PERSONAL IDENTIFIABLE INFORMATION: CALDICOTT APPROVAL & INFORMATION GOVERNANCE REVIEW

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1 INTRODUCTION

1.1 The Academic & Clinical Central Office for Research & Development (ACCORD) is a joint office comprising clinical research management staff from NHS Lothian (NHSL) and the University of Edinburgh (UoE).

1.2 The Data Protection Act enforces strict legal rules to the storage, maintenance and access to personal information.

1.3 A Caldicott Guardian is a senior person within NHSL responsible for protecting the confidentiality of people's health and care information and making sure it is used properly, in accordance with the Caldicott Principles. This includes the use of personal identifiable information by NHS staff, partner NHS organisations and non-NHS partner organisations e.g. Universities.

1.4 The Community Health Index (CHI) number has unique status in Scotland. CHI is a unique identifier that is disclosive (includes date of birth, gender and other information). If CHI is requested, rationale for collecting CHI numbers should be discussed/agreed with the Sponsor/local R&D and Caldicott Guardian, where appropriate.

2 PURPOSE

2.1 The purpose of this SOP is to outline the procedure that Researchers and ACCORD personnel must follow if a research study includes collection, transfer and storage of personal identifiable information, including CHI numbers. This also extends to identifiable information about NHSL staff.

3 SCOPE

3.1 This SOP applies to Researchers, the NHSL R&D Caldicott Reviewers, NHSL and UoE Research Governance staff performing Sponsorship and R&D Governance review of research studies and the R&D Admin team.

4 RESPONSIBILITIES

4.1 It is the responsibility of the Researcher, or designee, to apply and complete an application for Caldicott or Public Benefit and Privacy Panel (PBPP) approval, if required.

4.2 It is the responsibility of the Researcher, or designee, to provide or arrange provision of information to allow the NHSL Information Governance (IG)/IT Security team to undertake review of IG/IT security arrangements (whether Caldicott/PBPP approval is needed or not), if required.

4.3 It is the responsibility of the Sponsorship Reviewer to determine (in accordance with ACCORD SOP GS003 Sponsorship Approval);

- If personal identifiable information is being processed e.g. accessed or collected,
- What identifiable information is being processed,
- If this data is being transferred/stored out with NHSL or the NHS,
- If identifiable data leave the UK and/or the EEA,
- How the data will be transferred and where it will be stored,
- Who will access this data and for how long,
- If the data processing involves a mobile device, application, database or cloud-based data capture system,
- Whether Caldicott or PBPP approval is required,
- Whether IG/IT Security review is required,
- Whether data security arrangements comply with NHSL policies (in conjunction with NHSL IG/IT Security where required). Further clarification will be sought from the NHSL R&D delegated Caldicott Reviewer or IG/IT if required.

4.4 The delegated Caldicott Reviewer is primarily the R&D eResearch Lead but this role can be fulfilled by the Deputy R&D Director, the Principal R&D Manager or the Head of Research Governance (NHSL). It is the responsibility of the R&D delegated Caldicott Reviewer to;

- Log and review local Caldicott applications and issue approval, where appropriate.
- Track local Caldicott applications and provide monthly reports to the NHSL Caldicott Guardian detailing all local Caldicott approvals granted.
- Provide guidance to researchers on requirements for NHSL Caldicott and IG/IT Security review.
- Maintain a log of NHSL IG/IT Security reviews undertaken for applications managed under delegated Caldicott review.
- Review (and approve where appropriate) checklists for Caldicott Proportionate Review (Use of Portable Media Checklist).

4.5 The NHSL R&D Governance Reviewer is responsible for ensuring that all items detailed in section 4.3 have been addressed by the Sponsor Reviewer for studies Sponsored by NHSL and/or UoE. If they have not, the NHSL

Governance Reviewer must address these prior to R&D Management Approval (SOP GS001).

4.6 For studies hosted by NHSL, the R&D Governance Reviewer is responsible for addressing all items detailed in section 4.3.

