Standard Operating Procedure	**CBE/HTA-PR-SOP005**

Title:	SETTING UP AND EDITING PROJECTS IN THE PROCURO DATABASE

Location:	CBE

1. <u>PURPOSE</u>

To describe the procedure for the creation and update of the Procuro database register to track and ensure the traceability of HTA licensable material for research.

2. <u>SCOPE</u>

As part of the CBE Quality Management System (QMS) for research, this procedure applies to all persons involved in the receipt, labelling, tracking and storage of HTA licensable material under the University's HTA licence for research, in accordance with the requirements of the HTA legislation, the HTA Codes of Practice and the University's HTA Licence Compliance Quality Manual. Where appropriate, this procedure may be applied to track human material samples not held under the University's HTA Licence.

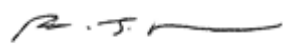| Version 002	Effective Date: 02/01/2026	Review Date:02/01/2028
Written by: P.Hourd/C.Kavanagh Date: 26.01.2016 Reviewed by: C.Kavanagh Date: 08/12/2025	Reviewed by: R. Thomas Date: 09/12/2025	Approved by: M.Gleeson Date:28.01.2016 Approved by : Karen Coopman Date: 09/12/2025

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Standard Operating Procedure	**CBE/HTA-PR-SOP005**

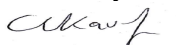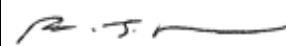| Title:	SETTING UP AND EDITING PROJECTS IN THE PROCURO DATABASE

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3. RESPONSIBILITES

3.1. The departmental Quality Manager (dQM) shall ensure that this SOP is aligned with the University procedure for the acquisition and storage of HTA licensable material and that it does not conflict with any other part of the CBE Quality Management System.

3.2. The Principal Investigator (PI) or Person Responsible (as delegated by the PI, and appropriately trained), as custodian of the material, is responsible for ensuring all licensable material is entered and tracked using the CBE Procuro database, in accordance with the requirements of this SOP.

3.3. Individuals proposing to acquire or currently holding HTA licensable material shall liaise with the responsible authority for the Procuro database to ensure that details of the material are recorded in the relevant fields of the register and that details are updated by the person(s) responsible for the material whenever material is transferred, processed or disposed of.

3.4. The responsible authority for the Procuro database shall ensure that the database is secure and appropriately maintained and updated by those responsible for the material when material is received, moved, changed or disposed of.

3.5. The dQM is responsible for ensuring that the records of holdings within the CBE are reviewed annually and crosschecked with appropriate consent, research protocols or material transfer agreements along with the location of the storage.

4. REFERENCES

The Human Tissue Act (2004) and

https://www.hta.gov.uk/guidance-professionals/codes-practice-standards-and-legislation/codes-practice/code-e-research

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The University HTA Licence Compliance Quality Manual

The CBE Quality Manual

Procuro Users

Manual and Procuro: A User's Guide

The new features of Procuro V4 as stated by the manufacturer are available to review in the document associated with the following link, http://www.pro-curo.com/resources/Version4_Screens/Pro-curo%20V4_%20Whats%20new%2001062016.pdf

5. **PROCEDURE**
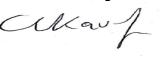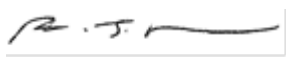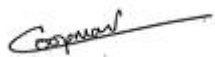
5.1. Setting up a New Project in Pro-curo

NOTE: This can only be done by Admin for Pro-Curo which in the CBE is the Departmental Quality Manager.

