UCLH-UCL Data sharing guidance

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Purpose:

This guidance lists a set of FAQs, setting out the requirements for UCL researchers requesting data from UCLH for research purposes and the expectations for data management.

FAQs:

1. When is data considered anonymous?

UCLH considers any request of data derived from medical records to be identifiable. Whilst the data requested may not contain directly identifiable data, it is considered as information that could allow indirect identification and therefore cannot be regarded as anonymous.

The HRA states that '*Patient information is personal data under data protection legislation if it is identifiable, or has the potential to be identifiable, on the basis of the information held by the organisation holding the data. So, patient information may be de-identified to a researcher but still be classed as personal data as far as the organisation holding the data is concerned.*'[1]

UCLH will only consider requests for aggregated data as anonymous, where the aggregated data meets the ONS definition[2]. The UCLH Information Governance (IG) team will undertake checks in line with UCLH policy to ensure that appropriate anonymisation steps have been implemented before the data is released. Decisions on whether aggregated data is considered anonymous will be taken on a case-by-case basis. This could be considered via the completion of a data protection impact assessment (DPIA), or via the UCLH **Data Access Process for Research (DAP-R)**[3]. If the request falls under the criteria, it should be noted that datasets from small numbers of patients, even where de-identified, will be at risk of re-identification and therefore are unlikely to be considered anonymous.

2. What is a Data Protection Impact Assessment (DPIA) and when is it required?

A DPIA is a process to help you identify and minimise the data protection risks of a project.
A DPIA must:

- describe the nature, scope, context and purposes of the processing;
- assess necessity, proportionality and compliance measures;
- identify and assess risks to individuals; and
- identify any additional measures to mitigate those risks.

[1] https://www.hra.nhs.uk/covid-19-research/guidance-using-patient-data/

[2] *Anonymisation ONS definition: The samples are anonymised, contain no identifiers, and the data is treated to protect the confidentiality of the people who's responses are within the sample. It is therefore neither possible to identify any individual or household from the data, nor possible to disclose any information on any individual or household, using these samples.*

[3] https://my.uclh.nhs.uk/Interact/Pages/Content/Document.aspx?id=22617&SearchId=1159995&utm_source=interact&utm_medium=general_search&utm_term=RDAC

More information can be found here: https://ico.org.uk/for-organisations/guide-to-data-protection/guide-to-the-general-data-protection-regulation-gdpr/accountability-and-governance/data-protection-impact-assessments/.

The UCL DPIA template can be downloaded here: https://www.ucl.ac.uk/data-protection/guidance-staff-students-and-researchers/practical-data-protection-guidance-notices/data-protection.

The UCLH DPIA template can be requested from uclh.igqueries@nhs.net .

Any research project using identifiable data must complete a DPIA for UCL and/or UCLH that must be submitted to the UCL Data Protection Office and UCLH IG team respectively.

3. **What measures must be in place for UCLH to release data to UCL?**

UCL DPIA:
Any data from UCLH must be transferred and managed within a secure environment that meets the requirements of the Data Security and Protection Toolkit (DSP Toolkit). At UCL, this is currently the UCL Data Safe Haven (DSH). Information on how to access the DSH can be found here: https://www.ucl.ac.uk/isd/it-for-slms/research-ig/articles/data-safe-haven-assurance. A study specific UCL DPIA will be required and must be submitted to the UCL Data Protection Office to ensure the study is registered for data protection purposes. Further information on UCL DPIAs can be found here: https://www.ucl.ac.uk/data-protection/guidance-staff-students-and-researchers/practical-data-protection-guidance-notices/data-protection

The UCL DSH team expect all necessary approvals to be in place, (this includes sponsorship, NHS REC and HRA approvals), before data can be transferred into the DSH. Data management plans must be in place and follow the principles of data minimisation. For research projects, the data management plan may be included as a section of the research study protocol.

UCLH DPIA:
All requests for UCLH data must also include a study specific UCLH DPIA. The risk assessment questions on the UCLH DPIA should be completed for **all** studies, whether deemed anonymous or not, to determine whether a full DPIA is required. If so, this will be reviewed by the UCLH IG team (contact via uclh.igqueries@nhs.net) to see if this can be approved via the pre-approvals process or via the usual DPIA route.

