**Standard Operating Procedure Title:** BSTOP Standard Operating Procedure for Clinical Data, Sample Collection and Partner Site Storage

**Intended for:** Clinical and Research Staff as so indicated

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**Related SOPs**  
Inter-site Transport, Processing of clinical data and samples and long term storage.

**Purpose / Scope**  
To provide a standard operating procedure for Sample Collection, Partner Site Storage and transport to Central Co-ordinating Site, St Johns Institute of Dermatology, Guy’s hospital.

NB Clinical samples e.g. blood, serum etc should NOT be handled in offices at any time and should be taken directly to the lab and not transited though offices where food and drink may be consumed. All sample labelling etc should take place in the lab or clinical area.

The appropriate study consent must be in place from patients prior to sample collection, processing and storage.

**Requirements**

Each site must have as a minimum:

- Venepuncture facilities
- Centrifuge (only if collecting serum samples)
- -20°C freezer (where -80°C not available)
- Sample collection and storage tubes (to be provided by Study team)
- Secure storage facilities for data and samples
Procedures

Sample Labelling:

- Ensure all tubes are labelled appropriately. Label the blood collection tube after the sample has been collected.
- Partner sites entering BSTOP study data onto the St John’s Institute of Dermatology database (The CAPTURE database) should label all sample tubes and Eppendorf tubes with: the patient’s anonymised study identification number, date of sample collection, and the unique sample identification number generated in CAPTURE. Partner sites entering BSTOP study data onto paper CRFs should label all sample tubes and Eppendorf tubes with: the patient’s anonymised study identification number, the patient’s initials and date of sample collection.
- Use a fine tip, black Staedtler™ Lumocolor™ permanent marker to label the samples.

Sample Collection, Preparation and Storage (Guy’s & St Thomas’ NHS Foundation Trust sites only):

Blood samples from patients at Guy’s and St.Thomas’ NHS Foundation Trust (GSTT) campuses are stored at 5°C in Dermatology Out-patients prior to transfer to the St Johns Institute of Dermatology on the 9th Floor, Tower Wing, Guy’s campus.

Whole Blood for DNA

- Collect DNA blood from every BSTOP patient at the baseline visit unless special allowance is made to collect saliva
- Collect 12 ml of whole blood in 2x 6ml K$_3$EDTA Vacuette tubes (pink top).
- Label the tubes as per labelling instructions detailed above.
- Write the date and time the blood was drawn on Sample request form.
- Store whole blood at -20°C or colder (ideally -80°C) until transported to the St John’s Institute of Dermatology.
- Write the date and time the blood was frozen on the Sample request form.
- For sites collecting Methotrexate samples: If a patient has a Methotrexate and DNA sample collected on the same day, post the Methotrexate and the DNA sample to the St John’s Institute of Dermatology in the in Royal Mail Safe boxes at ambient temperature in the same box. Include the corresponding sample slips.
Whole blood for RNA

- Only BSTOP supersites collect RNA samples.
- Collect RNA samples at Baseline (before treatment start), 1 week, 1 month and 3 months after a patient has started their treatment.
- Collect 3ml of whole blood in a Tempus RNA isolation tube (blue top).
- Label the tube as per labelling instructions detailed on page 2. Write the date and time the blood was drawn on Sample request form.
- Vortex or shake vigorously for 10 seconds immediately after collection to ensure thorough mixing.
- Store at -20°C or colder (ideally -80°C) until transported to the St John’s Institute of Dermatology.
- Write the date and time the blood was frozen on sample request form.

Whole blood for Serum

- Longitudinal sites and supersites collect serum for biomarker analysis.
- These sites collect serum from all patients at each visit.
- Collect 5ml whole blood in 1 x 5ml serum separating clotting factor Vacuette tube (yellow top).
- For patients on biologic therapies: Collect an extra serum sample (e.i. 2 x 5ml yellow top serum tubes in total).
- Write the date and time the blood was drawn on the sample request form.
- Invert 3x to mix blood with clotting factor and rest for at least 30 minutes, ideally in an upright position.
- If longer than 30 minutes, then store serum samples upright in a 5°C refrigerator prior to centrifugation.
- Centrifuge samples ideally within 2 hours of but a maximum of 4 hours after blood collection.
- Centrifuge at 1000g for 15 minutes at ambient temperature.
- Write the date and time of centrifugation on the sample request form.
- Immediately following spin, use a pipette to transfer the separated serum into 2ml Eppendorf tube.
- Use a fresh pipette for each serum tube.
- Use only one Eppendorf tube if all the serum can fit into one tube.
• Leave some space at the top of each Eppendorf tube as the serum will expand in the tube once frozen. Fill to the 1.5ml graduation line (approximately ¾ full).
• Label the Eppendorfs as per labelling instructions detailed on page 2. Store at -20°C or colder (ideally -80°C), until transported to the St John’s Institute of Dermatology.

**Whole Blood for methotrexate (MTX) pK drug levels**

• Longitudinal sites and supersites collect PK drug levels from patients taking Methotrexate at each visit. Collect 4ml whole blood in 1x K$_2$EDTA Vacuette tube (purple top).
• Invert 5x to mix thoroughly.
• Label the tube as per labelling instructions detailed on page 2. Write the date and time the blood was drawn on sample request form.
• Post Methotrexate samples at ambient temperature in postal safe boxes to the St John’s Institute of Dermatology.
• Post the corresponding sample slip with the Methotrexate sample.
• If the Methotrexate sample is collected on a Monday, Tuesday or Wednesday, post the sample to the St John’s Institute of Dermatology on the day of collection.
• If the Methotrexate sample is collected on a Thursday or Friday, store the Methotrexate sample at 5°C over the weekend, and post to the St John’s Institute of Dermatology on the following Monday.

**Whole Blood for MTX – Guy’s and St. Thomas’ campuses only**

• Collect 4ml whole blood in 1x K$_2$EDTA Vacuette tube (purple top)
• Store at 4°C prior to transfer to Purine Laboratory, 4th Floor North Wing, St. Thomas’ campus
• All samples must be transferred to Purine lab within 48 hrs of reception.

**Saliva for DNA**

• Saliva for DNA may be collected in special circumstances, contact the BSTOP Study team to discuss.
• 2ml saliva in a 1x Oragene®-DNA collection kit (DNA Genotek Inc., Canada)
• Ensure lid is affixed securely
• Label as per labelling instructions detailed on page 2.
• Placed inside a zip-lock specimen bag
• Store at ambient temperature until transported to central co-ordinating site within 1 month or when 10 samples have been collected, which ever is sooner.

**Transportation of Samples to Central Site:**

• Contact the BSTOP study team to arrange shipment of frozen samples.
• When transferring sample between sites, always include the anonymised Sample Request Form for each sample.

See related SOP for transportation