



**UCL DPO AND JOINT UCL AND UCLH RESEARCH OFFICE GUIDANCE
TRANSPARENCY AND PRIVACY NOTICES FOR CLINICAL RESEARCH –COMPLIANCE WITH DATA
PROTECTION LEGISLATION**

TO WHOM DOES THIS GUIDANCE APPLY?

This is advice is for Heads of Divisions, all Chief Investigators, Principal Investigators and Departmental Managers. It applies to Clinical Research projects in which UCL is sponsor and controller.

For other arrangements, please consult UCL DPO at data-protection@ucl.ac.uk or the Joint Research Office uclh.randd@nhs.net.

DEFINITIONS

Clinical Research: any study requiring Health Research Authority approval.

Controller: the organisation or public authority which, alone or jointly with others, determines the purposes and means of the processing of personal data. [GDPR, Article 4]

Data minimisation: the principle that personal data should be adequate, relevant and limited to what is necessary in relation to the purposes for which they are processed, eg the use of pseudonymisation to minimise the amount of data processed

Data protection legislation: means all laws and regulations relating to the Processing of Personal Data as the same may be in force from time to time

Sponsor: An individual, company, institution, organisation or group of organisations that takes on responsibility for initiation, management and financing (or arranging the financing) of the research. See www.hra.nhs.uk/planning-and-improving-research/research-planning/roles-and-responsibilities/

Personal data: any information relating to an identified or identifiable living individual. The definition of personal data in law is broad and covers direct identifiers (like a person's name) and indirect identifiers (like a full postcode). An **identifiable individual** is one who can be identified:

'...directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person'

[GDPR, Article 4]

Processing:

'any operation or set of operations which is performed on personal data or on sets of personal data, whether or not by automated means, such as collection, recording, organisation, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction.'

[GDPR, Article 4]

WHAT DOES TRANSPARENCY MEAN?

Transparency is an overarching principle of GDPR. Transparency means:

- Being clear, honest and open about who we are, how and why we are using research participants' personal data throughout the information lifecycle
- Setting out what personal data you hold on people

TRANSPARENCY REQUIREMENTS

Staff must ensure that they tell individuals about how they are using their personal data in a way that is accessible and easy to understand. Notices and information sheets must use clear and plain English.

For personal data that has been collected directly from the research subjects, the Controller is obliged to provide all the information listed in Appendix 1.

Where the personal data is obtained from a third party and there is no direct relationship with the individual, i.e. when collected for secondary analysis, then the Controller must still consider transparency. In such cases it can be even more important to be transparent as people may not know that their personal data is being used.

Are there any exemptions from the requirement for transparency?

If the data is obtained from a third party, for example for secondary analysis, then you do not need to provide the data subjects with privacy information in following circumstances

- Where an individual already has the information
- Where providing the information would be impossible
- Where providing the information would require disproportionate effort
- Where providing the information would seriously impair the achievement of the research objectives

Where information is collected directly from research participants, the transparency requirement applies for **all** processing of personal data, eg identifiable information, including storing historic datasets.

WHAT INFORMATION NEEDS TO BE SUPPLIED TO RESEARCH PARTICIPANTS?

Data protection legislation stipulates what information must be supplied – this is shown in Appendix 1. Some of the information is generic, for example, the details of the Controller, i.e. UCL; other required information can be supplied by reference to, or providing a link to the *UCL Privacy Notice for Participants In Health And Care Research*:

www.ucl.ac.uk/legal-services/privacy/participants-health-and-care-research-privacy-notice.

Participants will have been made aware of much of information through the Patient Information Sheet (PIS), but there may be some items that would not have been communicated through the PIS if written before 25 May 2018, or where the arrangement may have changes and are project specific. For example:

- o Recipients (or Categories of Recipients)
- o Details of transfers to third countries

HOW TO COMPLY - SEE TABLE 1

While the GDPR stipulates what information should be supplied, it does not stipulate how that information should be conveyed to research participants. We suggest the following simple ways of achieving compliance.

a. **New studies**

Provide the information in Appendix 1 in the PIS

b. **Other studies,**

All UCL Divisions should ensure that the project website refers to the UCL *Privacy Notice for Participants in Health and Care Research*:

www.ucl.ac.uk/legal-services/privacy/participants-health-and-care-research-privacy-notice

Note that the UCL *Privacy Notice for Participants in Health and Care Research* is a general statement and cannot provide two specific items of information in Appendix 1, that is:

