Guidance for Accessing CTR Data and Samples

# CTR data and sample requests

Requests for data and samples held by the CTR are reviewed internally and by trial specific committees where relevant to ensure that the request is compliant with regulations, participant confidentiality and participant consent. To make a request, please follow the steps below;

**Step 1**

###  Check the trial protocol

If you wish to explore study data and/or samples, the study protocol may provide you with the information that you need to decide whether the data/samples fit in with your research questions.

**Step 2**

###  Complete the data and sample request form

For support in completing the form, or if you would like further information about the study data/samples, contact ctr@cardiff.ac.uk. The form aims to gather the following information about your research proposal.

*Study design and objectives*

*Qualifications and suitability*

*Ethics and R&D approval*

*Data and samples required*

*Intellectual property and publication*

*In some cases, a detailed protocol and statistical analysis plan may be required.*

It is important that you include as much information regarding the data fields that you need on this form as this will impact the review process. Information should be as complete and as accurate as possible.

**Step 3**

###  Review process

**Internal review:** CTR staff will review your proposal alongside key study documents to check:

- that the original participant consent covers the research proposal.

- how participant confidentiality will be maintained and whether data fields require further anonymisation (see below for more information on participant confidentiality).

- existing study agreements to ensure the request is consistent with current approvals (eg for data providers such as NHS Digital). In some cases, new agreements will be required, or existing agreements amended.

- whether the proposal will require additional review by a research ethics committee.

- resource required to process the proposal. This may include further data and/or sample processing/preparation. We may ask the requester to cover reasonable costs in which case the CTR will contact you.

**Peer review:** This may include review by the TMG (Trial or Study Management Group)/TSC (Trial Steering Committee) /DMC (Data Monitoring Committee) depending on the stage of the study. The reviewers will consider:

- Scientific merit of the proposal.

- Whether the release of data would jeopardise the study in anyway.

- Whether there has already been a similar research proposal/request.

**Biobank review:** if you are requesting samples held in a biobank, the request may need to be reviewed by the biobank.

The final decision to release data rests with the sponsor. You will be contacted to discuss the outcome of the above review.

**Step 4**

###  Contract drafting

If your proposal is approved, a data transfer agreement (DTA) or material transfer agreement (MTA in the case of sample release) will be drafted by the contract manager. The contract manager will contact your institution to complete signing of the agreement. The details required for the agreement will be taken from the data/sample request form.

**Step 5**

###  Data and/or sample preparation

QA review will be undertaken by CTR to;

-Process data fields where required

-Ensure that data/samples are appropriately anonymised/pseudonymised

**Step 6**

###  Data and/or sample release

A member of the CTR will be in contact with you to let you know when to expect the data and or samples. Data will be shared using a secure data sharing system.

**Participant confidentiality**

Data collected as part of the trial may be classed as;

* Clinical data: Data collected as part of standard clinical care
* Trial data: Data collected specifically as part of the study
* Personal data: Data that may directly or indirectly identify a participant (for example, be date of birth/death).

It is important to know which data fields are required as this will impact the review process and risk to participant confidentiality and whether adequate anonymity can be maintained. Certain data fields may be formatted/amended to reduce the risk of participant re-identification. For example, data ranges maybe used to replace exact figures and dates.