**DL-Work Instructions – IG and Sponsorship Review**

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| **DOCUMENT NO.:** | **GS014-WI01 v1.0** |
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| **ISSUE DATE:** | **15 APR 2024** |
| **EFFECTIVE DATE:** | **29 APR 2024** |

# FOREWORD

## 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).

## DataLoch (“DL”) is a data service and hosts a repository of routine health and social care data for the Edinburgh and South East Scotland region. The DL repository and the services associated with it have been established to help address the current health and social care challenges and supports research, service management and innovation projects. DL is underpinned by the DL Governance Framework

## This work instruction focuses on the steps undertaken primarily by the IG Facilitator in initiating and completing delegated sponsorship review. These instructions are to be read in conjunction with SOP - **GS014 Sponsorship Approval for DataLoch Research Studies**. Steps within this work instruction also covers projects that are deemed not to be Research and not requiring delegated or full Sponsorship review.

## [please note a DL supported research study is referred to as a project within DataLoch]

# INSTRUCTIONS

## **IG/Initial Sponsorship Review – completed for all projects by IG Facilitator**

### *Comes after Feasibility review but before Tech Specification and DCA review*

**IG Facilitator:**

### Requirement for IG/Initial sponsorship review will be received from DataLoch Service Manager

*[linked to GS014 SOP section 5.2]*

### Save blank GS014-F01 DataLoch (DL) Study Sponsorship Review into project folder in UoE Teams renaming as **DLPROJECTNUMBER\_GS014-F01 DataLoch (DL) Study Sponsorship Review** (the “study specific DL Study Sponsorship Review form”)

**All projects:**

### Review the DL research study documents (application form and any other relevant documents – variable list, study protocol etc if provided) against the study specific **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

### Additional guidance on what to highlight is captured in the **Initial IG Review questions** section of the **GS014\_Ref01 Reference document**

### While reviewing the Application form and associated documents note any issues/recommendations as comments on the application form in the relevant sections. Write in a form clear enough for an applicant to understand what is required.

### Document comments to be fed back to the Investigator in the study specific **DL Study Sponsorship Review form (GS014-F01)** and complete this Sponsorship Review form as well as possible.

### If unsure, consult with IG Manager/ACCORD Sponsorship Review team and note on the study specific **DL Study Sponsorship Review form (GS014-F01)** and **Application Form** that consultation in progress and response.

### If project deemed not to be researcher and sponsorship is not required, note this in the study specific **DL Study Sponsorship Review form (GS014-F01)** and jump to 2.1.13

**Research projects only:**

### Enter DL research study details in the ACCORD sponsorship tracker on the ACCORD SharePoint, assigning an ACCORD sponsorship identifier e.g. ACYY123.

### Record ACCORD Sponsorship identifier within the study specific **DL Study Sponsorship Review form (GS014-F01)**

### If project not within generic ethics for DataLoch/LRSH, note on application form and confirm with Service Manager and Applicant what will need to happen. If applicant confirms they want to proceed as is, send all documentation immediately to [resgov@accord.scot](mailto:resgov@accord.scot) for full review and note on application form. Note actions on study specific **DL Study Sponsorship Review form (GS014-F01**) and skip to 2.2.13 within this WI.

### Complete [Accord Sponsorship Sharepoint Tracker](https://uoe.sharepoint.com/sites/accord/Lists/Tracker/AllItems.aspx?CT=1634133401200&OR=OWA%2DNT&CID=7730f87c%2Dd0d0%2D6dba%2Dc246%2D56a24d64e930) (see GS014\_Ref01 for guidance) and add Sponsorship number to the study specific **DL Study Sponsorship Review form (GS014-F01**) and save

### **All projects:**

### *[linked to GS014 SOP section 5.3 & 5.7]*

### If extra contracts or IT Security review required, liaise with IG Manager in first instance. Then contact Doug Young (Principal R&D Manager, NHS Lothian) or [itsec@nhslothian.scot.nhs.uk](mailto:itsec@nhslothian.scot.nhs.uk) (if IT security review required) and legal team of other contracting organisation. Notify/request Service Manager informs applicant that agreements/review will need to be put in place.

### Update card on the Teams Project Planner to inform Service Manager that IG/Initial Sponsorship review complete/referred, application form updated and briefly note any issues.

*Application form will now be reviewed by Analyst (Technical Specification) and signed off by researcher and analyst that we will proceed. Then goes to DCA review. After DCA review, project comes back to IG facilitator for ethics and final sponsorship review – usually prompted via email from Service Manager/AdobeSign notification when DCA completes review.*

* 1. **Final Sponsorship Review Process – completed for all projects that fall within DL governance thresholds – by IG Facilitator**

*Process comes after DCA and ethics responses received*

**IG Facilitator:**

### *[linked to GS014 SOP section 5.4]*

### Consider any feedback from the DAG review prior to considering completion of the IG review and delegated sponsorship approval.