4.7 The R&D Admin team are responsible for filing the authorised Use of a Portable Media Checklist.

5 PROCEDURE

For research studies reviewed within ACCORD, that are deemed to require further scrutiny in relation to Caldicott principles or IG/IT security issues, the Sponsorship Reviewer and/or the R&D Governance Reviewer will advise the Researcher to engage with the delegated R&D Caldicott Reviewer and/or NHSL IG/IT Security, where appropriate.

5.1 Local Caldicott – Single Site

5.1.1 A Researcher will seek local Caldicott approval for any study where there will be access to personal identifiable data, or transfer/storage of identifiable data out with NHSL (which may include CHI where this is not normally identified and processed by the clinical care team through standard procedures) without the personal's knowledge or consent. This includes access to records of the deceased. Caldicott approval is also required where portable media are used to store or transfer identifiable data, including for example USB devices, iPads and recording devices (see section 5.4), even where consent is in place to do so.

5.1.2 The Sponsorship or R&D Governance Reviewer will ensure that the Researcher submits a Local Caldicott and/or Information Governance Application Form (GS008-F01) to ACCORD (accord@nhslothian.scot.nhs.uk).

5.1.3 The Researcher must complete all sections (A, B and C) of the Local Caldicott and/or Information Governance Application Form (GS008-F01) prior to submission to ACCORD.

5.1.4 On receipt of the completed application, the delegated R&D Caldicott Reviewer will allocate a Caldicott reference number and add an entry into the Caldicott Enquiries and Applications tracker held on the NHSL R&D shared F: drive (Research & Development/Research Governance/Caldicott/Projects & Enquiries). This reference number will be added to the Caldicott application form and included in all correspondence.

5.1.5 The delegated R&D Caldicott Reviewer will review the completed form to ascertain if the proposed study procedures comply with the Caldicott principles, the NHSL R&D Generic Data Protection Impact Assessment (DPIA) for Research (see SOP GS001 R&D Management Approval and

GS003 Sponsorship Approval), and the NHSL Digital and IT Security Policy and Information Governance Policy.

5.1.6 When compliance is confirmed, the delegated R&D Caldicott Reviewer will grant Caldicott approval by letter. The letter will set out any conditions or recommendations and will be e-mailed, together with the approved Caldicott application, to the researcher.

5.1.7 Approval will be issued by the delegated R&D Caldicott Reviewer and the Sponsorship and/or R&D Governance Reviewer will be copied in the e-mail, as will accord@nhslothian.scot.nhs.uk.

5.1.8 Where the original application does not comply fully with the Caldicott principles, the R&D Generic DPIA for Research, and/or the NHSL Digital and IT Security Policy and Information Governance Policy, the delegated R&D Caldicott Reviewer, Sponsorship or R&D Governance Reviewer will assist the applicant, where possible, to address the outstanding issues to ensure compliance.

5.1.9 Where the application continues to have outstanding issues and/or to be out of scope for delegated review and approval, the researcher will be advised that the Caldicott application needs to be escalated to the NHSL Caldicott Guardian by the delegated R&D Caldicott Reviewer (caldicott.guardian@nhslothian.scot.nhs.uk).

5.1.10 The rationale for escalation will be documented by the delegated R&D Caldicott Reviewer in the Caldicott Enquiries and Application tracker on the NHSL R&D shared F: drive, and the application provided to the NHSL Caldicott Guardian by e-mail.

5.1.11 The delegated R&D Caldicott Reviewer will record the outcome of the review by the NHSL Caldicott Guardian in the Caldicott Enquiries and Application tracker on the NHSL R&D shared F: drive, and inform the researcher and the Sponsorship and/or R&D Governance Reviewer, where applicable.

5.1.12 Confirmation of Sponsorship can be issued prior to local Caldicott approval but R&D management approval cannot be issued prior to Caldicott approval unless agreed with the R&D Senior Management team. This is a local issue and will not hold up any R&D generic reviews.

