SPONSORSHIP APPROVAL FOR DATALOCH RESEARCH STUDIES

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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 DataLoch (DL) is a data service hosting a repository of routine health and social care data for the Edinburgh and South East Scotland region to help find solutions to current health and social care challenges. DL is underpinned by the DL Governance Framework.

1.3 The DataLoch team facilitates managed access to this repository for a variety of approved projects. A DL research study (project) is classified as a study that is supported by DL approval processes, where data extracts from within the DL repository are either accessed via a Trusted Research Environment analytic platform (also referred to as a Secure Data Environment) or are released directly to the Investigator. They include studies where analysis of Investigator supplied datasets is conducted within a SH analytic platform, without the need for access to DL hosted data, where approval is sought through DL approval processes.

1.4 DL research studies intended for Sponsorship by NHSL and/or UoE are reviewed to ensure that the design of the study meets appropriate standards and that all necessary arrangements are in place to ensure appropriate conduct and reporting.

2 PURPOSE

2.1 To document the procedure for obtaining Sponsorship approval from NHSL and/or UoE for research studies conducted in the DL.

3 SCOPE

3.1 This SOP applies to all researchers requesting Sponsorship approval for DL studies co-Sponsored by NHSL or UoE. This SOP applies to NHSL/UoE DL governance staff involved with the oversight of DL research studies, including performing Sponsorship review.

4 RESPONSIBILITIES

4.1 It is the responsibility of the Investigator, or designee, to provide all necessary research study information/documentation to the DL governance team.

4.2 It is the responsibility of the DL Service Manager, or designee, to;

- Triage DL project enquiries, assign a DL project reference number, and provide guidance on DL procedures,
- Review DL research study application documentation and ensure all required documents are received and suitable for submission to the DL Information Governance (IG) Facilitator to progress sponsorship review/approval, where required,
- Act as the main point of contact for the Investigator, or designee, providing them with feedback on the review/approvals process and delivery,
- Inform the NHSL R&D IG Lead when a DL research study has sponsorship approval,
- Keep the DL IG Facilitator informed of received/relevant DL research study information that may affect sponsorship.

4.3 It is the responsibility of the DL IG Facilitator, or designee to;

- Enter and maintain DL research study details in the ACCORD sponsorship tracker on the ACCORD SharePoint, and assign an ACCORD sponsorship identifier,
- Conduct an initial sponsorship review of DL research study documents before the study is submitted to the DL Data Access Group (DAG),
- Review Investigator feedback and the outcome of the DAG review prior to completing sponsorship review and approval,
- Provide the DL Service Manager with sponsorship comments to feedback to the Investigator,
- Review amendments to DL research studies with the DL IG Manager, where required, and sign off DL research study amendments, where DAG review of the amendment is not required.
- Consult with the DL IG Manager, ACCORD Research Governance teams (UoE and/or NHSL), UoE/NHSL Contracts, IG/IT Security and ACCORD Quality Assurance (QA) team, where required.

4.4 It is the responsibility of the DL IG Manager, or designee to;

- Seek Caldicott approval, where escalation for consideration by the NHSL Caldicott Guardian is required,
- Review NHSL IG/IT security risk assessments for DL research studies under the delegated Caldicott authority within DataLoch, or escalation for consideration by the NHSL Caldicott Guardian,
- Review DL research study considerations escalated by the DL IG Facilitator e.g. IT security and Caldicott queries, contractual queries,

4.5 The R&D IG Lead is responsible for uploading all relevant documents and DL research study information to the SReDA database.

5 PROCEDURE

5.1 Identification of New Studies

5.1.1 The Investigator, or designee, will contact the DL team directly to enquire about conducting a research study in the DL. This will be done via the enquiries inbox (dataloch@ed.ac.uk).

5.1.2 At initial contact, as a minimum, the Investigator or designee will provide the following information to the DL Service Manager, or designee as captured within the DataLoch Application Form;

- Chief Investigator (CI) name, employment & contact details (within DataLoch application project specific lead roles are referred to as Applicant and clinical lead)
- CI honorary contract status
- Working title of the research study
- whether project is part of a wider programme or work (e.g. multi-centre)
- Draft DL Application Documentation (see DL-SOP-001 DataLoch Application Process) includes:
    - Application Form
    - Statistical Analysis Plan (SAP) – if available
    - Dataflow diagram – if available

5.1.3 The DL Service Manager, or designee, will process new DL enquiries for research studies in accordance with the DataLoch Application Process SOP (DL-SOP-001), ensuring that all required documents have been submitted and are completed.

5.1.4 The DL Service Manager will assign a DL project reference number to the enquiry.

5.1.5 The DL Service Manager will seek guidance from the DL IG Facilitator on any DL governance issues raised while triaging the DL Application documentation (see DL -SOP-001 DataLoch Application Process) and associated documents.