5.1.1. Under the Administration/ projects/ add new tab define the project name (see Figure 1).

5.1.2. The project name is chosen by the user. It must be unique and cannot be longer than 50 characters in length. .

5.1.3.   Add the names of all of the people involved in the project..
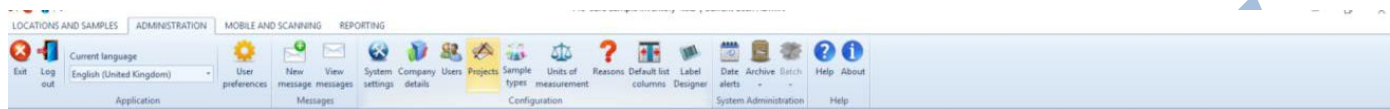
In the administration tab Go to the Projects button

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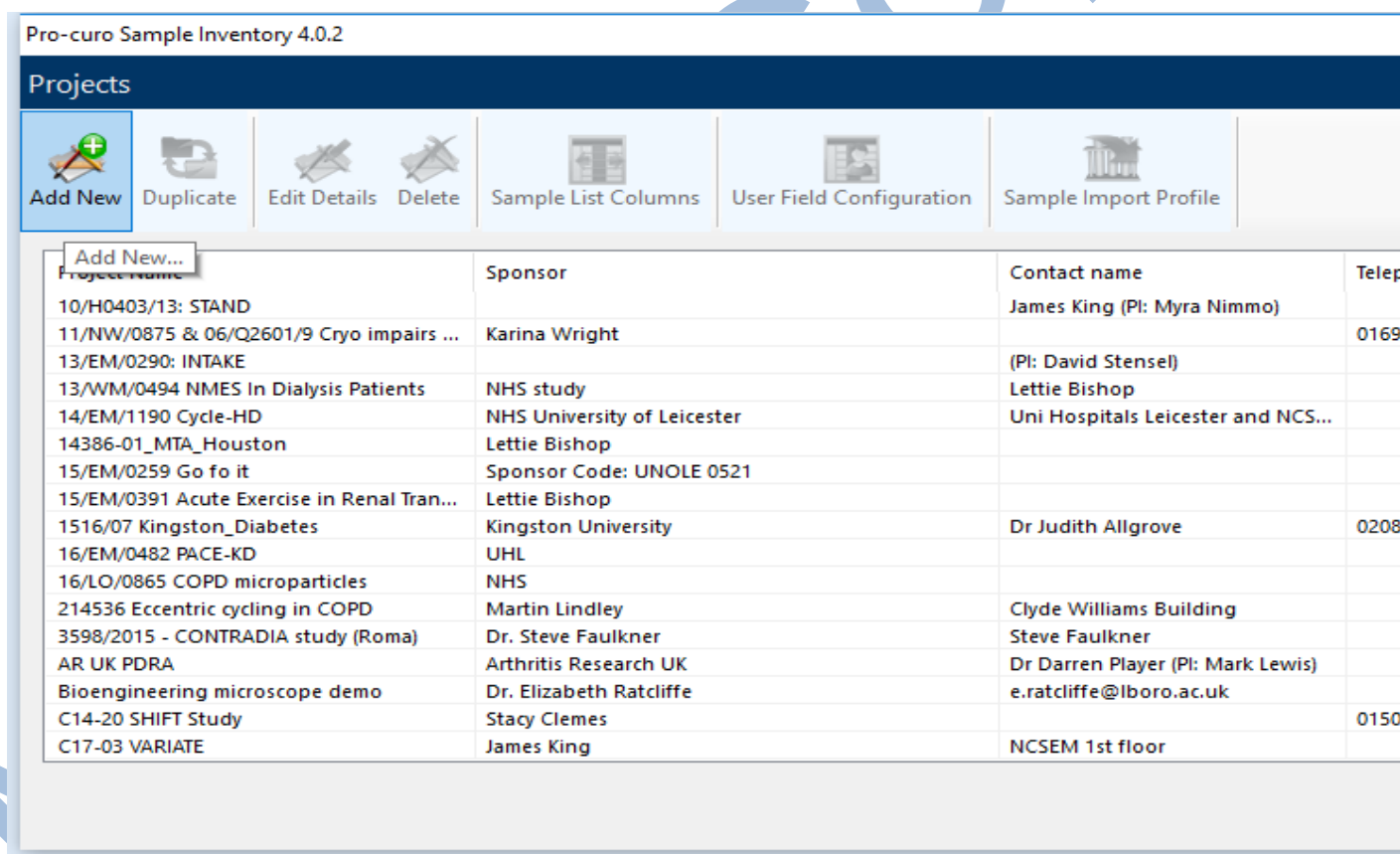## Standard Operating Procedure   CBE/HTA-PR-SOP005