[linked to GS014 SOP section 5.5]

### Check the study specific **DL Study Sponsorship Review form (GS014-F01**) is fully completed and all queries in the review form and signed application form have been answered. If not, refer back to Service Manager for response from Applicant. If so, use today’s date as date Sponsorship approved and send through AdobeSign (assign to self) for signature, save .pdf of this and the study specific **DataLoch Approvals Review Summary (DL-002\_T05)** in Project Folder.

### Inform the Service Manager that IG review has been completed and, for research projects, that Sponsorship has been confirmed.

**Signoff:**

### If agreements/contracts outside of DataLoch approvals are required, check we have them saved in Teams. If not, refer back to Service Manager for response from Applicant.

### If notification isn’t through AdobeSign: Put signed version of application form (pdf) through AdobeSign (use Fill and Sign function to assign it to yourself)

### If notification isn’t through AdobeSign: Complete application form (Change Control (add comment on what done, Outcome of review by the delegated ethics panel and Sponsorship details) with results. Sign and save as new version (pdf)

### If notification is through AdobeSign: Complete relevant sections showing approval dates/sponsorship number and signature.

## **Maintaining record**

## **Saving documents:**

### Save all relevant documents in DataLoch SharePoint/Teams project folder

### For research projects under DL delegated sponsorship save copies of all relevant documents on ACCORD Sponsorship Sharepoint (Click on link in StudyLinkFolder)

Files to go in Study Documents folder:

* 1. Current Approved documents: Save Application form (that shows DCA approval), variable list, protocol/SAP and signed study specific **DataLoch Approvals Review Summary (DL-002\_T05)**
  2. Sponsor Review, R1 (review 1) – save study specific **DL Study Sponsorship Review form (GS014-F01)**

**Update Trackers:**

### Add dates of ethics and sponsorship completed on Project Tracker (main sheet)

### Add any comments from any reviews to IG Tracker tab on Project Tracker/Learning Loop Tracker

### Update card on the Teams Project Planner to inform Service Manager and analysts that approvals completed.

## **Amendments:**

*[linked to GS014 Sponsorship Approval for DataLoch Research Studies SOP section 5.9]*

### Review proposed amendment, to determine whether the amendment needs to be submitted to the DAG for review and if review for continued Sponsorship approval is required, consult IG Manager where required (i.e. substantial amendment)

### Update study specific **DL Study Sponsorship Review form (GS014-F01**) with any substantial amendments and save on ACCORD: [Sponsorship SharePoint](https://uoe.sharepoint.com/sites/accord/Lists/Tracker/AllItems.aspx?CT=1634133401200&OR=OWA%2DNT&CID=7730f87c%2Dd0d0%2D6dba%2Dc246%2D56a24d64e930) and add any further documentation required in Current Approved Documents folder

### Notify Service Manager and R&D IG Lead when complete.

# REFERENCES

[GS014 Sponsorship Approval for DataLoch Research Studies](https://uoe.sharepoint.com/sites/DataLochProjectTeam-Phase1Alpha/Shared%20Documents/IG/Project%20Review%20and%20approvals/Sponsorship/GS014%20Sponsorship%20Approval%20for%20DataLoch%20Research%20Studies%20v1.0%20-%20signed.pdf) (SOP).

[GS014-F01 DataLoch (DL) Study Sponsorship Review](https://uoe.sharepoint.com/:w:/r/sites/DataLochServiceDelivery/Shared%20Documents/DataLoch%20Delivery/General%20info/0.3%20Form%20Templates%20%26%20Guidance/DL-20YY-0XX_GS014-F01%20DataLoch%20(DL)%20Study%20Sponsorship%20Review%20v2.0.docx?d=w7def8022e7744595b43d72173bd39328&csf=1&web=1&e=JoILDI)

[ACCORD Sponsorship Tracker](https://uoe.sharepoint.com/sites/accord/Lists/Tracker/AllItems.aspx?CT=1634133401200&OR=OWA%2DNT&CID=7730f87c%2Dd0d0%2D6dba%2Dc246%2D56a24d64e930)

GS014\_Ref01 DL-IG and Sponsorship Review – Reference Information

[DL-002\_T05 DataLoch Approvals Review Summary Template](https://uoe.sharepoint.com/:w:/r/sites/DataLochProjectTeam-Phase1Alpha/Shared%20Documents/IG/Document%20Catalogue/DL-002%20Project%20Review%20and%20Approvals/DL-002_T05%20DataLoch%20Approvals%20review%20summary%20TEMPLATE%20v1%20.docx?d=wf0b5d843c6e740b1a9db91886aa78b4e&csf=1&web=1&e=TE6yhn)