ERUPT
Evaluation of Real-world Use of Pulmonary embolism Thrombolysis
Caldicott Approval Form Template

Purpose of this document

Individual trusts will use their own Caldicott approval form. This will record details of identifiable information sent from the Trust to other organisations ensuring sensitive information is transferred in a secure and confidential manner, approved by the Trust’s Caldicott guardian where necessary.

This document provides template responses for sections commonly contained with the Caldicott approval form, focusing on addressing the 7 Caldicott Principles. Individuals can judge how to apply this information locally, seeking advice from local R&D/audit departments or ERUPT project leads.

Template responses

Description of proposal: A multi-centre audit of use of systemic thrombolysis for treatment of pulmonary embolism (PE) in adult hospital inpatients. Patient who received thrombolysis for PE during a specified 1-year period will be identified and data including basic demographics (see below for details), treatment and outcome recorded on a secure web application (Redcap). The database will be accessed and overseen by the project leads (named below).

Purpose: Healthcare medical purpose (primary)

Data requested: Age, sex at birth

Time period for data required: Data from September 2021 to September 2022.

Regularity: Following approval, data will be entered roughly weekly until all identified patient data uploaded; cut-off for this will be by March 2023.

Trust appointed person/safe haven responsible for release of data: The local participant/user.

Receiving organisation/individuals: University of Cambridge; Dr Akhilesh Jha; aj580@cam.ac.uk

Recipient’s location: UK

Who else will have access to the data: The full database will only be accessible by Dr Akhilesh Jha and the two project leads: Dr Joseph Kibbler (Northumbria Healthcare NHS Foundation Trust) and Dr Ruth Sobala (South Tyneside and Sunderland NHS Foundation Trust). Any data exported for further analysis will not be identifiable; pseudonymisation of location data will be used to facilitate this.

Method of data transfer: Entry to secure web application (Redcap).

Communication with service users: As this project is not considered Research by the NHS as per the HRA decision tool, users identified for inclusion in the audit will not be contacted or asked for express consent.

Data storage: Data will be uploaded to Redcap and hosted on the Cambridge Integrated Data Environment server https://ide-cam.org.uk/redcap/. There is no requirement for local storage.
Caldicott Principle 1: Justify the purpose

Real world data about the safety outcomes from thrombolysis for PE is lacking. The treatment is carried out relatively rarely, perhaps monthly at an average sized hospital, hence the need for a multicentre approach to capture sufficient cases for meaningful conclusions. This justifies the extra risk to patient data associated with a multicentre approach. Although the conclusions will not be generalisable, as there is no comparator group, it is hoped that publishing the findings will highlight avenues for future research and provide impetus for the inception of a national PE registry.

Caldicott Principle 2: Don’t use service user-identifiable data unless it is absolutely necessary

It is important that the age and sex of patients is recorded as these are likely influences on outcome, so will need to be controlled for. Similarly, the location of the patient needs to be recorded so that evaluation of outcome based on locally provided specialist PE services can take place.

Caldicott Principle 3: Use the minimum necessary service user-identifiable information

Apart from age, sex and treatment location, no other service user-identifiable information (such as Name, DOB, hospital/NHS number) is being captured, as it is not strictly necessary. Information use has been carefully minimised during the design of the project.

Caldicott Principle 4: Access to service user-identifiable data should be on a strictly need-to-know basis

Only the project leads, Dr Akhilesh Jha, Dr Ruth Sobala and Dr Joseph Kibbler, will have access to the full database, which will be password protected. At local sites, only the local project participant will have secure access to input their local data.

Caldicott Principle 5: Everyone with access to service user-identifiable data should be aware of their responsibilities

All participants in the project at a central and local level will be reminded of their responsibilities to respect service user confidentiality at study set-up meetings.

Caldicott Principle 6: Understand and comply with the law

Locally, the Caldicott guardian and their deputies will have responsibility for ensuring the organisation complies with legal requirements.

Caldicott Principle 7: The duty to share information can be as important as the duty to protect patient confidentiality

If local participants in the project identify information that they feel should be shared in the best interests of a patient or patients, outside of the framework detailed in this document (for example any patient safety concerns), they are encouraged to consult with their local R&D/audit department and/or clinical supervisors in the first instance.

Other supporting information e.g. ethics approval: HRA decision tool: study not considered

Research by the NHS