Title: SETTING UP AND EDITING PROJECTS IN THE PROCURO DATABASE
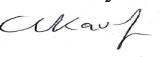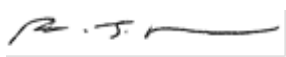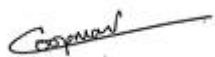
Location: CBE

Figure 1 The Procuro Task Bar

5.1.4 In the Projects dialogue box, click the "Add New" button;

Figure 2 The Projects Dialogue Box

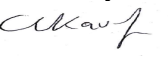| Version 002	Effective Date: 02/01/2026	Review Date:02/01/2028
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A dialogue box for data entry will be shown

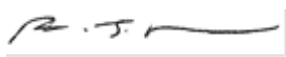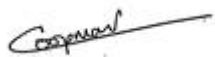| Version 002	Effective Date: 02/01/2026	Review Date:02/01/2028
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Pro-curo Sample Inventory 4.0.2

Add New Project

Project name
*

Sponsor

Contact name

Address

Town

County

Country

Postcode

Telephone

Box grid view data fields

Show data from this data field in the cell ID label

Sub-location ▼

Show data from this field in the link label

Sample number ▼

Notes

Save   Close

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Figure 3- Setting up the Project Information File. Note, project sponsor should be noted. If this is not an external organisation then the principle investigator should be entered into this field. The essential fields (aside from the Project Name which should be filled in according to section 5.2) to fill on this screen are the 'project sponsor', 'contact' and 'notes fields'. Other information that can go into the notes fields includes any other collaborators, or information about any other sites that work may be carried out at

Enter project info:- see the instructions in section 5.2.

5.2 Principles Underlying The Nomenclature of a Project file

The project name forms an essential part of the audit trail, demonstrating the chain of custody of the samples, and also providing a reference point. For samples, such as **non-primary cell lines** that have been commercially brought, there is no ethics requirement. For Samples with an ethics code this could be used. If there is no ethics code please start the project name with 'No-Ethics'. In order to distinguish the samples from the CBE from other departments please add this in the project name. The last part of the project name is the choice of the laboratory users (it is usually the title of the Biological Risk assessment or a shortened version due to the 50 character limit).
Example: No Ethics-CBE- XXXX

NOTE: It is encouraged that all material is logged, even if it is under ethics.

5.3 Approved users

To assign users to a project select the "Users" button.
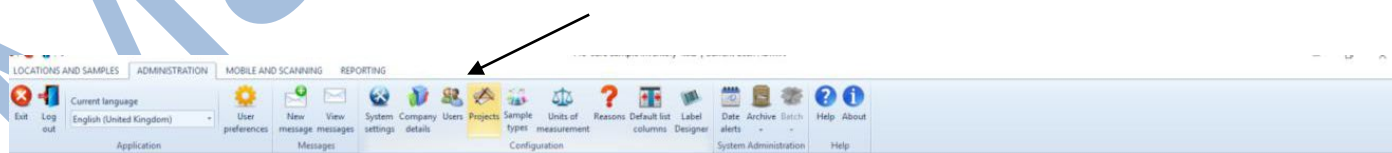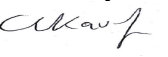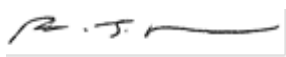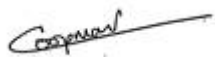

Figure 4 The Procuro task bar

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To add a new user click on the "Add New" button. A dialogue box will be shown "add new user". Enter in the users University login ID and press ok.

Once this has been done, select change password and ask the user to enter in a password of their choice. An administrator can change the password on subsequent occasions but for the initial set up the password needs to be set with the user present.

