NIHR Leicester Cardiovascular Biomedical Research Unit

Work Instruction: GENVASC: Obtaining consent (Un-Witnessed Process)

1. Patients who are going to be invited to have the cardiovascular health check can also be invited to take part in GENVASC if they are: 40-74 years old with no existing CVD or known blood transmissible infection. Invitation to take part in GENVASC can be made opportunistically or via post.

2. Patients invited to take part in GENVASC either via post or in the practice must be provided with an un-witnessed consent form to complete and a detailed full information leaflet **(the short information leaflet is only to be used in conjunction with the witnessed consent process)**.

3. Un-witnessed consent forms are located in electronic patient systems as a template.

4. Patients that attend for their health check or phlebotomy appointment with a completed consent form, need to have their form checked for completeness and be given the opportunity to ask questions.

5. Only people that have received the GENVASC training (or had it cascaded) should check the consent forms or answer questions regarding the study.

6. The participant needs to have ticked yes in **all** of the boxes 1-6. The only field that is optional is number 7. If the participant has ticked no in any of the boxes 1-6, check that this is correct and they have not done it in error. If the answer remains no to any of the fields 1-6 then the consent is not valid and recruitment must not proceed. The consent form should then be checked to ensure that the participant has recorded their address, name and date and signed the form.

7. If any errors have been made on the consent form they need to be corrected with one line through then initialled and dated by the person completing the form.

8. The original wet ink consent form needs to be filed in the site file and enough copies of the consent form need to be made for one to be given to the participant, one to be attached to the samples and one to be scanned into the participant's medical notes. It is up to the recruiting site to best decide how to generate these copies. The process must also be documented in the patient's medical notes.

9. Along with the patient copy of the consent form give the participant a withdrawal form to take home (withdrawal form is also printed from electronic patient systems).

10. Highlight to the participant the contact telephone numbers for the Cardiovascular Biomedical Research Unit if they have any questions, so that they do not contact the surgery unnecessarily.

11. No participants should have GENVASC samples taken prior to obtaining informed consent.

12. If informed consent is taken after the GENVASC samples are obtained, this should be recorded as a protocol violation in the protocol deviation log and the study team informed.