Standard Operating Procedure

CBE/HTA-PR-SOP005

Title: SETTING UP AND EDITING PROJECTS IN THE PROCURO DATABASE

Location: CBE

1. PURPOSE

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.

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3. <u>RESPONSIBILITES</u>

- 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. <u>REFERENCES</u>

The Human Tissue Act (2004) and HTA guidance and Code of Practice E

The University HTA Licence Compliance Quality Manual

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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/Procuro%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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Title:	SETTING U	UP AND EDITIN	G PROJE	CTS IN THE	E PROCURO DATABASE	
Location:	CBE					
LOCATIONS AND SAMPLES ADMINISTI Dial Log out Current language English (United Kingdom) Application	RATION MOBILE AND SCANNING REP User puelerences Messager Messages	ORTING		ter Administration		- H 0
Figure 1 The Pro	ocuro Task Bar					

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

ro-curo Sample Inventory 4.0.2					
rojects					
dd New Duplicate	Sample List Columns	User Field Configuration	Sample Import Profile		
Add New	Sponsor		Contact name	1	Tele
10/H0403/13: STAND			James King (PI: Myra Nimn	no)	
11/NW/0875 & 06/Q2601/9 Cryo impairs	Karina Wright			(016
13/EM/0290: INTAKE			(PI: David Stensel)		
13/WM/0494 NMES In Dialysis Patients	NHS study		Lettie Bishop		
14/EM/1190 Cycle-HD	NHS University of Leices	ter	Uni Hospitals Leicester an	nd NCS	
14386-01_MTA_Houston	Lettie Bishop				
15/EM/0259 Go fo it	Sponsor Code: UNOLE 0)521			
15/EM/0391 Acute Exercise in Renal Tran	Lettie Bishop				
1516/07 Kingston_Diabetes	Kingston University		Dr Judith Allgrove	(020
16/EM/0482 PACE-KD	UHL				
16/LO/0865 COPD microparticles	NHS				
214536 Eccentric cycling in COPD	Martin Lindley		Clyde Williams Building		
3598/2015 - CONTRADIA study (Roma)	Dr. Steve Faulkner		Steve Faulkner		
AR UK PDRA	Arthritis Research UK		Dr Darren Player (Pl: Mark	Lewis)	
Bioengineering microscope demo	Dr. Elizabeth Ratcliffe		e.ratcliffe@lboro.ac.uk		
C14-20 SHIFT Study	Stacy Clemes			(01
C17-03 VARIATE	James King		NCSEM 1st floor		

Figure 2 The Projects Dialogue Box

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A dialogue box for data entry will be shown

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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 la	bel	
Sub-location		-
Show data from this field in the link label		
Sample number		•
Notes		2

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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.

LOCATIONS AND SLAPELS ADMENSTRATION MOBILE AND SCANENG REPORTING The Log ext English (Linke Kingdom) - User Application Messager message Application Compared States Compa

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Figure 4 The Procuro task bar

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.

Add New Retire	Reinstate Delete	Lock Out Unlock	Force Pass	word Change Change Password	
Users	Ourrent	Retired		System permissions for selected user	Project permissions for selected user
Pro-curo Samp	le Inventory 4.0.2		×	System Administrator (full permissions)	Project
Add New U	ser			User can:	10/H0403/13: STAND
			_	Manage users	11/NW/0875 & 06/Q2601/9 Cryo impairs M
Enter the nev	/ User Name				13/EM/0290: INTAKE
				Manage projects	13/WM/0494 NMES In Dialysis Patients 14/EM/1190 Cycle-HD
				Manage sample types	14386-01_MTA_Houston
				Manage locations	15/EM/0259 Go fo it
	0	K Can	ncel	Add new samples	15/EM/0391 Acute Exercise in Renal Transpl. 1516/07 Kingston_Diabetes
				Edit existing samples	16/EM/0482 PACE-KD
CGKA				Split samples	16/LO/0865 COPD microparticles
CGKC3 CGKKE					214536 Eccentric cycling in COPD
CGKKE CGLM2				Retire/Dispose samples	AR UK PDRA
CGNMW				Book samples out	Bioengineering microscope demo
CGPH3			√	Book samples in	C14-20 SHIFT Study
CGSB3 CMAJC3				Move samples	C17-03 VARIATE
CMMAT					Select All Deselect All
			•		Destett All
					Save Clo
					Jure