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Figure 5 Shows the user management page. This is where new users can be set up, and project permissions allocated. In this image the add user button is highlighted.

To allocate an existing user to a project highlight their user name from the list on the left hand side.

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Set up the users system permissions in the middle column. Most users should only have the following permissions;

- • Add New Samples
- • Edit Existing Samples
- • Split Samples
- • Retire/ Dispose Samples
- • Book Samples Out
- • Book Samples in
- • Move Samples

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1. Managing sample types, managing projects and managing users should only be given to highly
    Competent users and Pro-curo adminsitrators.
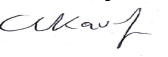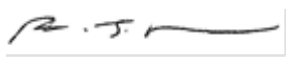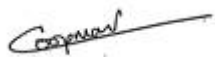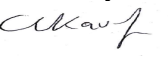Note; Do NOT give SYSTEM ADMIN permissions to general users.
To select the projects the user has permissions to, select the relevant project from the project
permissions box on the right-hand side. Please only allocate people to projects that they are working on.

2. Customise a new project
   Once a new project is created the appropriate fields need to be created. Pro-Curo has several
   Standard fields that are not readily editable. In order to use Pro-Curo according to this SOP several
   new fields need to be added to a project. See section 5.4 on how to do this.

5.4 User fields

To add user fields to a project, the project first needs to be set up as in section 5.1. Once the project
code and name is set, pick the project from the list of project names on the right hand side. Once the
relevant project is highlighted, select the "user field configuration" button from the task bar running
across the top of the dialogue box. A "user field configuration" box will be shown (on the RHS of the
figure below). Project Data entry fields can be set up here. There are options to setup drop down lists,
free text fields, numeric fields and date fields. **Please ensure a sample/ consent Expiry date is added to
one of the date fields in the "user field configuration" box.** Usage of the other fields is dependent on
the nature of the project. Drop down lists could include possible assays that the experimenter wishes to
select (to prevent error). Free text fields could include a sample Identifier (that makes sense to the user-
Procuro allocates each sample a unique ID anyways, but this is consecutive and done as samples are
entered).

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Figure 7 Shows how to set up user fields within a particular project.

5.5. Setting up new samples in Procuro.

1. Load up the Procuro Software (obtain via IT Services) and open the program as usual.

2. (If you do not have a Procuro user account, please request one from the Departmental Quality Manager)

3. Go to > Location and samples > Samples > New tab (see Figure 2)

Figure 2. How to initiate manual sample entry in Procuro.

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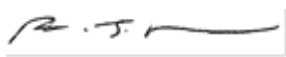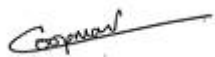Location: CBE

5.5.1.   New window opens: 'Sample Information' (see Figure 3).

5.5.2.   Choose your project name using the drop-down list.

5.5.3.   Once a project name is chosen additional tabs may appear.

5.5.4.   Enter sample type using the drop-down list. If the sample type is different to the choices available, liaise with the responsible authority to create a new sample type (See Procuro manual).

5.5.5.   All sample records within a project file MUST include the following:

- Unique identifier/ sample uniquely identifiable (generated by Procuro),
- Research study,
- Tissue type,
- Date of collection/receipt from other establishment and where it came from,
- Storage location,
- Consent/Material transfer details (including where the documentation is held),
- Dates of sample processing,
- Information regarding transfer to and from other locations (if relevant),
- Date and details of disposal,
- Reason for disposal,
- Name of the project sponsor – the Principal Investigator based within the CBE who is responsible for ensuring that the project's samples comply with the HTA.
- Other researchers involved - to be added to the notes field.

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Figure 3.   ***The field names marked in blue cannot be readily edited, those in red are compulsory***

5.3. Description and use of fields within the Procuro register

- ➤ Sample number: A unique number that is assigned by Procuro to each sample.

- ➤ Project name: taken from project information

- ➤ Sponsor: taken from project information

- ➤ Sample type: drop down list of tissue type

- ➤ Batch number: This is an unfortunately named field. In case of donated material, we can use it for the participant identity number. If this is not the case, it is not relevant.

