Standard Operating Procedure Title: Inter-site Transport, Processing of Clinical Data and Samples and Long Term Storage

Intended for: Clinical and Research Staff as so indicated

Written by: Angela Pushpa-Rajah Authorised by: Professor Catherine Smith

Written: December 2010 Last revised: 10 January 2017

Revised by: Michael Duckworth, David Baudry and Mike Allen

Authorised by: Professor Catherine Smith

Date for review: January 2018

Related SOP’s:
Standard Operating Procedure for Clinical Data and Sample Collection, and Partner site Storage.

Purpose / Scope:
To provide a standard operating procedure for the inter-site transport of human samples from partner sites and for transport between Guy’s and St. Thomas’ campus, and for processing of samples at the central laboratory at the St John’s Institute of Dermatology (Guy’s Hospital). This SOP is written in accordance with the Human Tissue Act 2004, Regulations 2006 & 2007 and King’s College London, Guidelines for the Transport of Biohazardous Goods, for the distribution of human samples where appropriate.

Procedures
1). At Partner sites

1.1) Sample Transport from Partner Sites
To maintain participant anonymity send all samples to the St John’s Institute of Dermatology separately to their patient and clinical data. Label all sample tubes appropriately. For partner sites using the St John’s Institute of Dermatology’s database (ChArting PaTient outcomes Using an online Resource - CAPTURE) to enter study data, label samples with: a patient study identification number, a sample identification number (generated from CAPTURE) and the date the sample was collected. For partner sites using a paper based data capture system, label samples with: a patient study identification number, date the sample was taken, and the patient’s initials.
Samples collected at partner sites are transported to the St John’s Institute of Dermatology at the following address:

Skin Therapy Research Unit
9th Floor, Tower Wing
Guy’s Hospital
Great Maze Pond
London, SE1 9RT

- Prior to transport of samples the partner site research team should ensure that the central co-ordinating centre is aware that the samples are to be transported and are able to receive them upon arrival.
- Transport frozen blood (whole and cells; RNA Tempus® tubes) and serum samples on dry-ice by specialist courier service – contact central co-ordinating centre for details and packaging instructions.
- Post methotrexate Samples to the St John’s Institute of Dermatology in a blue Royal Mail Postal Safebox - provided by the central co-ordinating centre. Postage on these Safeboxes are pre-paid.
- If saliva kits are used to collect DNA, place the saliva samples in Jiffy® bag, seal securely and post via Royal Mail Freepost service – supplied by central co-ordinating centre.

1.2) Transport of Relevant Clinical Information from Partner Sites

Label sample slips and case report forms (CRFs) with the corresponding patient study identification number, DOB, Initials and gender to allow the clinical data to be matched to the sample at the central co-ordinating centre. Send all clinical study data to the St John’s Institute of Dermatology. If CAPTURE is used to enter clinical study data at a partner site, do not return CRFs to the St John’s Institute of Dermatology. If a paper CRF is used to capture clinical study data at a partner site, send all completed CRFs to the central co-ordinating centre via secure email or using Royal Mail Freepost service. Store original copies of paper CRFs securely in the study site file. Partner sites will find Freepost Labels in section L of the Site File to label envelopes when sending study documentation.

The central co-ordinating centre will acknowledge receipt of clinical data and samples to the partner site via e-mail.
Partner sites retain participant consent forms until the conclusion of the study, at which time the central co-ordinating site will make arrangements for the transfer of all study documents. Principle Investigators at participating sites ensure that up-to-date consent is received from study participants, that consent forms are completed correctly and stored securely in the study file.

2). At Central co-ordinating centre (applicable to Guy’s and St Thomas' NHS Foundation Trust sites only)

Relates to samples collected in Dermatology Out-patients at Guy’s and St Thomas' Hospital campuses and received at the St John’s Institute of Dermatology. Transfer all clinical data from Guy’s and St Thomas’ campuses to the St John’s Institute of Dermatology separately from the samples.

