be reviewed at least annually. All staff will be informed when the policy is updated. All members of the Perinatal Institute staff will be given a paper copy. The policy is filed on the shared network drive and is available to download from the Perinatal Institute website.

6 Training of Staff

The named lead for Data Protection will ensure all new staff receive training in this area so that they are aware of the policy and what actions they need to take to work in line with this policy.

Staff members will be instructed as to their security and disclosure level on commencement of their employment. Access and disclosure rights of information will be reviewed regularly and updated.

All staff will sign an appropriate declaration covering use of laptops and other equipment off site.

The Caldicott Guardian and Lead for Data Protection Compliance will review any updates to the Caldicott or Data Protection requirements.

Training sessions covering the policy will be given annually, or more frequently in the event of significant changes in the policy. All staff must attend these sessions.

7 Leaving Procedure

Whenever a member of staff leaves, any relevant security system codes should be changed and all keys should be handed in.

The Team leader is responsible for notifying the Perinatal Institute IT administration team that the member of staff is leaving so that all network access will be revoked.

8 Code of Conduct

All staff of the Perinatal Institute must understand and comply with this policy. They must be aware of the relevant legislation and carry out all work with regard to this policy and the legislation.

9 Breach of Policy

All Perinatal Institute staff should sign a declaration, which refers to this policy, and this will be binding. Breach of any part of this policy will be a serious disciplinary offence.

- Any breaches of this policy will be reported firstly to one of the Leads for Data Protection Compliance who will then act together with the Caldicott Guardian to ensure the breach ceases
- Anyone suspecting a breach or discovering a situation where a breach could occur should discuss this with the Caldicott Guardian
- Deliberate passing of confidential information to unauthorised people is a disciplinary matter which may lead to dismissal

Perinatal Institute Protocol for Publication or Release of Non-Identifiable Data January 2012

1 Background

Health data is considered sensitive and therefore subject to significant issues of confidentiality. Whilst these issues are mostly related to data which is explicitly linked to an identified individual, there are circumstances in which non-identifiable data can give rise to confidentiality concerns. These are largely related to the publication of data in which small cell counts appear and from which it may be possible to infer the identity of some of the individuals covered within the data. For the purposes of this protocol therefore, non-identifiable data is defined as which, although it does not directly identify a specific individual, could in certain circumstances allow the identity of an individual to be inferred or discovered.

Given however that many of the health 'events' that are recorded are by their very nature rare or unusual, it is important to ensure that a need to ensure confidentiality does not compromise the ability to identify the analysis and identification of the rate and pattern of occurrence of such events.

This protocol sets out the approach Perinatal Institute (PI) will take in making available non-identifiable data.

2 Scope of the Protocol

This protocol covers the approach the PI will take to the release of non-identifiable data only. This will be data in the form of data tables or graphs for analytical or reporting purposes. Such data will, by definition, not include any direct personal identifiers such as NHS number, name or other unique identifier.

Procedures covering the release of identifiable data are considered to be outside of the scope of this protocol.

3 Objective of the Protocol

The objective of this protocol is to provide staff in the PI with a framework and guidelines on how to approach the release and publication of non-identifiable data in which small cell counts may occur.

4 Protocol

The approach adopted within the PI to the publication and release of non-identifiable data is centred round risk assessment and management. This is constructed around a process of assessing the confidentiality risks of presenting non-identifiable data in a particular way against the value of releasing it in that format.

4.1 The senior manager responsible for the data set will ensure that prior to release, a risk assessment is carried out on the data and format in which it is presented.

4.2 The components of the risk assessment must include the following dimensions;

- How 'sensitive' is the nature of the underlying data?
- What is the true likelihood of an individual being identifiable from that data in conjunction with other data already in the public domain?
- Who is the intended audience for the released data?
- How specific is the data being released?
- What benefits are there in releasing the data in the proposed format?
- Who owns the data in question?

4.3 The outcome of the risk assessment can only be either to approve the release in the assessed format or to reject it. Where the decision is to reject release, there are a range of possible transformation processes that could be applied to the data to reduce the risk to acceptable levels.

