UNIVERSITY OF LIVERPOOL GCP labs LCTU	**LCTU GCPLab** **Standard Operating Procedure** **OBTAINING INFORMED CONSENT FOR PARTICIPANTS FOR THE CHRONIC PANCREATITIS RESEARCH TISSUE BANK**

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1. WHO?

This Standard Operating Procedure (SOP) applies to personnel on the delegation log for the Chronic Pancreatitis Research Tissue Bank (RTB) who have been delegated the task of consenting individuals for the biobank.

2. BACKGROUND

The Chronic Pancreatitis RTB is a resource for researchers studying chronic pancreatitis. SOPs for the study give clear, precise and unambiguous details and instructions on how to perform each particular task or operation. SOPs should be followed as instructed with no deviation.

Informed consent is the process by which an appropriate individual voluntarily confirms his/her willingness to participate in a study, having been informed of the full details of the project. Informed consent is documented by means of a written, signed and dated informed consent form.

Informed consent involves:

- Providing participant with suitable information
- Discussion and clarification of the information
- Receiving witnessed verbal or written consent form the appropriate individual

Considerations should be made to ensure adequate adjustments are made when seeking consent from participant with language, literacy or hearing difficulties. An explanation of any adjustments made should be recorded.

Written consent is always the preferred method of consent recording however, subject to ethics committee approval, witnessed verbal consent may be permissible in circumstances where written consent is not possible.

3. PURPOSE

The purpose of this SOP is to define the procedure for obtaining informed consent (in conjunction with GCLPTSS055) from adult participants, defined as an individual 18 years of age or over, with capacity to give informed consent for research.

4. SCOPE

This SOP applies to personnel who have been delegated the task of obtaining informed consent on the chronic pancreatitis RTB.

5. PROCEDURE

5.2 RESPONSIBILITY

- It is the responsibility of the Chief Investigator (CI)/Clinical Lead (CL) to ensure ethical approval is in place prior to obtaining consent for a study.

- It is the responsibility of the CI/CL for the chronic pancreatitis RTB to maintain oversight of tasks which they have delegated.
- It is the responsibility of the CI/CL to ensure personnel are suitably trained to carry out consenting procedure (GCLPPPD014 and GCLPPPD014/F1) and that the delegation log naming all personnel authorised to obtain consent has been completed.
- It is the responsibility of the CI/CL to ensure compliance of all personnel and to ensure only authorised and trained individuals perform tasks using the specific SOPs (GCLPPPD014 and GCLPPPD014/F1).
- It is the responsibility of the CI/CL of the chronic pancreatitis RTB to ensure all personnel on the delegation log are fully trained to both obtain and manage informed consent, carry out the management of the consenting procedure, in accordance with LPRG Policy document GCLPPPD014 and GCLPPPD014/F1,
- It is the responsibility of all staff delegated to obtaining and managing consent to follow precisely this SOP in conjunction with the procedure in GCLPTSS055 (section 5.2.2 and 5.2.5) for identifying a potential patient for recruitment to the Chronic Pancreatitis RTB. Any deviation from these SOPs must be submitted as a Quality Incident (QI) report (GCLPFAC005/F1) to the CI/CL/Operational Director (OD)/Quality Assurance Manager (QAM).
- It is the responsibility of all personnel on the delegation log of the Chronic Pancreatitis RTB to inform and submit a QI report (GCLPFAC005/F1) when there has been a deviation from an SOP to the CI/CL/OD/QAM who will take the appropriate action.
- It is the responsibility of the CI/CL/OD/QAM to identify any appropriate preventative measures and implement these measures within an accepted timeframe.

NB: *For all staff that consent patients for the Chronic Pancreatitis RTB, as part of their role (including research assistant (non-clinical), research nurses and clinical fellows) prior to taking informed consent, they must undertake informed consent training and provide evidence of this. Staff must contact the Royal Liverpool University Hospital (RLUH) Research, Development and Innovation (RDI) for training or contact https://learn.nihr.ac.uk. All staff whose role is to also take blood samples at the time of taking informed consent must have completed a certified Phlebotomy training course at RLUH and provide evidence of this, prior to any taking of any blood samples from potential patients. They can be contacted by emailing clinical.skills@rlbuht.nhs.uk. All staff must also have undertaken a Good Clinical Practice (GCP) course and provided evidence of this which must be refreshed every three years in compliance with local requirements (GCLPPPD014 and GCLPPPD014/F1).*

5.2 PROCEDURE

5.2.1 Details for Taking Informed Consent:

Prior to approaching a patient for consent, a patient will have been identified for potential donors to the study following procedure described in SOP GCLPTSS055 (section 5.2.2 and 5.2.4).