- Samples collected in Dermatology Out-patients at Guy’s Hospital: all study samples are collected at the end of clinic by a member of the study team in the central co-ordinating centre, and transported by hand to the St John’s Institute of Dermatology.
- Use of Viapath pathology service: Take all samples for transport between Guy’s and St Thomas’ campuses to the Viapath drop off point at 4th floor Southwark Wing at Guy’s Hospital and collecte them from North Wing St. Thomas’ campus, and visa versa.
- Transfer whole blood for DNA, whole blood for RNA, serum and saliva to the St John’s Institute of Dermatology (Guy’s Hospital).
- Transfer whole blood for methotrexate sampling to the Purine Laboratory, FAO Monica Arenas, 4th Floor, North Wing, St. Thomas’ Hospital.
- Pack any samples kept at ambient temperature (Methotrexate sample and saliva samples) in a Jiffy® bag clearly labelled with name, address and contact number of recipient. Delivery time between campuses is ~1 hour.
- Transfer frozen samples (Serum, whole blood for DNA and whole blood for RNA) between Guys’ and St Thomas’ sites on dry-ice in a secure biological material transfer container in accordance with UN PI650 (see KCL, Transport of Biological and Human Tissue Samples between College campuses) using a KCL approved specialist courier service, to the appropriate laboratories (0207 880 1111).
- Methotrexate samples: Log all methotrexate samples received at GSTT and sent to the purine lab on a spread sheet. Keep a record of:
  - Patient’s study ID number
3). Clinical Data and Sample Processing (applicable to Guy’s and St Thomas’ NHS Foundation Trust only)

Relates to samples and data received in the St John’s Institute of Dermatology, Guy’ hospital.

- Partner sites shall send study samples and clinical study data separately. There may be a lag between receipt of clinical data and samples. All clinical data is collated and matched to the respective samples to ensure that the patient has been consented to the study and the appropriate clinical information has been obtained.
- In the event of missing/incorrect clinical data, missing samples or damaged samples, the central co-ordinating centre contacts the participating site to request that the missing/ incorrect clinical study data be sent, or to notify them of the missing/damaged samples.

3.1). Sample Processing

- Ensure that all samples received at Guy’s and St. Thomas’ campuses and from partner sites have their details on the tubes cross-checked with that given on the sample slips before any sample processing takes place. Any discrepancies should be flagged with the site from which the sample was taken.
- Assign all samples collected at Guy’s and St. Thomas’ campuses and from partner sites a unique sample identification number. Enter the sample information onto the CAPTURE database and into the laboratory sample log book with the following information:
  - Unique patient study ID number
  - Unique sample identification number – see below
  - Initials
  - Date of birth
  - Gender
  - Date of sample
  - Type of Sample
  - Disease and Protocol
• In addition for those samples collected at Guy’s and St Thomas’ campuses, enter the patient’s name into the laboratory sample log book.

• Assign all samples a unique sample identification number, that is sequentially generated. Write this number on the sample tube prior to storage, record it on the accompanying clinical data sheet and enter it onto the CAPTURE database.

3.2). Clinical Data Processing

Once all clinical data and samples have been collated, enter all clinical data and sample information onto the CAPTURE database.

Security and Storage of Clinical Data and Samples

i) Storage

• Store samples in the appropriate manner prior to further analysis/extraction
  • Store whole blood for DNA at -20°C
  • Store serum at -80°C
  • Store whole blood for RNA at -80°C
  • Store saliva at ambient temperature

ii) Security

• Store all clinical data separately in study specific site files in a locked office at the central co-ordinating centre. Access to the central co-ordinating centre (9th Floor, Tower Wing, Guy’s Campus) is by swipe access.

• Store all electronic information regarding clinical data and samples on a password protected secure NHS server.

• Store all samples within a secure laboratory at the central co-ordinating centre. Access to this laboratory is by swipe access, as is access to the central co-ordinating centre itself.

• All historic sample log books are stored in a secure, locked office in the central co-ordinating centre. Photocopies of the log books are made and stored separately in secure locked cupboards within the central co-ordinating centre. The current sample log books are stored in the central co-ordinating centre laboratory.

• All data stored on CAPTURE is stored on the Guy’s and St Thomas’ NHS Foundation Trust Fire wall. All processes for data collection, transfer and storage are fully compliant with ICH Good Clinical Practice, the Data Protection and Human Tissue Acts.
4) DNA Extraction and Long Term Storage
Extract DNA from whole blood and saliva within 7 working days from receipt of samples.
Remove all accompanying patient data to ensure patient anonymity. Ensure DNA is only identified by the laboratory number assigned upon sample receipt, Patient Study ID number and the date the sample was collected. Aliquot the DNA samples into 2 aliquots and stored at -20°C at the central co-ordinating centre, the St John’s Institute of Dermatology, Guy’s Campus, for long term storage.

5) Serum Aliquotting and Long Term Storage
Remove all accompanying patient data from samples to ensure patient anonymity. Ensure serum is only identified by the laboratory number assigned upon sample receipt, Patient Study ID number and the date the sample was collected. Aliquot the Serum samples into 6 aliquots within 1 week from receipt of sample, and store at -80°C at the central co-ordinating centre, the St John’s Institute of Dermatology, Guy’s Campus, for long term storage.