If the request is deemed anonymous, it can be considered under the Data Access Process for Research (DAP-R) and will be reviewed by the UCLH Research Data Access Committee and then via the patient engagement group at the Data Trust Committee (DTC).

Regardless of the path followed the data set should only be transferred to the UCL Data Safe Haven. Any exceptions will need to be discussed and agreed with the relevant IG teams. UCL/UCLH reserves the right to audit and monitor to ensure compliance with agreed data management/DPIA.

For research studies, the UCLH/UCL Joint Research Office (JRO) governance teams (https://www.ucl.ac.uk/joint-research-office/contact-us) will support researchers through the relevant approval processes.

Any data sharing agreements must also be in place before data is transferred.

4. **When is an agreement required for data transfers between UCLH and UCL?**

An agreement for data sharing should be in place for research projects requiring data transfers.

For research, the type of agreement used to capture the data sharing requirements will depend on the type of project being undertaken. For some projects, data transfers from UCLH to UCL, where there are no commercial collaborators and the research is non-interventional, a non-commercial Organisation Information Document (OID) will be used as the agreement between sponsor and participating NHS/HSC organisation. However, there will be instances where a more formal agreement is required. Support and advice on contract requirements are provided by the relevant JRO teams.

UCLH investigators wishing to use UCL Data Safe Haven for their own projects will need a senior UCL academic to act as the Information Asset Owner (IAO); this role is accountable to UCL, so must be a UCL substantive employment contract holder. More details on the IAO role can be found here: https://www.ucl.ac.uk/isd/it-for-slms/research-ig/articles/information-asset-owner-owner.

5. Amendments to a study

Once a DPIA is submitted to the UCL or UCLH IG service to register a research project, it is the responsibility of the PI to ensure the DPIA is reviewed when any substantial study amendments are made to ensure the DPIA information remains correct or is updated as necessary. Changes to the DPIA must be submitted to the relevant IG team. The IG teams can provide further help and support to investigators if they are unsure whether their DPIA requires updating.

An update may be required if you are making a substantial change, e.g., data processing was anonymous and will now be identifiable, an IT platform is used, AI is used as part of the study. If a data request was initially made via the UCLH DAP-R the data concierge should be contacted to bring this to the attention of the committee.

The PI or IAO is also responsible for notifying the relevant IG teams of leavers- e.g. UCLH leavers notifying UCL DSH; UCL investigators leaving notifying UCLH IG/JRO.

6. Requirement of UCLH honorary contracts

The JRO follows the NHS algorithm to determine the requirement of an honorary contract/research passport/letter of access for non-UCLH staff and students.
https://www.myresearchproject.org.uk/help/help%20documents/The-Research-Passport-Algorithm-of-Research-Activity-and-Pre-Engagement-Checks.pdf

If you are planning to undertake research at UCLH but do not have an employment contract with the trust, you will need to obtain one of the above (depending on the type of research activity). More information on how to apply for this can be found on the NIHR website. Contact the JRO on uclh.jro-communications.nhs.net for further information. For more information please see the Research Passports page.

7. Are the requirements stated above, applicable only to research or do they apply to other purposes such as service evaluation, data registries and development of methodologies (such as AI algorithms)?

Requests and management of UCLH data for service evaluations, data registries, research data bases, audits and development of advanced methodologies such as AI should be no different to research data.

All requests for UCLH data going to UCL DSH will need a data sharing agreement in place.

Service evaluations and audits are approved at local clinical divisional level and by UCLH IG. JRO does not support service evaluation, research data bases (with the exception of those seeking NHS REC review), or audits, and these must be referred to UCL/UCLH IG teams when using health and/or staff records from UCLH. A DPIA must be completed and approved by the relevant UCLH Division and provided to the UCLH IG team for final approval before data can be transferred to UCL DSH.

8. Data Archiving

As UCL does not yet have a secure archive facility, data already in the DSH can be held in the DSH long term.

Staff responsible for the data, i.e. the IAO and/or PI, are responsible for ensuring archived data is appropriately managed and the appropriate IG teams notified when leaving either organisation.

9. Future sharing of data

Future sharing of data should be in accordance with any contractual requirements.