1. **Objectives**

To describe the procedure for the collection and storage of the EDTA-blood samples from VORTEX patients who have given their consent to participate in the VORTEX-BIOBANK translational study.

2. **General Points**

- Only after a patient is confirmed as needing radiotherapy (RT) by the clinical oncologist will they be randomised and a blood sample taken.
- The Trial Co-ordinator in Birmingham also notifies the ‘Named Responsible Person’ (as given on the feasibility questionnaire) that a patient has consented to the BIOBANK and that a bar-coded blood kit will be sent down to them.
- Birmingham Cancer Research UK Clinical Trials Unit (CRCTU) is responsible for the co-ordination between the participating centres and Manchester.
- Manchester is responsible for the storage, record and treatment of the samples.
- Centres will be reimbursed £5 total for the collection and delivery of the two blood samples.

3. **Collection from centres**

   a) Following randomisation of each patient into the VORTEX trial (prior to RT), the CRCTU alert Manchester that a blood kit is required. CRCTU sends by fax to Manchester office:
      - Patient registration number (as used for the fresh tissue samples)
      - Patient date of birth (to cross check with the BIOBANK records/database)
      - Contact details of ‘Named Responsible Person’ as given on the completed feasibility questionnaire

   b) Personalised blood kit* sent directly from Manchester to ‘Named Responsible Person’ e.g. a research nurse. They need to:
      - Check the bar-code labels display the same VORTEX registration number throughout the kit and that they match that on the patient’s notes
      - Check when patient is expected into clinic for their planning appointments and pass kit to available research nurse (if not the ‘Named Responsible Person’)
      - Mark patient notes to remind clinician that bloods need to be taken into specific VORTEX-BIOBANK labelled tubes and ask patient to visit research nurse
NOTE Timing:
- Bloods should preferably be taken prior to radiotherapy or in the first week of treatment (to avoid low lymphocyte count)
- Only draw bloods Monday-Wednesday to avoid samples arriving in Manchester over the weekend period (affects DNA quality)
- Not necessary to prescribe a specific appointment when bloods should be taken because we can be flexible

c) Research Nurse takes the bloods into two 10ml blood tubes (bar-coded with patient’s registration number) according to the local institution’s standard venepuncture procedure.
- Must ensure each tube is inverted 8-10 times to mix blood thoroughly with the EDTA additive
- Place each blood tube in the mailing tubes provided and tighten cap to secure inner blood tube

d) Research Nurse completes the Blood Sample ID card (green) pre-printed with the patient’s registration number.
- Additional information required on ID card: Date bloods taken; NHS Trust Number; Hospital/ Site; Name of researcher; Contact number
- Place the two blood tubes and the completed ID card in the pre-paid, pre-addressed jiffy bag provided

e) Return jiffy bag to the ‘Named Responsible Person’ (if appropriate) who must:
- Ensure bloods are put in the post that same day
- Complete and send the FAX Confirmation sheet to Manchester

f) On receipt of bloods in Manchester, VORTEX-BIOBANK technician will double check that the patient ID card matches with the bar-coded blood tube and the details faxed on the confirmation sheet
- Bloods stored at -80°C in the Paterson Institute of Cancer Research (PICR).

* Blood kit comprises:
  - 2 DNA-EDTA blood tubes (with bar-coded VORTEX registration number)
  - BD Vacutainer single-use needle and holder
  - 2 mailing tubes
  - Pre-addressed pre-paid jiffy bag (with registration number sticker)
  - Blood Sample ID card (with registration number sticker)
  - Patient FAX Confirmation sheet (with registration number sticker)
  - Instructions for blood collection and return
4. **Documentation required**

- Completed Blood Sample ID card accompanying samples in the post.
- Patient FAX Confirmation Sheet.

5. **Storage of samples**

- On arrival, samples undergo a further check and the VORTEX-BIOBANK Office confirms to CRCTU receipt of the blood tubes.
- In the VORTEX-BIOBANK Office samples will be logged and placed at -80°C for storage until ready for DNA extraction and SNP analyses.

6. **VORTEX-BIOBANK Office Contact Details**

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7. Schema

Following patient's randomisation, CRCTU alerts Manchester that a blood kit is required for a specific patient in the BIOBANK

Named Person (or RN) holds onto blood kit until patient is attending clinic for RT planning appts. (can be flexible)

Two 10ml EDTA-blood samples taken into pt registration bar-coded tubes. *Time Critical – Do NOT take or post bloods just prior to the w/e*

Each blood tube placed in a 2° mailing container and posted with completed blood sample ID card ASAP in the jiffy bag provided. *Do NOT send bloods that will arrive during w/e. Last postal day Wed. pm*

Send FAX Confirmation sheet to Manchester

On receipt in Manchester, all details checked and then stored at -80°C for long-term storage