#### **Glasgow Clinical Trials Unit Guideline**

Guideline number	Guideline 59.005A	Version	1.0
Title	Adding Researcher-Created Files To Projects		

Guideline to add files submitted by research teams to use as part of their project analysis

Many projects will be part of a wider programme of work and so will have data already collected. Often researchers want to use this data along with the data extracted by the Safe Haven.

There are two types of these files;

- Administrative data e.g. financial costing of procedures, national statistics
- Patient data e.g. a cohort file with a Study ID/CHI key, patient-level data previously collected

If the file provided by the research team includes administrative data only:

### Project is being sent across the Portal to the Safe Haven Analysis Platform;

These files need only be included on the Access form by name and then sent across with the extracted files.

### Project is not being sent across the Portal to the Analysis Platform;

- Sending to Another Safe Haven use the same procedure as above minus the access form
- Sending straight to the research team (limited circumstances) there should be no need to include the original files sent by the research team as they already have them

#### If the file provided by the research team includes patient data:

#### Project is being sent across the Portal to the Safe Haven Analysis Platform;

- These files must be linked together with the extracted data by using the CHI and/or CHI-Study ID key
- All original CHIs and Study IDs should be stripped out and anonymised by being replaced with the Safe Haven ID
- All files for the project should be detailed on the Access form

### Project is not being sent across the Portal to the Analysis Platform;

- Sending to Another Safe Haven use the same procedure as above minus the access form
- Sending straight to the research team (very limited circumstances) use the same procedure as above minus the access form

# **Glasgow Clinical Trials Unit Guideline**

## **Guideline signatories**

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### **Document history**

Version	Date	Description
1.0		First Release

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