GENVASC Study Sampling Process LLR

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Approved by _____ Date: _____.
Wet Ink Signature *Wet Ink Date (dd / mmm / yyyy)*

Review Date

Supersedes V3

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1 Scope

This SOP covers the sampling process for patients recruited to the GENVASC study.

1.1 General Principles

- SOP's describe **what** is to be done. Not to be confused with working instructions that describe **how** it is to be done.
- Responsibilities should be stated.
- The information contained in the SOP is mandatory. Unless in italics, in which case it is optional.
- Line managers ensure that the individuals performing the tasks are appropriately qualified and trained.
- Reference documents are listed in the Appendices.

2 Purpose

The purpose of this SOP is to ensure the following:-

- Harmonised process and procedures within the Leicester Cardiovascular Biomedical Research Unit and the UHL department of Haematology and Biochemistry and GP Practices within the NHS Leicester City Clinical Commissioning Group
- Protection of patients and staff from avoidable harm
- Demonstration of best practice against current standards within University Hospitals of Leicester NHS Trust (UHL), University of Leicester and national guidance and the NHS Leicester City Clinical Commissioning Group
- Compliance with applicable Regulatory requirements
- Compliance with University Hospitals of Leicester and the NHS City Clinical Commissioning Group clinical governance policy
- Compliance with University Hospitals of Leicester and the NHS City Clinical Commissioning Group vicarious liability policy

3 Procedure

GENVASC participant consent forms are to be made available to the healthcare professional obtaining the research blood samples. This may be either during a one stop visit when consent and samples are obtained during the same consultation. Or, if samples are obtained during a subsequent follow up appointment. Patients presenting at follow up appointments to have their health check blood samples +/- their research samples taken must have a signed and dated copy of their consent form for the phlebotomist to see prior to collecting the research blood samples. Practice in LLR should where possible also tick GENVASC participant on Sunquest ice.

If GENVASC blood samples have been requested on Sunquest ice, but there is no signed and dated consent form present, it is acceptable to print a copy from the participant's medical notes or take a photocopy of the original consent form held in the Site File. If there is no consent form samples may still be obtained, but only if the patient is first consented by a person who has completed the GENVASC training and signed the Practice Personnel Log. Once informed consent is confirmed, the research samples can be obtained. **If taking clinical samples at the same time as the research samples, the clinical samples must be taken first**. The GENVASC samples are: 3 x 2.7ml EDTA samples (red) and 1 x 4.9ml Serum sample (brown), taken in this order.

The research samples should be labelled with the patient's details and placed in a sample bag with a GENVASC sticker attached. A copy of the consent form should also be attached to the bag and then sent to the UHL Department of Haematology and Biochemistry using the same method used for sending clinical samples. If it has not been possible to obtain all of the research samples, then the empty sample bag with the GENVASC sticker and consent form attached should be sent to the UHL Department of Haematology and Biochemistry. If it has not been possible to obtain any or all of the samples, this does not need to be recorded on the Deviation Log.

If there is no consent form, blood samples must not be taken.