Obtaining Caldicott Approval for Research

NJRO-GOV-SOP-001

Contents

1. Background/Introduction

The Caldicott Principles were devised by the Caldicott Committee (under the Chairmanship of Dame Fiona Caldicott), which reported in 1997 following a review of patient identifiable information. The principles were devised in conjunction with the Data Protection Act (1998) in order to provide a framework for good practice in the use of person identifiable data within the NHS, between NHS organisations and from NHS to non-NHS bodies. Access to patient information should be restricted to those who have justifiable need to know that information in order to carry out their work. In 2013 a further review was performed with a focus on the appropriate sharing of identifiable information, leading to a seventh Caldicott principle.

The 7 Caldicott Principles are as follows:

1. **Justify the purpose of using confidential information:**
   Every proposed use or transfer of patient-identifiable information within or from an organisation should be clearly defined.

2. **Only use it when absolutely necessary:**
   Identifiable data should not be included unless essential for the specified purpose(s). The need for patients to be identified should be considered at each stage.

3. **Use the minimum that is required:**
   When considered essential, each individual item should be justified with the aim of reducing identifiability.

4. **Access should be on a strict need-to-know basis:**
   Only those individuals who need to should be able to access the information, and only the information that they need to see.

5. **Everyone must understand his/her responsibilities:**
   Both clinical and non-clinical staff should be aware of their obligations to respect patient and staff confidentiality.

6. **Understand and comply with the law:**

Every use of patient-identifiable information must comply with legal requirements.

7. **The duty to share information can be as important as the duty to protect patient confidentiality:**
   Health and social care professionals should have the confidence to share information in the best interests of their patients, within the Caldicott principles framework. They should be supported by the policies of their employers, regulators and professional bodies.

Caldicott approval is a requirement for all research studies taking place within The Newcastle upon Tyne Hospitals NHS Foundation Trust (NUTH FT). All collection, use and transfer of person identifiable data within or outside the NHS organisation must be approved by the Trust's Caldicott Guardian in order to ensure adherence to the Caldicott principles outlined above. This applies to research studies involving the collection of identifiable data from both NUTH FT patients and from NUTH FT staff.

Overall responsibility for approval of Caldicott applications rests with the Trust's Caldicott Guardian.

2. Purpose

This Standard Operating Procedure (SOP) is written to outline the requirements and processes of NUTH FT for applying for and obtaining Trust Caldicott approval.

The SOP aims to:

1. Give clear guidance to investigators regarding under what circumstances Trust Caldicott approval is required for a research study.

2. Give clear guidance to investigators regarding the process of applying for Trust Caldicott approval.

3. Scope of Document

This SOP applies to all investigators who are in the process of applying for Trust Research & Development (R&D) approval for their research project and who require

NUTH FT Caldicott approval in order to gain permission to conduct their research project within the Trust.

4. Procedure

4.1. Submitting an Application

The Caldicott Online Form can be accessed from the Trust intranet page for NUTH FT staff. This page also has a link to advice for filling in the Caldicott application. Investigators external to NuTH can access the forms by contacting the Information Governance team - nuth.caldicott@nhs.net

Investigators should fully complete the Caldicott application form, giving as much detail as possible. The form can either be submitted online or a copy emailed directly to nuth.caldicott@nhs.net (if not able to access NUTH FT intranet). Investigators completing the Caldicott application form can seek support and advice on its completion by:

- Using the advice found on the Information Governance Web Page on the Trust's Intranet (under 'C' for Caldicott)
- Emailing nuth.caldicott@nhs.netwith queries
- Speaking to the Information Governance (IG) Team directly

The IG Team will review all completed and submitted Caldicott application forms in the first instance (all applications will be reviewed and approved on Wednesday and Friday afternoons). The IG team will contact the investigator directly with any queries or questions regarding the information provided in the Caldicott application form. Any Caldicott forms requiring further information from applicants that have been outstanding for 3 months will be rejected. Applicants will be informed by the IG team and will be invited to resubmit when information becomes available.
The Caldicott application should be printed out and stored in the Trial Master File (TMF) or Investigator Site File (ISF), as appropriate. A revised Caldicott application may be required if there are significant changes made to the handling and/or processing of data throughout the study.

4.2. Caldicott Approval

Once all queries are resolved, the IG Team will issue the Caldicott Approval via email. This will be sent to all study contacts listed within the Caldicott application form. A copy of the approval email should be stored in the TMF or ISF.

In addition, a copy of the approval email must be submitted to the R&D team as part of the process of granting NHS permission for the research study.

Investigators must inform the IG team of any amendments to the research study that involve significant changes from the original Caldicott application regarding the collection, use and transfer of person identifiable data within or outside of the NHS Organisation.

5. Review and Monitoring

This document will be monitored and updated in line with any changes to the Trust Caldicott guidance/regulations. The use of the SOP will be monitored during the annual audit cycle of research projects performed by Trust Research & Development.

6. References

6.1 NUTH FT Information Governance, Caldicott Principles -http://nuth-intranet/cms/SupportServices/InformationGovernance/CaldicottPrinciples.aspx

6.2 NJRO Website - https://newcastlejro.com/

6.3 The Caldicott Guardian Manual 2010, Department of Health (accessed via Health & Social Care Information website) – http://nuth-vintranet1/cms/SupportServices/IT/InformationGovernance/CaldicottPrinciples.aspx

7. Appendices

None