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| **DataLoch (DL) Study Sponsorship Review** | | | | | |
| **DataLoch Number:** | **DL-202X-0XX** | | **Status/Date of Sponsorship Approval:** | |  |
| **Short Title:** |  | | | | |
| **Chief Investigator (CI):** |  | | | | |
| **Sponsorship Number:** |  |  | |  | |
| **Reviewer Name:** |  | **Reviewer Signature:** | | |  |
| **Approved docs (& versions):** |  |  | | |  |

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| **Considerations** | **Guidance** | Response | **Comment for researcher** |
| Is the CI substantively employed by UoE/NHSL? QA1 | *If no, the research will not be sponsored by UoE/NHSL.*  *Note – pre-doctoral students cannot be CI.* | No Yes |  |
| Is the project considered health related research?  QB5 | *Use aims/objectives to determine this.* [*HRA decision tool*](http://www.hra-decisiontools.org.uk/research/) *and* [*table*](http://www.hra-decisiontools.org.uk/research/docs/DefiningResearchTable_Oct2017-1.pdf) *can be used. If still in doubt discuss with ACCORD Research Governance Team.*  *If no, Sponsorship not required.* | No  Yes |  |
| Is the project SBRI/HISES funded? | *If SBRI/HISES funded – academic/NHS partner should take on CI role to allow ACCORD to sponsor.* | No  Yes |  |
| Is the clinical lead identified and appropriate? | *Clinical leads should be NHS employed. Clinical Lead can be CI but not when completing this project as part of a qualification.*  *Clinical Lead may not be required in some studies – consult with IG if unsure.* | No  Yes  N/A |  |
| Is the project covered by Safe Haven generic Research Ethics Committee approval?  QB5 and DSF | *Generic Research Ethics: use of pseudonymised NHS Lothian data within analytic platform for research/service management. Use of pseudonymised data within NHS for service management/audit.*  *If no, the Investigator should be referred to the ACCORD Research Governance team for Sponsorship review.* | No Yes |  |
| Has ethical approval (including public value) been obtained? |  | No Yes  N/A |  |
| Is this project part of a larger programme/protocol/project?  QC10 | *If the answer to this is yes, ACCORD sponsorship may be inappropriate as this should come under sponsorship of another institution.*  *Is this application part of the other projects objectives or is this a study in its own right?* | No Yes  . |  |
| Therefore – what Sponsorship is required?  QB5 | *If DataLoch – complete form as evidence – follow GS014..*  *If ACCORD – record sponsorship number above, link to Sharepoint folder and send all documentation to ACCORD*  *If Other – obtain evidence of Sponsorship approval from relevant organisation* | DataLoch delegated  ACCORD  Other – evidence rec’d  N/A |  |
| Has the study been added to the ACCORD sponsorship tracker? | *Add details into the studies tracker on the ACCORD SharePoint, create an AC number and upload documents to the DataLoch folder.* | No  Yes N/A |  |
| Have relevant documents been uploaded to ACCORD Sharepoint? | *Application form, Data Selection Form, Data Flow Diagram, Approvals Summary (emails saved on DL system), this template, SAP, any non-DL approval documentation. Note version numbers of signed off docs here.* | N/A or Date: |  |
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| Is the lay summary section of the DL Application Form written in lay friendly language?  QB6 | *Summary of the project must use clear and concise language which can be easily understood by non-clinical/non-technical colleagues and partners.* | No  Yes |  |
| Has the applicant provided evidence of consent for this processing of the data/is the reason for not requesting consent justifiable?  QB5 | *Potentially request consent forms, which should relate to this use of the data.*  *Justifiable reasons for not obtaining consent relate to obtaining consent potentially seriously impairing/harming the research.* | **☐** No **☐** Yes |  |
| Are there any other institutions, organisations or third parties involved? | *What is this involvement?*  *Is any data being sent/received and where?*  *Is it more appropriate that these organisations sponsor the project?*  *If commercial organisation involved consider best practice of consent.*  *Are there any agreements in place? Usually a collaboration agreement is needed. Others may be required – UoE* [*ERO contracts team*](mailto:ero.contracts@ed.ac.uk) *can advise.* | No Yes  . Click or tap here to enter text. |  |
| If a commercial organisation is involved, has an organisational assessment been completed?  QA3 | *Assessments required for any third/private sector organisation getting access to data (not if purely funders)*  *Put link to completed organisational assessment if required.* | No  Yes |  |