5.1.13 A summary of each application approved under delegated authority is added to the approvals report maintained on the Caldicott folder on the NHSL R&D shared F: drive (Research & Development/Research Governance/Caldicott/Projects & Enquiries/Projects-Approved). A dated copy of the report is copied to the NHSL Public Health shared drive Caldicott Application folder (PublicHealth/CHI&Caldicott/R&D Monthly Reports) for the NHS Lothian Caldicott Guardian. The reports are flagged to the NHSL

Caldicott Guardian by the delegated R&D Caldicott Reviewer on a monthly basis by email to caldicott.guardian@nhslothian.scot.nhs.uk.

5.2 National Caldicott

5.2.1 If the study is multi-centre involving more than one site in Scotland, and the collection, transfer and storage of personal identifiable information has not been consented, the researcher must make an application to the PBPP.

5.2.2 The Sponsorship or R&D Governance Reviewer will provide the researcher with details of the PBPP website (http://www.informationgovernance.scot.nhs.uk/pbpphsc/), which contains contact details (phs.edris@phs.scot / 0131 275 7333), guidance and an application form.

5.2.3 If there are sites in England or Wales, the researcher must seek approval from the Confidentiality Advisory Group (CAG).

5.2.4 If there are sites in Northern Ireland, the researcher must seek approval from the Privacy Advisory Committee (PAC).

5.3 IG/IT Review

5.3.1 If the Sponsorship, R&D Governance Reviewer or delegated R&D Caldicott Reviewer believes that a study requires assessment by IG/IT Security, they may refer the issue for further guidance or review e.g. transfer of personal identifiable data out with the NHS, use of new software on NHS systems (e.g. eConsent systems), storage of personal data on mobile devices/online platforms.

5.3.2 Advice and/or review can be sought directly from the R&D IT Security Project Manager (contact details can be provided by the delegated Caldicott Reviewer or by the Sponsorship/R&D Governance Reviewer) or by e-mailing Lothian.ITSec@nhs.net. NHSL personnel can also log a call using the online Assyst portal system (e8050). The reference number issued by NHSL IT Security should be used in all future correspondence relating to this query.

5.3.3 The R&D IT Security Project Manager, or designee, will work with the researcher to complete the necessary NHSL IT Security Checklist in accordance with NHSL Approval Triage Process for R&D (this is covered under separate NHSL Digital & IT Security SOPs, and out with the scope of this SOP). The outcome of this process is a risk assessment that will be e-mailed to the delegated R&D Caldicott Reviewer, Sponsorship/R&D Governance Reviewer and/or the Researcher who logged the call with IT Security.

5.3.4 The delegated R&D Caldicott Reviewer will consider the outcome of the risk assessment and if appropriate issue a letter or e-mail to the Researcher

setting out any outstanding mandatory requirements from the risk assessment.

5.3.5 If requested by the delegated R&D Caldicott Reviewer or Sponsor/R&D Governance Reviewer, the Researcher must provide written confirmation on how they will comply with any recommendations made by NHSL IG/IT Security.

5.3.6 Where the IT Security risk assessment is linked to a Caldicott application, this will be taken into consideration by the delegated R&D Caldicott Reviewer prior to issue of Caldicott approval.

5.3.7 Confirmation of Sponsorship can be issued prior to receipt of NHSL IT Security approval, however this approval must be received prior to R&D management approval unless agreed with the R&D Senior Management team.

5.3.8 This is a local issue only and should not hold up any generic reviews.

5.4 Proportionate Caldicott Review for Portable Media

5.4.1 The NHSL IT Security Policy dictates that any use of portable media to collect personal information requires local Caldicott approval.

5.4.2 Where the R&D Governance Reviewer identifies a study involving the use of portable media, they will complete the Use of Portable Media Checklist (GS008-F02) during the R&D governance review using the information detailed in the study documents. This checklist will only be completed in the absence of a local caldicott application form.

5.4.3 The R&D Governance Reviewer will send the completed checklist to the delegated R&D Caldicott Reviewer.

5.4.4 Where the R&D Governance Reviewer has been able to answer 'Yes' to all questions in the checklist and there are no outstanding issues, the delegated R&D Caldicott Reviewer will sign off the checklist and pass it to the R&D Admin team to file in the appropriate study folder in the NHSL R&D F: drive.