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Pro-curo Sample Inventory 4.0.	.2							
Lloor Management								
User Management								
● ● ●	S (2	-	0			
<u> </u>								
Add New Retire Reinstate	Delete Lock	k Out Un	lock Forc	e Password Change	Change Password			
Users Cu	urrent	O Retired	0	All System pe	ermissions for selected u	ser	Project permissions for selected user	
		_	_		Administrator (full perm	uissions)		
User name	Retired	Locked out	PW Change				Project	
ADJH19				User can:			10/H0403/13: STAND	
ADLC15				Man	lage users		11/NW/0875 & 06/Q2601/9 Cryo impairs M.	
ADMIN					-		13/EM/0290: INTAKE	
ADSP17				Man	age projects		13/WM/0494 NMES In Dialysis Patients	
ADSR4				Man	age sample types		14/EM/1190 Cycle-HD	
CGAE3			√				14386-01_MTA_Houston	
CGBAD2				Man	age locations		15/EM/0259 Go fo it	
CGDM3 CGDM5				Add	new samples		15/EM/0391 Acute Exercise in Renal Transp 1516/07 Kingston_Diabetes	
CGDM5 CGJB2					existing samples		16/EM/0482 PACE-KD	
CGKA				Edit	existing samples		16/LO/0865 COPD microparticles	
CGKC3				Split	samples		214536 Eccentric cycling in COPD	
CGKKE					re/Dispose samples		3598/2015 - CONTRADIA study (Roma)	
CGLM2				Keti	re/Dispose samples		AR UK PDRA	
CGNMW				Boo	k samples out		Bioengineering microscope demo	
CGPH3			√	Boo	k samples in		C14-20 SHIFT Study	
CGSB3							C17-03 VARIATE	
CMAJC3				Mov	e samples		CBE-DUMMY PROJECT FOR TRAINING	
CMMAT							Select All Deselect All	
image the add user h	button is hi	ighlighte	d.	s is where new			Save Clo permissions allocated. In this	ose
image the add user h	button is hi	ighlighte	d.	s is where new	users can be set		Save	ose
image the add user h	button is hi	ighlighte	a projec	s is where new	users can be set heir user nar		Save Clo permissions allocated. In this	
To allocate an e	button is hi	ighlighted	a projec	is where new thighlight t	users can be set heir user nar	ne from the l	Save Cle permissions allocated. In this ist on the left hand side. Review Date:03/01/2	
To allocate an example of the second	button is hi	ighlighted	a projec	t highlight t	users can be set heir user nar	ne from the l	Save Cle permissions allocated. In this ist on the left hand side. Review Date:03/01/2 by: M.Gleeson	
To allocate an example of the second	button is hi	ighlighted	a projec	is where new thighlight t	users can be set heir user nar	Approved Date:28.0	Save Che permissions allocated. In this ist on the left hand side. Review Date:03/01/2 by: M.Gleeson 1.2016	
To allocate an example of the second	button is hi	ighlighted	a projec	is where new thighlight t	users can be set heir user nar	Approved Date:28.0	Save Cle permissions allocated. In this ist on the left hand side. Review Date:03/01/2 by: M.Gleeson	
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Location: CBE



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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Current language	<u> </u>	🔮 🖂 🔮	3 휅 🥵 🚸 🏭	৯ আঁচ 📍		Pro-curo Sample								
Projects					-	User Field Co								
2 🔁 🔏	* =		1			Project: R15-P1	131 GI hormo	ones and GRP variants						
Add New Duplicate Edit Details	Delete Sample List Columns	User Field Configuration					Use	Caption	Drop-dowr items	Data is mandatory		Use	Caption	Data is mandato
						(01) Text	\checkmark	HTA sample		\checkmark	(11) Text		Participant ID	
Project Name	Sponsor		Contact name	Telephone	^	(02) Text		User Field 02			(12) Text		User Field 12	
R15-P031 GI hormones in saliva an	d blo David Stensel						_					_		
R15-P038 arm cranking at raised co	re te Dr Christof Leicht					(03) Text	\checkmark	Time Point		\checkmark	(13) Text		User Field 13	
R15-P044 BFR cuff type	Dr Richard Ferguson					(04) Text		Analyte			(14) Text		User Field 14	
R15-P055 Heating, HSPs and gluco	se re Steve Faulkner						_							
R15-P064-Compression Garments	Laura Barrett			01509 226395		(05) Text		User Field 05			(15) Text		User Field 15	
R15-P095 Perception arm-crank mo	daliti Christof Leicht (PI)			01509 226306		(06) Text		User Field 06			(16) Numeric	_	User Field 16	
R15-P107 Accumulated physical ac						(UD) Text		User Field 06			(ity) realizerie		Oser Field 16	
R15-P120 TMW ECCENTRIC TRAININ		/N and Martin Lindley	TOM MADEN-WILKINSON and M			(07) Text		User Field 07			(17) Numeric		User Field 17	
R15-P124 Fatty Acid Eccentric Train	ng Martin Lindley		Martin Lindley	01509 226349			_					_		
R15-P128 Appetite Reproducibility	David Stensel					(08) Text		User Field 08			(18) Numeric		User Field 18	
R15-P131 GI hormones and GRP va				01509 226344		(09) Text		User Field 09			(19) Date		Consent Date	
R16-P010	Vicky Tolfrey		Loughborough University								(13) 0010	_		
R16-P033 Motivation as predictors		aylor				(10) Text		User Field 10			(20) Date	\checkmark	Sample Expiry	
R16-P050 Inflammation hot water						_								
R16-P067: HEX	James King			01509228457		User fields	1 to 10 (drop	o-downs) are strict selection only						
R16-P072 control study	Lettie Bishop		NCSEM Loughborough University											
R16-P074 Motivation as predictor	f epi Dr Sarabjit Mastana		Beth Hussey and Richard Steel	01509 226444	~								Save	Close