As the choice of these processes will be dependent on the nature of the data and the perceived risk, it is considered as outside of the scope of this protocol to discuss these here. However, further guidance on transformation processes can be found in the ONS document:

'Review of the Dissemination of Health Statistics: Confidentiality Guidance Working Paper 3; Risk Management' ONS 2006.

4.4 The risk assessment and result must be recorded and dated on the required form which must be retained for future reference (see Appendix 1).

4.5 Where there are future releases of the same data tables (albeit the content of the tabled cells may have changed) a fresh risk assessment will only be required where there has been some significant change to one or more of the risk dimensions.

4.6 The outcome of the risk assessment should be approved by the PI Caldicott Guardian.

5 Undertaking the Risk Assessment

Dimension 1: How sensitive is the nature of the underlying data?

Clearly some health data will be more sensitive than others. From a confidentiality perspective data such as birth weight is likely to be considered less sensitive than data relating to discovery of some form of abnormality.

The data therefore needs to be positioned somewhere on the 'sensitivity scale' so that more weight would be given to confidentiality concerns for data at the more sensitive end of the spectrum.

Dimension 2: How likely is it that an individual could be identified from the data in the form that it is intended to release?

As the data itself is non-identifiable, it would only be by accessing some other piece(s) of information that identity might be discovered. Consideration therefore needs to be given to what pieces of additional information would be required and how likely these are to either be already known or obtainable without disproportionate effort.

Dimension 3: Who is the intended audience for the released data?

Typically the PI will release information which is intended for an NHS audience. Consequently employees or contractors to the NHS will be bound by contractual conditions of confidentiality and consequently may be expected to treat the released data appropriately. It would therefore in these circumstances seem reasonable to take a more relaxed view of the risks than if the intended audience was a non-NHS one.

Dimension 4: How specific is the data being released?

Clearly where the data cells in any data table represent counts occurring in small or specific organisational or geographic entities the potential confidentiality risks are greater than for larger entities. For example, show in counts in a specific post code area or to a specific month for a specific neonatal unit would carry greater risks of confidentiality concerns than if the same data was made available at a PCT level of aggregation or a whole year for a neonatal unit.

Dimension 5: What are the benefits of releasing the data in the proposed form?

Any risk assessment must balance the negative aspects against the positive aspects of an action so it is important to consider the reasons why it would be beneficial to release the information in the proposed format. There are benefits in understanding any patterns in the occurrence of rare events in terms of both geography and time. Clusters of events may indicate a deeper issue which needs to be investigated further. As such the 'need to know' aspects may often outweigh the potential of confidentiality compromises.

It is possible to think of rare or unusual clinical events as analogous to air crashes. It would be inconceivable to take a view point that the incidence of air crashes would not be made available because it might compromise confidentiality of individuals involved. Presentation of the incidence of unusual or rare medical events can be viewed in a similar fashion whereby the need to know and understand any causal underlying factors outweighs any confidentiality risks. In fact it may be more appropriate to take a view that the presumption will be that information will be released unless the confidentiality risk is deemed to be of such extreme importance as to outweigh any benefits of release.

Dimension 6: Who owns the data in question?

There are two major aspects to this consideration. Firstly, the Perinatal Institute may have access to non-identifiable information made available to it from another organisation. In such circumstances it is appropriate for the Institute to abide by any rules of the supplying organisation impacting on the onward release of that information. In other words if a supplying organisation has rules about publication of low cell count data then the Institute will respect those rules for that set of data.

Secondly, the Institute holds data at an identifiable level which has been collected by different NHS organisations. At the very least these organisations have some joint ownership of the data they have collected in their organisation. It would therefore be good practice for the Institute to inform an organisation when some non-identifiable data is to be released about that organisation. This is not to imply that such organisations have a veto over release of information which describes them.

The question of PCT access to information also arises in this context. It seems reasonable to adopt a position which sees PCTs as commissioners of care for their population and as a result they should have access to non-identifiable information about the care being provided to their population. Agreement already exists between PCTs that they each should be able to view all PCTs information held by the Institute for comparative purposes, therefore

Release of information back to the originating Trust, clinical network or to an individual PCT for its population would not be considered as release of the information into a wider environment and therefore not subject to a formal risk assessment

This concept of ability to view other organisations non-identifiable data for comparative purposes has been extended to cover Trusts. This agreement includes a shared understanding of the Institute's policy in relation to releasing non-identifiable information as set out in this protocol.