- Recipients (or Categories of Recipients), ie the recipients of personal data, e.g. funders, collaborators, organizations who may be processing or managing the data for you.
- Details of transfers to third countries. If there are any international transfers to countries or organisations outside the UK, then provide a statement to the effect that a contract will be in place to safeguard the rights of subjects. There is some further guidance on transfers of personal data overseas: www.ucl.ac.uk/legal-services/guidance/guidance-note-transferring-personal-data-outside-eea

i. *For studies that are actively recruiting.*

We advise that the Chief Investigator provide a transparency leaflet as required by HRA see:

www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/templates/transparency-wording-public-sector/

In cases where it is impossible to comply with the HRA wording, because for example it may not fit the configuration of the study, then you should develop your own transparency leaflet based on the requirements in Appendix 1.

ii. *For other studies* i.e. those finished recruiting or historic datasets, supply specific study information on the website. Biobanks, Research Database and where datasets where information is being released should include the terms and conditions for access to the dataset.

iii. *For stored datasets*, Departments or Chief Investigators should consider whether the dataset should be destroyed. Data minimisation is one of the key principles of the GDPR, so deleting datasets which are of no further use will help with the compliance effort and reduce risk. If kept then the dataset should either be de identified in such a way as to make the personal data anonymous, in which case data protection legislation would not apply or should be further minimised. See MRC advice on data minimisation, referenced below.

If the dataset is kept, then the UCL advice on appropriate safeguards will apply:

[www.ucl.ac.uk/legal-services/sites/legal-services/files/guidance for researchers on appropriate safeguards under gdpr 2016 and dpa 2018.pdf](http://www.ucl.ac.uk/legal-services/sites/legal-services/files/guidance%20for%20researchers%20on%20appropriate%20safeguards%20under%20gdpr%202016%20and%20dpa%202018.pdf)

Table 1

Status of study	High compliance*	Adequate compliance*
Still recruiting	Full HRA statement or equivalent in a leaflet handed or posted to participants or study specific information on website	Full HRA statement or equivalent in a leaflet handed to participants or on in study specific information on website
All protocol required activities concluded for all patients and study sites closed out	Study specific transparency information on website	Study specific transparency information on website
End of study notified to HRA	Study specific transparency information on website	generalised information on website
Historic datasets	Specific dataset information on website with details of terms of access	generalised information on website

* All transparency information on website should contain a link to the *UCL Privacy Notice for Participants in Health and Care Research*

SOURCES OF FURTHER INFORMATION

- Health Research Authority website
- Information Commissioners Office website
- UCL - <https://www.ucl.ac.uk/legal-services/ucl-general-data-protection-regulation-gdpr>
- MRC Regulatory Support Centre <https://mrc.ukri.org/research/facilities-and-resources-for-researchers/regulatory-support-centre/gdpr-resources/>
- For GDPR geeks Working Party 29 Guidelines on Transparency under Regulation 2016/679 https://iapp.org/media/pdf/resource_center/wp29-transparency-12-12-17.pdf

APPENDIX 1 Requirements from EU Working Party 29 Guidance

Requirements	“Direct” data collection i.e. Face to Face	Personal Data NOT obtained directly from the Data Subject	COMMENTS
The identity and contact details of the controller and, where applicable, their representatives	Required	Required	For individual studies, the Data Controller will usually be the sponsor. For the required general statement from the Data Controller, see http://www.ucl.ac.uk/jro/who-are-we/data-protection
Contact details for the data protection officer, where applicable	Required	Required	UCL’s Data Protection Officer can be contacted on data-protection@ucl.ac.uk . Please do not put the DPO name in here.
The purposes and legal basis for the processing	Required	Required	This is also in the general statement http://www.ucl.ac.uk/jro/who-are-we/data-protection and can be just referred to. The legal basis for processing will be public task (public interest) and purpose of processing is research.
Categories of personal data collected or processed	Not required	Required	E.g. Health records
Recipients (or Categories of Recipients)- this should include controllers or joint controllers or processors as well as third parties	Required	Required	To whom will the information be passed? e.g. funders, any collaborators, organizations who may be processing or managing the data for you.
Details of transfers to third countries	Required	Required	Any international transfers to countries or organisations outside the UK? The statement that a contract will be in place to safeguard the subject’s rights.
The storage period or criteria used to determine storage period	Required	Required	How long will the records be kept?
The rights of the data subject	Required	Required	See HRA wording about limited rights.
The right to lodge a complaint with ICO	Required	Required	
The source from which the Data Originated	Not Required	Required	E.g. the health records of NHS Trusts,
The existence of automated decision-making including profiling – the logic used and the significance of the consequences	Required	Required	It not likely that any studies will be engaged in automated decision making.