GENVASC: Obtaining consent (Un-Witnessed Process)

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

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Supersedes V2

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1 Scope

This SOP covers the process of obtaining consent using the un-witnessed process.

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 obtaining consent using the un-witnessed process should be used when the first point of contact is via mailshot, reception staff or clinical staff during an opportunistic visit. **Practices employing the un-witnessed process must use the un-witnessed consent form in conjunction with the full GENVASC information sheet.**

Patients who are eligible to be approached for recruitment onto the GENVASC study are those who are being invited to attend for a cardiovascular health check and meet the inclusion/exclusion criteria as listed in the practice study pack. Invitation to take part can be opportunistic or via mail shot. Patients invited to take part must be provided with a consent form. The consent template is located on electronic patient records systems, where it can be printed from and either posted to the patient or provided at a practice visit. Participants who wish to take part in the study should be advised to bring the completed consent form/s to their health check appointment.

Participants who bring a completed un-witnessed consent form to their health check/phlebotomy appointment should have the form checked for completeness and be given an opportunity to ask questions. Therefore only people that have received the GENVASC training (or had it cascaded) can check the consent forms and answer questions. The participant must have ticked 'yes' to each of the boxes 1-6. The only field that is optional is number 7. If the patient has ticked no to any of the boxes 1-6 the consent form is not valid and recruitment must not proceed. The consent form must be checked to confirm that the participant has recorded their address, name and date and signed the form. *Where possible the form should have been completed in black ink.*

The original consent form completed by the participant 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. The participant must also be given a withdrawal form to take home and it must be documented in their medical notes that they have consented to take part in the study or declined.

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.