It will be apparent that none of the above dimensions should, or indeed can, be considered in isolation from each other. Many of them impinge on each other and will need to be considered 'in the round' in the context of the particular circumstance of the data being considered for release. Undertaking and documenting the risk assessment should therefore clearly show that the relationships between the dimensions have been considered.

6 Reviewing the Protocol

This protocol should be reviewed for effectiveness and efficiency on a 2 yearly cycle.

7 Further Guidance

'Review of the Dissemination of Health Statistics: Confidentiality Guidance' ONS 2006

'Freedom of Information Act 2000 (Section 50) Decision Notice Ref FS50122432'
Information Commissioners Office 28th July 2008

'Review of the Dissemination of Health Statistics: Confidentiality Guidance ; Working Paper 2 Risk Assessment' ONS 2006

'Review of the Dissemination of Health Statistics: Confidentiality Guidance Working Paper 3; Risk Management' ONS 2006.

RISK ASSESSMENT FORM

Data Set Assessed

Date of Assessment

Regular Release
Or Ad Hoc?

Regular/ Ad Hoc (delete as appropriate)

Full Risk assessment Required? Yes / No (delete as appropriate)

If NO Reason for no Risk Assessment

	Tick
Data back to originating Trust	
Data to PCT concerning only its population	
Data back to originating clinical network concerning that network only	
Other – detail:	

Manager Responsible for Assessment

Risk Factors Considered

Dimension 1 Sensitivity of the Data

Dimension 2 Likelihood of Identification

Dimension 3 Intended Audience

Dimension 4 Degree of Specificity of the data

Dimension 5 Benefits of Release

Dimension 6 Data Ownership Considerations

Outcome / Decision of Risk Assessment

Approved Caldicott Guardian

West Midlands Consent Protocol for Secondary Use of Perinatal Data



The protocol is built around the Pregnancy Notes, which are in standard use. *

1. All mothers should be informed at booking that information is collected for secondary use, with reasons given. Explanatory text is as provided in the Pregnancy Notes
2. Details should be given about where further information can be obtained, including the Perinatal Institute's web pages (www.perinatal.nhs.uk/data) where many results of secondary analysis are presented.
3. At booking, the midwife or other caregiver should sign in the notes that information has been given and data collection / purpose of use etc have been explained.
4. Where the mother does not understand English sufficiently, an interpreter should be made available to provide the same information.
5. If the expectant mother decides, at booking or at any time during her pregnancy, that she does not want any details about her or her baby to be used for secondary analysis, she should contact the Perinatal Institute as advised on page 2 of the Pregnancy Notes. The Institute will send her an opt out form to complete.
6. The Perinatal Institute will then use the unique identifier (NHS Number) to ensure that the mother's or her child's data is not held for secondary analysis.

* Any unit still using its own Notes will be asked to make similar provisions.

West Midlands Consent Protocol for Secondary Use of Neonatal Data



1. This protocol is built around the Parent Information Leaflet - "A guide to recording information on your baby's care in the Neonatal Unit" - which is in standard use in the West Midlands.
2. All mothers should be given the parent leaflet as soon as possible following admission of their baby to the Unit.
3. The caregiver should complete the stamp in the baby notes that information concerning data collection / purpose of use etc has been explained.
4. Details should be given about where further information can be obtained, including local contacts and details of the Perinatal Institute, as detailed on the back page of the leaflet.
5. If the mother does not have sufficient understanding of the English language, an interpreter should be made available.
6. If the mother decides, at any time, that she does not want any details about her baby to be used for secondary analysis, this information should be recorded in the baby notes and the Perinatal Institute support team should be notified by Phone 0121 687 3434 or Email: helpdesk@pi.nhs.uk
7. The Perinatal Institute will ensure that an 'opt-out' form is sent to the mother for completion or the Clinical Lead in the Unit should email the IT Manager. The unique identifier (NHS Number) will be used to ensure that her baby's data is excluded from extraction for secondary analysis.