5.1.6 The DL Service Manager will notify the DL IG Facilitator that the research study is ready for sponsorship review.

5.2 Sponsorship Review

5.2.1 The DL IG Facilitator will enter and maintain DL research study details in the ACCORD sponsorship tracker on the ACCORD SharePoint, assigning an

ACCORD sponsorship identifier e.g. ACYY123 (where 'YY' is the last 2 digits of the year and '123' is the next available consecutive number in the tracker),

5.2.2 The DL Facilitator will save all documents required for sponsorship review in the study specific files in the DL folder on the ACCORD SharePoint. Required documents are listed in the DL Study Sponsorship Review form (GS014-F01),

5.2.3 Prior to submission to the DAG (DL-SOP-001 DataLoch Application Process), an initial sponsorship review will be conducted by the DL IG Facilitator.

5.2.4 The DL IG Facilitator will review the DL research study documents against the DL Study Sponsorship Review form (GS014-F01), ensuring that all points have been addressed, or will be addressed in development and delivery of the study. Any issues or recommendations will be noted in the relevant sections on the application form. The DL Study Sponsorship Review form (GS014-F01) will be used to document comments to be fed back to the Investigator.

5.2.5 Where the DL IG Facilitator is unsure whether the DL research study falls within the remit of the generic Research Ethic Committee (REC) approval for the NHSL SH/DL, they will consult with the DL IG Manager and/or ACCORD Research Governance teams (UoE and/or NHSL).

5.2.6 The DL IG Facilitator will forward any research studies that fall out with the generic REC approval for the NHSL SH/DL to the ACCORD Research Governance team (resgov@accord.scot). Under these circumstances, the study will progress as per ACCORD SOP GS003 (Sponsorship Approval) e.g. a study specific REC opinion and R&D management approval may be required.

5.2.7 When the initial sponsorship review is complete or when sponsorship approval must be sought through ACCORD (SOP GS003), the DL IG Facilitator will inform the DL Service Manager.

5.3 Agreements and Indemnity

5.3.1 At the time of the initial Sponsorship review, the DL IG Facilitator will liaise with the relevant NHSL and/or UoE contracts team to alert them that study specific agreements may be required (where DL template agreements are not suitable).

5.4 DAG & Investigator Feedback

5.4.1 The DL Service Manager, or designee, will provide the Investigator, or designee, with any comments from the initial sponsorship review, or advise them that sponsorship review via ACCORD is required (SOP GS003).

5.4.2 On receipt of further communication from the Investigator, or designee, the DL Service Manager will pass this on to the DL IG Facilitator.

5.4.3 The IG Facilitator will review any updates to documents and feedback will continue following 5.2.2-5.2.7 until all comments are addressed and any outstanding issues resolved.

5.4.4 The DL IG Facilitator will also take into consideration the DAG review of the DL research study (DL-SOP-001 DataLoch Application Process) prior to issuing sponsorship approval.

5.4.5 If any issues remain that could give the DL IG Facilitator cause to decline sponsorship, they will be communicated to the ACCORD Research Governance teams (UoE and/or NHSL) for guidance.

5.5 Confirmation of Sponsorship

5.5.1 Once the Investigator feedback process has concluded, with all queries answered to the satisfaction of the DL IG Facilitator, they will advise the DL Service Manager, or designee.

5.5.2 The DL Service Manager, or designee, will advise the Investigator (by email) that they have Sponsor's authorisation for the study by sending a copy of the approved Application that includes details on sponsorship signoff. The NHSL R&D IG Lead will be copied into this email. A separate sponsorship letter will be drawn up by the DL IG Facilitator and provided to the Investigator, if requested by the investigator. Copies of these correspondence will be held within the DL project folder.

5.5.3 The IG Facilitator will ensure the completed DL Study Sponsorship Review form (GS014-F01) is finalised and signed in tandem to confirmation of sponsorship with the Investigator.

5.5.4 Sponsorship review documentation will be saved electronically in the appropriate study specific Sponsorship Review folder in the DL folder on the ACCORD SharePoint by the DL IG Facilitator (or designee).

5.5.5 The DL IG Facilitator, or designee, will update the ACCORD Sponsorship tracker with any relevant study information and will continue to do so throughout the life of the study.

5.5.6 On receipt of any study specific enquiries related to sponsorship, the DL IG Facilitator will provide the Investigator, or designee, with any necessary guidance throughout the life of the study. This communication will be via the DL Service Manager.

5.6 Caldicott Approval

5.6.1 During the sponsorship review process, the DL IG Facilitator will consult with the DL IG Manager around the need for Caldicott approval for research studies seeking access to data outside of a Trusted Research Environment, and those falling outside of the remit of the delegated Caldicott assessors within DataLoch (DL-SOP-001 DataLoch Application Process).