For all staff delegated to obtaining informed consent this SOP must be strictly adhered too, and specifically in conjunction with GCLPTSS055 section 5.2.5 (consenting the patient).

- The person(s) responsible for obtaining consent must ensure they are completely familiar with all aspects of the Chronic Pancreatitis RTB as described in the latest version of the protocol approved by REC.
- The Consent Form (approved by REC) must be checked to ensure it has the correct title and version number for the study and relates to the written patient information sheet given to the participant.
- All potential participants should be given information about the Chronic Pancreatitis RTB prior to inclusion in the research tissue bank.
- The dignity of the potential participant should be taken into consideration, (if possible) a private area should be used for the consent process, if required.
- Participants who potentially fulfil the inclusion/exclusion criteria will be identified earlier (GCLPTSS055, section 5.2.2) and approached. A verbal explanation of the study must be given to the potential participant/subject and, if necessary, diagrams should be used to explain the study. The discussion should allow time for questions to be asked and adequately addressed.
- On the above information has been verbally discussed with the participant the participant should be provided with a written patient information sheet (PIS) detailing the Chronic Pancreatitis RTB.
- The participant should be given adequate time to read the PIS and discuss with family or friends (if applicable), prior to agreeing to participate.
- The participant should not be coerced to participate, and should be reassured that refusing to enter the study will not affect their care.
- Once the participant has had time to read the PIS and is satisfied that their questions have been adequately addressed they can be asked if they wish to sign the written informed consent form relating to the study.
- The informed consent form must be personally signed and dated in ink easily visible on photocopies by both the person seeking consent and the patient. Each should also clearly print their name by their signature. The consent form **must** be completed before any aspect of the participant's involvement in the study begins.
- Once all parties have signed the written informed consent form, the participant should receive a signed and dated copy, together with the patient information sheet and any other written information provided to the participant. A copy of the above must be placed in the participant's medical notes and a copy kept in the study file located in UCD, 3rd Floor, Room 3.301.
- All participants must be provided with contact details where they may obtain further information about the study. This will also be the same contact details should they wish to withdraw their samples at any time.

NB: If at any time a participant is deemed to be too unwell to understand or comprehend the information and is incapable of making a decision, no samples should be taken at this time.

Once the consent process has been completed and the patient has agreed to donate their blood sample to the RTB, the staff member must adhere precisely to procedure in GCLPTSS055, section 5.2.6 and 5.2.7, inclusive.

NB: The informed consent process should not end once the informed consent form has been signed. The practice of giving information about the study to participants/subjects should be an ongoing process performed by all research personnel and any associated healthcare professionals. This is particularly important if protocol amendments are introduced, or if important new information that may be relevant to the participant's willingness to continue taking part in the study is discovered.

6. REPORTING

When any deviations from an SOP occurs, it should be brought to the attention of the CI/CL and a **QI Report** (GCLPFAC005/F1) should be completed and forwarded to the OD/QAM. The OD/QAM must review the **QI report** and determine if the participants/subject is required to be correctly re-consented or removed from the study.

7. ABBREVIATIONS

QI	Quality Incident Report
CI	Chief Investigator
CL	Clinical Lead
OD	Operational Director (GCP)
QA	Quality Assurance Manager
REC	Research Ethics Committee
RTB	Research Tissue Bank
SOP	Standard Operating Procedure

8. OTHER RELATED PROCEDURES AND DOCUMENTS

Documents:

GCLPFAC005/F1	GCP Facility Quality Incident Form
GCLPPPD014	LPRG Training Policy
GCLPPPD014/F1	LPRG Training File Checklist
	Delegation Log
	Informed Consent Form
	Patient Information Sheet
	University of Liverpool Supporting Document – Consenting for Research SDS001

SOPs:

GCLPTSS055	Collection of Samples for the Chronic Pancreatitis Biobank