GENVASC: Obtaining consent at the first point of contact (Witnessed Process)

Authored by **Emma Beeston**

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

Review Date

Supersedes V3

NIHR Leicester Cardiovascular Biomedical Research Unit
University of Leicester
Department of Cardiovascular Sciences
Clinical Sciences Wing
Glenfield Hospital
Groby Road
Leicester, LE3 9QP (UK)

1 Scope

This SOP covers the process of taking informed consent (witnessed process) for 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 Practice Study Sites.
- 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 Primary Care.
- Compliance with applicable Regulatory requirements
- Compliance with University Hospitals of Leicester and Primary Care clinical governance policy
- Compliance with University Hospitals of Leicester and Primary Care vicarious liability policy

3 Procedure

The process of taking informed consent for participants onto the GENVASC study should only be undertaken by persons who have completed the GENVASC training (or had the training cascaded) and signed the Practice Personnel Log.

Patients who are eligible to be approached for recruitment onto the GENVASC study are those who are being invited to attend for an NHS Health Check. At the first opportunity patients should be provided with the Abbreviated Patient Information and verbal information about the study. If necessary there is a GENVASC 'crib sheet' available in the study site file, which clearly explains the key points of the study and can be used as a narrative/prompt.

If the patient understands the information being given and is willing to participate, they should be consented using the approved current version of the consent form. The consent template is located on the electronic patient registration system, where it can be printed from. The participant must initial in each of the boxes and sign, date and write their signature in black ink. The person taking informed consent must also sign, date and write their name in black ink. The original consent form must be held in the site file, a copy must be given to the participant, a copy scanned into the participant's medical notes and a copy attached to the blood samples. It must also be documented in the patient's medical notes that they have taken part or declined to take part. The participant must also be given a copy of the GENVASC full information leaflet and a withdrawal form to take home (withdrawal form also printed from the electronic patient record system).

No participants should have GENVASC samples taken prior to obtaining informed consent. If samples are obtained prior to gaining informed consent this should be recorded as a protocol violation in the protocol deviation log and reported to the study team immediately.