5.6.2 The DL IG manager will review these with the delegated Caldicott authority in R&D (ACCORD SOP GS008 Personal Identifiable Information: Caldicott Approval and Information Governance Review), or escalate for review by the NHS Lothian Caldicott Guardian.

5.7 IG/IT Security Review

5.7.1 During the sponsorship review process, the DL IG Facilitator will consult with the DL IG Manager around the need for an additional IT security assessment for studies seeking access to data outside of a Trusted Research Environment. Where required, the DL IG Facilitator will submit a request to the R&D Information Security Project Manager (NHSL Information Governance Approval Process for R&D) and request the DL Service Manager, or designee, informs the Investigator.

5.7.2 Information security assessments undertaken in connection with DL research studies will be reviewed and, if appropriate, signed off by the DL IG Manager in collaboration with the delegated Caldicott authority in R&D or escalation for signoff by the Caldicott Guardian (ACCORD SOP GS008 Personal Identifiable Information: Caldicott Approval and Information Governance Review).

5.7.3 Where changes to the data transfer processes are required, or recommended by NHSL IT Security, this will be passed to the DL Service Manager to engage with the Investigator to make the necessary changes to the study documents, where required.

5.8 R&D Notification

5.8.1 Once sponsorship approval (under delegated Sponsorship review) is confirmed for a DL research study that involves NHSL patient data/tissue, staff or NHSL facilities, the DL Service Manager will notify the R&D IG Lead (R&DOffice@nhslothian.scot.nhs.uk) as set out in 5.5.2 The R&D IG Lead will upload the necessary DL research study documents, held within the DL project folder on the ACCORD SharePoint and study information to the SReDA

database. Under the existing DL Governance Framework for DL research studies, R&D management approval is not required.

5.9 Amendments

5.9.1 The Investigator, or designee, will submit proposed amendments to their DL research study to the DL team (dataloch@ed.ac.uk).

5.9.2 The DL IG Facilitator, or designee, will file the documents in the study specific file in the DL folder on the ACCORD SharePoint.

5.9.3 Amendments will be reviewed by the DL IG Facilitator, in consultation with the DL IG Manager, to determine whether the amendment needs to be submitted to the DAG for review and if review for continued Sponsorship approval is required. Amendments requiring DAG review and/or Sponsorship approval are classed as substantial amendments

5.9.4 Assessment of each new study specific amendment will be documented on GS014-F01 'Amendments', and the documented review and outcome saved in the relevant study specific file in the DL folder. Substantial amendments will also be filed on the ACCORD SharePoint.

5.9.5 Once amendment approval (under delegated Sponsorship review) is confirmed for a DL research study that involves NHSL patient data/tissue, staff or NHSL facilities, the DL Service Manager will notify the Investigator (by email). The R&D IG Lead (R&DOffice@nhslothian.scot.nhs.uk) will be copied into this email notification if the amendment is classed as substantial. The R&D IG Lead will upload the necessary DL research study documents, held within the DL project folder on the ACCORD SharePoint, and study information to the SReDA database. Under the existing DL Governance Framework for DL research studies, R&D management approval of amendments is not required.

6 REFERENCES AND RELATED DOCUMENTS

- GS003 Sponsorship Approval
- GS008 Personal Identifiable Information: Caldicott Approval and Information Governance Review
- GS014-F01 DL Study Sponsorship Review form
- GS014-WI01 DL-IG and Sponsorship Review Work Instruction
- DL SOP-001 DataLoch Application Process
- DL F01 DL Application Form
- DL Governance Framework
- NHSL Information Governance Approval Process for R&D
- UK Policy Framework for Health and Social Care Research

7 DOCUMENT HISTORY

Version Number	Effective Date	Reason for Change
1.0	02/07/2021	New SOP.
2.0	29 APR 2024	Noting issues/recommendations within the Application form in addition to the Sponsorship review form added to section 5.2.4 Change of responsibility for signing non-substantial amendments and handling notification of sponsorship to Investigator and the R&D IG Lead in section 5.5.2. Section 5.9 updated regarding filing of substantial amendments within the ACCORD SharePoint and SReDA. Reference to Sponsorship review work instruction GS014-WI01 added. GS014-F01 updated to v2.0, which was piloted from May 2023.

8 APPROVALS

Sign	Date
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Heather Charles Heather Charles (Apr 12, 2024 11:41 GMT+1) APPROVER: Heather Charles, Head of Research Governance, NHSL, ACCORD	Apr 12, 2024
Chris Coner (Apr 12, 2024 11:25 GMT+1) APPROVER: Chris Coner, Research Coordinator, UoE, ACCORD	Apr 12, 2024
L. Mackenzie AUTHORISED: Lorn MacKenzie, QA Manager, NHSL, ACCORD	Apr 12, 2024

GS014 Sponsorship Approval For DataLoch Research Studies v2.0

Final Audit Report 2024-04-12

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