5.4.5 Where the R&D Governance Reviewer has not been able to answer 'Yes' to all questions and/or there are any outstanding issues, the R&D Governance Reviewer may seek advice from the delegated R&D Caldicott Reviewer and/or IG/IT Security. If required, the Investigator may be requested to complete a full Caldicott application as detailed in section 5.1.

5.5 Record Retention

5.5.1 The delegated R&D Caldicott Reviewer will retain completed Caldicott application forms, approval letters, and associated correspondence in the study specific Caldicott folders on the NHSL R&D shared F: drive.

5.5.2 The Sponsorship reviewer will retain the hard copy of the completed application form and approval letter in the Trial Master File/Sponsor File (CTIMPs and studies that have undergone Combined Risk Assessment in accordance with SOP GS002) and/or an electronic copy in the relevant study folder on the ACCORD SharePoint (all studies).

5.5.3 The completed and authorised Use of Portable Media Checklist (GS008-F02) will filed by the R&D Admin team in the appropriate study folder on the NHSL R&D shared F: drive.

5.6 Review of Data Storage Locations and IT Systems

5.6.1 NHSL IG/IT Security will maintain an inventory of safe systems, reviewed for research, in accordance with NHSL Digital & IT Procedure for Re-approving systems used by NHSL.

5.6.2 Where the Researcher, Sponsor Reviewer, R&D Governance Reviewer or delegated R&D Caldicott Reviewer is unsure if a system has already been risk assessed by NHSL IT Security, they must contact the R&D IT Security Project Manager or e-mail Lothian.ITSec@nhs.net

5.6.3 Where the system has been risk assessed before, IG/IT Security will issue a Re-approved System Record containing basic information about the service/system gathered during the last assessment to the person who logged the call. That person will be required to confirm that the Re-approved System Record is accurate for this subsequent use of the system and if not accurate, any differences noted and returned to IT Security.

5.6.4 IG/IT Security will confirm if the Researcher can proceed with using the product based on the information provided following review of the Re-approved System Record and any additional information provided.

6 REFERENCES AND RELATED DOCUMENTS

- GS008-F01 Local Caldicott and/or Information Governance Application Form
- GS008-F02 Use of Portable Media Checklist
- GS001 R&D Management Approval
- GS003 Sponsorship Approval

- NHSL Digital and IT Security Policies and Guidance documents https://www.accord.scot/researcher-access/digital-and-it-security-policy
- CEL 25 2012 NHS Scotland Mobile Data Protection Standard http://www.sehd.scot.nhs.uk/mels/CEL2012_25.pdf.
- NHS Scotland Public Benefit and Privacy Panel for Health & Social Care
- Data Protection Act 2018

7 DOCUMENT HISTORY

Version Number	Effective Date	Reason for Change
1.0	19 SEP 2016	New SOP
2.0	01 AUG 2017	The title and author of this SOP has changed. All sections of this SOP have been updated to reflect current procedure. This includes determining if identifiable data is being collected, transferred and stored at the Sponsorship review stage where possible and confirmed at R&D review. The procedure has been expanded to include additional requirements with regards to NHSL Information Governance and Security, which includes updated to GS008-F01 and additional guidance added as Appendix 1 & 2.
3.0	23 MAR 2021	Change in SOP title. Changes to all section of this SOP with inclusion of R&D Admin Team responsibilities, reference to Information Governance policies and procedures and the NHSL R&D Generic DPIA. Addition of a section on Proportionate Caldicott Review for Use of Portable Media and associated form.

8 APPROVALS

Sign	Date
SIGNATURE KEPT ON FILE AUTHOR: Pamela Linksted, e-Research Lead, ACCORD	
SIGNATURE KEPT ON FILE APPROVED: Fiona McArdle, Deputy R&D Director, ACCORD	
SIGNATURE KEPT ON FILE AUTHORISED: Lorn Mackenzie, QA Manager, NHSL, ACCORD	