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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CBE Location:

-1 😣 🖛	Ŧ		
Location	ns and Samples Administration	Mobile and Scanning Reporting	
New Du	uplicate Move Rename Delete Prin Iabe		My Retire Dispose View Print Iss history label
5.5.1.	New window opens:	'Sample Information' (see Figure	e 3).
5.5.2.	Choose your project	name using the drop-down list.	
5.5.3.	Once a project name	e is chosen additional tabs may a	appear.
5.5.4.		•	mple type is different to the choices
	manual).	the responsible authority to crea	te a new sample type (See Procuro
5.5.5.	All sample records v	vithin a project file MUST include	the following:
	Unique identifie	r/ sample uniquely identifiable (g	enerated by Procuro),
	Research study		
	• Tissue type,		
	Date of collection	on/receipt from other establishme	ent and where it came from,
	Storage location	١,	
	Consent/Materi	al transfer details (including wher	re the documentation is held),
	Dates of sample	e processing,	
	Information reg	arding transfer to and from other	locations (if relevant),
	Date and details	s of disposal,	
	Reason for disp	oosal,	
	Name of the pro	pject sponsor – the Principal Inve	estigator based within the CBE who is
	responsible for	ensuring that the project's sampl	es comply with the HTA.
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/		Charles Internet	

Cooperant

Date:13/12/2023

5.1

Date: 13/12/2023

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• Other researchers involved - to be added to the notes field.

Sample number(s)	(New)			
Project name	JS LIVE 💌	Sample document links	Batch document links	
Sponsor	James King			
Sample type				
Batch number				
External reference			8	
Mass	· · · · · · · · · · · · · · · · · · ·	Add Remove		View
Re-agent %				
Location	Pro-curo			
Sub location				
Notes				
HTA designated				
MTA if applicable	▼			
plasma treatment	· · ·			
sub location				
user				
consent date				
sample expiry	18/11/2014 □▼			
collection date	18/11/2014			
	Ad	d and duplicate	Add C	ancel

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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.

Version 002	Effective Date:03/01/2024	Review Date:03/01/2026
Written by: P.Hourd/C.Kavanagh Date: 26.01.2016 Reviewed by: C.Kavanagh	Reviewed by: R. Thomas	Approved by: M.Gleeson Date:28.01.2016 Approved by : Karen Coopman
Date: 04/12/2023	Date: 13/12/2023	Date:13/12/2023

Standard Operating Procedure

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Location: CBE

- 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.
- 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.

Version 002	Effective Date:03/01/2024	Review Date:03/01/2026
Written by: P.Hourd/C.Kavanagh Date: 26.01.2016 Reviewed by: C.Kavanagh	Reviewed by: R. Thomas	Approved by: M.Gleeson Date:28.01.2016 Approved by : Karen Coopman
allen f.	12.5.	Cooperant
Date: 04/12/2023	Date: 13/12/2023	Date:13/12/2023

Standard Operating Procedure

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Title: SETTING UP AND EDITING PROJECTS IN THE PROCURO DATABASE

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

SOP Version History

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

Version 002

Effective Date:03/01/2024

Written by: P.Hourd/C.Kavanagh	Reviewed by: R. Thomas	Approved by: M.Gleeson
Date: 26.01.2016		Date:28.01.2016
Reviewed by: C.Kavanagh		Approved by : Karen Coopman
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Date: 04/12/2023	Date: 13/12/2023	Date:13/12/2023

Standard Operating Procedure

CBE/HTA-PR-SOP005

Title:

SETTING UP AND EDITING PROJECTS IN THE PROCURO DATABASE

Location: CBE

Document Control

The Master Copy of all SOPs is filed by the dQM. The latest version is maintained on the CBE network. This document is not a controlled copy once printed from the network. If this SOP appears inadequate or outdated it is the responsibility of all staff to bring this to the attention of the dQM or their Supervisor immediately.

Security Statement

This SOP is the intellectual property of the CBE within Loughborough University, and as such, must not be circulated outside of the University without the written approval from the dQM and the author.

Acknowledgements

This SOP has been produced with advice and input from colleagues and with reference to Loughborough University School of Sport, Exercise and Health Sciences (SSEHS) SOPs and publically available SOPs used at a number of other UK universities. We also acknowledge the contributions of Amit Chandra to the original draft versions of this SOP.



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Reviewed by: C.Kavanagh	P2.5.	Approved by : Karen Coopman
Date: 04/12/2023	Date: 13/12/2023	Date:13/12/2023