DIRECT
DIABETES RESEARCH ON PATIENT STRATIFICATION

STANDARD OPERATING PROCEDURE (SOP)

Diabetes Research on Patient Stratification (DIRECT)

All Work Packages

PROCEDURE FOR THE IDENTIFICATION AND DESTRUCTION OF SAMPLES AND/OR DATA AFTER A PATIENT WITHDRAWS CONSENT AND REQUESTS THEIR SAMPLES AND/OR DATA BE DESTROYED/REMOVED

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Procedure for the Identification and Destruction of Samples and/or Data after a Patient Withdraws Consent and Requests Their Samples and/or Data be Destroyed/Removed

1. Purpose.

A robust procedure is required to enable all patient samples and data to be located and destroyed/removed in the event that a patient withdraws his/her consent and requests for this to be done.

Generally, patients who withdraw consent are content for any samples and data they have donated prior to making this decision to remain in the study cohort and to be analysed. However, on very rare occasions, a patient who withdraws consent decides to request that their samples and/or data be removed from the study analysis.

This SOP describes how samples and data are to be located, authorized for destruction and certified as destroyed.

2. Applicability.

This SOP applies to; Chief Investigator, Principle investigator, Co-Investigators, Specialist Diabetes Research Nurses, Clinical Trials Manager, [redacted] Laboratory, Analysis Laboratories and all study personnel.

3. Procedure.

Patient notification of withdrawal of consent

Patient notification of withdrawal of consent can take many forms eg. Phone call, letter, email and can be received via many possible routes eg. Directly to the study team or via the hospital complaints service. Participants must be able to withdraw consent without giving any reason for it. Study staff must follow up to ascertain if the samples and data that have been provided to date can be retained. In some instances the patient's consent includes statements about being unable to withdraw data after a certain point. In this eventuality the terms of the consent are followed.

Sample identification and destruction

Irrespective of the method of communication, if the patient requests that his/her samples be destroyed then the following process should be followed:

1. A member of staff at the clinical recruiting centre will complete the form "Request for Destruction of Patient Samples", sign this and immediately send it in pdf form to the [redacted] Laboratory by email to [redacted]. This form includes details of the Subject ID number and

Date of Birth. This is necessary in order to be able to look at the patient's registered samples in the DIRECT database.

2. Staff at [redacted] Laboratory will locate all the patients' samples using the DIRECT database and co-ordinate with other locations where the samples are held, by forwarding the request for sample destruction.
3. In addition, [redacted] Laboratory staff will notify the study centres and analysis labs of the relevant sample barcodes.
4. Samples are destroyed by the local approved method eg. Clinical waste bin followed by incineration.
5. A member of staff with administrator rights on the database at each location where samples have been located and destroyed will enter the DIRECT database and, using the sample barcode, in the "Repairs" function, change the status of the sample to deleted.
6. Once this has been done, this person will notify [redacted] Laboratory by email that the sample destruction at their location is completed.
7. When all the locations have completed the sample destruction and notified [redacted] Laboratory, the status of the samples in the DIRECT database will be checked and confirmed as deleted by a member of staff at the [redacted] Laboratory.
8. Every effort will be made to trace all derivative samples.
9. The form "Request for Destruction of Patient Samples" will be counter signed by a member of staff at the [redacted] Laboratory and will be sent in pdf form to the relevant clinical recruiting centre (particularly to the person who sent it in Step 1).
10. A member of staff at the clinical recruiting centre will be nominated to write to the patient to tell the patient that all their samples have been located and destroyed as per his/her wishes.
11. A member of staff at the clinical recruiting centre will set the status of the patient in the database to the applicable "Withdrawn" status.This process should be completed within 10 working days.

Data Removal

If the patient has asked that their data be removed from the study, the terms of the consent form will take precedence if removal of data is mentioned therein.

A member of staff at the clinical recruiting centre will set the status of the patient in the database to the applicable "Withdrawn" status, if this was not already done in step 10 above.

An email should be sent to [redacted] to notify this team that the patient's withdrawn status has been set and that data needs to be removed. Data will be held on earlier copies of the database will be retained but the data will be removed from the current database. Copies of the database going forwards will not contain the data for this study subject.

The DAC will help to track analysts working with data released on the analysis server to notify them that a patient's data has been removed and to instruct them to delete this data from their ongoing analysis. Prior/completed analyses will not need to be modified.

Clinical recruiting centres should destroy the CRF pages held for this patient, retaining only the eligibility page and placing a note in the CRF that the subsequent pages were removed and destroyed based on the patient's instruction.