| Where has the data come from? | *What source? What approvals are in place for the use of this?* | Data Source: |  |
| Is external (to DataLoch) data being used for any linkage? | *Where has this come from, is there permission for this use of this data?*  *Is this data pseudonymised?*  *Where is the link to this data stored?* | No Yes |  |
| Will any data be transferred outwith the UK? | *If yes, where is data going (name of organisation).*  *If the answer to this is yes, the research project does not comply with the Safe Haven generic ethics and the Investigator should be referred to the ACCORD Research Governance team for sponsorship review.*  *If yes, NHS Lothian Information Governance oversight is required if the data is identifiable – please refer researcher to R&D Information Security Project Manager.*  *Ensure that any transfer maintains the security and confidentiality of the data.*  *Include data flow diagram in documentation* | No Yes |  |
| Will any data be transferred outwith NHS L/UoE within the UK? | No  Yes |  |
| How will any data be transferred? | Method of Transfer: |  |
| Is the research project data or individual level derived output being used beyond the project?  QF17 | *Will study be archived within analytic platform? Will any individual level outputs be required (e.g. will data be onward used)?* | No  Yes |  |
| Is the data is being used in conjunction with/development of a device/AI/algorithm which might need registering (e.g. for commercialisation purposes)? | *Consider if the data is being used in conjunction with a device/AI/algorithm or combined with anything else? If so, contact ACCORD as full sponsorship might be required.*  *No data used in project can be used for registration of CMARK /Commercialisation Purposes – ask for intention of whatever is developed – and discuss with ACCORD* | No  Yes |  |
| Where is the research data being stored?  QF16 | *If other, needs full ACCORD sponsorship. This should be in a secure location. If outside NHS, should be in line with the UoE Research Data service (DataStore, DataShare, DataVault etc).*  [*https://www.ed.ac.uk/information-services/research-support/research-data-service/guidance*](https://www.ed.ac.uk/information-services/research-support/research-data-service/guidance) | Location:  EPCC NHS  Other |  |
| How will the data be archived?  QF18 | *How long, where, how, security arrangements?*  *If not EPCC, needs to be compliant with ACCORD SOP CR009 and GS005..* | Archive Location:  EPCC  NHS  Other |  |
| Are the data being linked with tissue?  QC11 | *Consider where this tissue is from? How has it been sourced? What consent is in place for this use? Do we have a copy of BioResource approval/application?* | No  Yes |  |
| Has the end of study been defined or study end date been given?  QB6 | *Need a defined study end date. Keep end date correct on the study tracker on the ACCORD sponsorship tracker on SharePoint* | No Yes  N/A |  |
| Have all sections of the Application Form been completed? | *Ensure sufficient detail has been given to give a clear picture of the project.* | No  Yes  N/A |  |
| Are the aims, objectives and research question consistent with the study design, and the data being accessed? | *Is there enough information to understand what is being asked for and what is being studied? Do outcomes relate to aims?*  *Consider data minimisation and de-identification. If not, seek additional information/discuss with analyst most relevant minimisation routes for e.g. dates and/or ask for documents to be updated.* | No  Yes  N/A |  |
| Has relevant IG Training evidence been received for all members of study team accessing data? | *See Health PBPP guidance on relevant training courses (MRC, ONS SRT)* | No  Yes |  |
| Have copies of all relevant other documentation been received? | *e.g. Caldicott (identifiable data), BioResource (tissue), PBPP/other data provider, SAP, data flow diagram, DPIA* | No  Yes  N/A |  |
| *Any further checks completed or issues considered and responses.* |  |  |  |
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| **Amendments** | | | |
| *Guidance:*  *Any change needs to be consistent with original intention of the study as outlined in the aims /objectives.*  *Consideration should be given to decide if the changes are still considered part of this study or comprise a new study.*  *Do the changes still fall within the remit of this sponsorship process or does the study need to go through a full sponsorship review?* | | | |
| **Amendment Number** | **Summary of Change** | **Outcome of Amendment Review** | **Amendment Reviewer (Name/Title) & Date** |
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