- ➤ Check External reference: details of sample transfer agreement.

- ➤ Mass: not relevant

- ➤ Reagent %: not relevant

- ➤ Location: give freezer, shelf and box location

- ➤ Sub location: not relevant.

- ➤ Notes: for free text - very useful for example when printing out labels for samples that have not yet been collected, a statement to this effect can be entered here.

- ➤ MTA: if the samples have been obtained from a 3rd party, reference to the documents relating to the original acquisition of those samples and the transfer to the CBE is required here.

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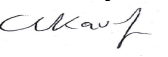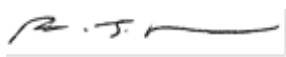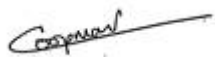| Title:	SETTING UP AND EDITING PROJECTS IN THE PROCURO DATABASE

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- ➢ Sub location: A compulsory field, if using the batch loading function, describing the location within the specified box, will be printed onto the label.

- ➢ Consent date: refers to the date that consent was give, by the participant, for the sample to be taken. The consent forms must be stored separately, in a secure location that can be accessed by the appropriate people if required. The HTA are particularly interested in following the audit trail from sample to informed consent.

- ➢ Sample expiry: The length of time that we can store the sample will be defined in the ethics documents or MTA; it will be 'N' years after it was collected. This date will be printed on the label so that it is readily apparent if samples should be disposed of.

- ➢ Collection date: date on which the sample was taken from the subject.

- ➢ The batch number, location, [sub location], HTA designated and sample expiry are compulsory fields.

- ➢ Note: before entering samples check that the location that is to be used has sufficient space.

- ➢ If you are adding a sample into Procuro which has not been received then ensure you add a note stating: 'Sample not received, and book the sample out.

- ➢ This sample can this either be added, or added and duplicated.

6. DOCUMENTATION

The following records are outputs of this SOP:

6.1.   Procuro database records maintained electronically.

These records will be filed in maintained for a minimum of ten years electronically.

Version 002	Effective Date: 02/01/2026	Review Date:02/01/2028
Written by: P.Hourd/C.Kavanagh Date: 26.01.2016 Reviewed by: C.Kavanagh Date: 08/12/2025	Reviewed by: R. Thomas Date: 09/12/2025	Approved by: M.Gleeson Date:28.01.2016 Approved by : Karen Coopman Date: 09/12/2025

Standard Operating Procedure CBE/HTA-PR-SOP005

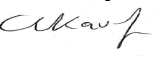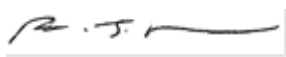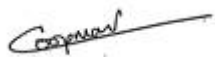Title: SETTING UP AND EDITING PROJECTS IN THE PROCURO DATABASE

Location: CBE

SOP Version History

Version Reviewed	Date Revised/ Reviewed	DCN	Revision Summary	New Version Number
1.0	4th December 2017 by C.Kavanagh	N/A	No Amendments required Minor editorials only including revision details	1.0 New version not required
1.0	20th June 2018	001	Update of SOP due to changes in the version of the Pro-Curo software to V4.	2.0
2.0	2nd December 2019 by C.kavanagh	N/A	No Amendments made Minor editorials only including revision details	2.0 New version not required
2.0	6th December 2021 by C.Kavanagh	N/A	No Amendments made Minor editorials only	2.0 New version not required
2.0	4th December 2023 by C.Kavanagh	N/A	Minor editorials only including revision details.	2.0 New version not required
2.0	8th December 2025 by C.Kavanagh	N/A	Minor editorial for broken links.	2.0 New version not required

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Standard Operating Procedure	**CBE/HTA-PR-SOP005**

Title:	SETTING UP AND EDITING PROJECTS IN THE PROCURO DATABASE

Location:	CBE

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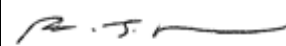
Acknowledgements

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