**GDPR Compliance**

1. **WHO IS THE DATA CONTROLLER FOR MY STUDY?**

For most studies, establishing the Data Controller will be simple and straightforward – it is the organisation that sponsored the study. If you are unclear about who is Sponsor and who is site you can obtain the information from the ethics submission.

A data controller determines the purposes and means of processing personal data, so if

• Sponsor is UCLH then the Data Controller will be UCLH.

• Sponsor is UCL then the Data Controller will be UCL.

But for a minority of studies which involve collaborations with industry, other Universities or charities, things may not be so simple. The other parties may suggest they will be the Data Controllers even though UCL is sponsor. Conversely, they may suggest that UCL is the Data Controller even UCL is not the main party in the collaboration.

**The JRO will assign the Data Controller based on sponsorship. Contact** **randd@uclh.nhs.uk** **if you feel the data controller for your study may not be the sponsor.**

Note that NHS Trusts who are sites in studies **are not** Data Controllers for the purposes of the study unless they are also the sponsor.

1. **THE HRA REQUIREMENT’S FOR PRIVACY AND TRANSPARENCY**.

Transparency concerns the information which needs to be given to the research subjects about the use of their data.

The HRA advise that we provide information to participants about how we are using their information. In most cases a formal amendment is not required. A leaflet which is given, emailed or posted to participants should be sufficient.

You should consult the HRA website (as below) to identify which changes to make and the recommended text to use within your amended documents.

**Scenarios**

First identify which scenario applies to your study: <https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/what-you-need-do/transparency/>

Within the scenario, you will see links to templates containing the wording to be used in your patient information leaflet. Choose the correct template (in this case, choose public sector sponsor templates).

*The HRA have stated that if these paragraphs are used verbatim that there is no need to submit a substantial amendment*.

Should you believe that a change in the *patient information sheet* is in fact required (e.g., other substantive amendments are to be made or a change could affect the perception of a participant about a study, then please contact the JRO asap on randd@uclh.nhs.uk).

**Study Types**

You will notice that there are study types referred to within the templates sections.

* **Study type A** is where face to face contact with research participants is possible, for example, at the research site (e.g., a clinical trial where the research participants are coming back for repeated visits)
* **Study type B** is mainly concerned with data collected from medical records.  This is often referred to as secondary analysis or “observational” studies.
* **Study Type C** is where data is intended to or likely to be used for future research (for example research databases)

For all study types, its recommended that once the sponsor’s research team updates the necessary documents, the site study team will ensure these are passed to the research participants. For UCL and UCLH studies, we'd advise this to be completed as soon as possible.

The HRA wording does not fit all type C studies. If you feel this is the case for your research database, please contact randd@uclh.nhs.uk

**Please note that in all transparency wording the statement last paragraph**

*“You can find out more about how we use your information [at URL and/or by contacting XXX]”*

**Should refer to link both the sponsors statement which can be found at http://www.ucl.ac.uk/jro/who-are-we “Data Protection Statement”**

**AND**

**also provide a contact from within your study.**

1. **DOCUMENTING AND DISSEMINATING CHANGES**

You will then need to

* Check your documents against the [Transparency Checklist](http://www.ucl.ac.uk/jro/conduct-study/regulatory-approvals-/transparency)
* Version any documents which you change or create (e.g., leaflet)
* Update your study file stating the change as “non-substantial, non-identifiable”
* Send the documents to site PI’S for them to give to new participants (or give, email or post to existing participants)
* Send the updated documents and a note to say sites have been informed to the sponsor office (JRO) on Randd@uclh.nhs.uk
* Add the changes to the study website (if it has one).