Glasgow Clinical Trials Unit Guideline

Guideline number	**Guideline 59.013D**	Version	**1.0**
Title	**Maintaining a Project**		

All projects move through different phases and pathways in the Safe Haven. Below you will find instructions on how to administer these changes once it has been created in the project management database.

To maintain a project, open the Safe Haven Research Projects Register database:
Now that you have created the project as per Work Instruction Guideline 59.013A – Creation of a New Project, it will need to be maintained and progressed throughout its life cycle.
During the project lifecycle open the following forms to change and add project details, as required:

Maintain A Project : 01 - Amend a Project

- Create a new record against the project number for each amendment
- Set amendment type
- Enter date amendment was requested by research team
- Enter date when amendment was approved
- Enter amendment reason

Maintain A Project : 02 - Update Clock Phase:

- Create a new record against the project number for each phase change
- Set clock phases as they change
- Include date for stopping the phase and starting the new phase
- Include the change reason for each phase change

Maintain A Project : 03 - Update Extract File Records

- Create a new record against the project number for each extract file
- Set clock phases as they change
- Include date for stopping the phase and starting the new phase
- Include the change reason for each phase change

Outcomes_Safe_Haven Table:

- Make sure this is updated once all permissions and approvals are gained
- There must be a 'master' record for the project
- There must be at least one other record for the project detailing the level of approval

Outcomes_Caldicott Table

Outcomes_Data_Controller Table

Outcomes_Data_Sharing_Agreement Table

Outcomes_Ethics Table

Outcomes_LPAC Table

Outcomes_Peer_Review Table

Outcomes_R&D Table

These seven tables should be updated, appropriate to the project, with the date and level of approval. Where a project should have a record in these tables, there must always be a 'master' record and at least one other record detailing the approval. The Applications to Safe Haven table indicates which projects need outcomes in these tables.

Not adding and updating outcomes in these tables where they are needed will cause future queries when managing the projects to fail.

Index_Data_Spec Table:

- A new record should be created for every version and revision of the data specifications document

Project Data Spec Table:

- A new record should be created for every version and revision of the data specifications document
- Associate each new record with the correct Spec_ID
- Attribute a version number to each re-issuance of the data specifications document
- Enter details as appropriate for each record, including dates
- Once a data specifications document has been agreed and signed off by the researcher, tick the Spec_Agreed field
- Once a data specifications document has been used to queue a project for extraction, enter the date the project was queued on the waiting list in the Queue_Date field
- Once a data specifications document has been used to create an extract, tick the Extract_Use field

Research Project Finance Table:

- Any additional details obtained about the project finance should be entered/updated

Research Projects Table:

- Enter the Became_Active date if it is not already filled in
- Update the P_Status field to reflect the current project status
- Enter the closing date in the Date_Closed field once all the work for the project has been completed and the analysis results have been released
- If the study is withdrawn, enter the date of being informed of the withdrawal in the Date_Withdrawn field

Once the data has been extracted/produced:

Extract_Waiting_List Table:

- Update the Priority Field to Extract Complete
- Update the Extract Status Field to 'To Be Checked' – the (P), (R), (U) status will depend on the type of extract/project being run

Extracts Table:

- Create a record against the project number for each file produced
- Enter the name of each file, exactly as it is called in the project folder
- Enter who was assigned the project for extraction in the Assigned_To field, if not already filled in
- Enter who produced the file in the Produced_By field
- Enter the date of extraction for each file – sometimes files for the same project will have different extraction dates
- Enter the type of file – this will be Single File for each file produced
- Enter the date of extraction in the 'master' record you created on receipt of the project application
- Enter the type of extraction as Complete File Set Extracted on the 'master' record, if not already filled in

When the files are ready to be checked and validated:

Extract_Waiting_List Table:

- Update the Priority Field to Extract Complete
- Update the Extract Status Field to 'To Be Checked' – the (P), (R), (U) status will depend on the type of extract/project being run

Extract_Validation Table:

- There must be a record for the project in this table
- Create a record against the project number for each file produced
- Each file record must be associated with the correct Extract ID in the Extracts table for that file
- Enter the person who has been assigned to check the file in the Initially_Assigned field

Once the files have been checked and validated:

Extract_Validation Table:

- Enter the date checking of the file started, if not already entered
- Enter the date checking of the file stopped
- Enter the person who *actually* checked and validated the file into the Staff_Member field. Sometimes the person assigned to the file changes.
- Enter the outcome level for each file (unconditionally approved, conditionally approved, rejected)
- If the file has been rejected, enter the reason for rejection in the Reject_Reason field
- Enter outcome level in the 'master' record and also make sure all the dates and staff members are filled in for this record.

Glasgow Clinical Trials Unit Guideline

Guideline signatories

Prepared by Signature	Charlie Mayor Date
Approved by Signature	Chloë Cowan Date

Document history

Version	Date	Description
1.0		First Release

This Guideline is a controlled document. The current version can be viewed on the GCTU website. Any copy reproduced from the website may not, at time of reading, be the current version.