NIHR Leicester Cardiovascular Biomedical Research Unit

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

1. Only persons who have completed the GENVASC training (or had it cascaded) and signed the training log can consent participants onto the GENVASC study.

2. Patients who attend for either a planned or ad hoc visit and are being invited to have the cardiovascular health check can be approached to take part in the GENVASC study if they are: 40-74 years old with no existing CVD or known blood transmissible infection.

3. The patient should be given a copy of the Short Information Sheet to read and verbal information about the study, plus time to ask questions. There is a 'crib' sheet available in the study site file if necessary to act as a narrative/prompt.

4. If the patient is willing to participate they need to complete a consent form. The consent form is located in SystMone/EMIS as a template. Ask the participant to initial in each of the boxes (1-6) and x or initial in box 7. The participant should then sign, date and write their name in black ink. Initialling in each of the boxes 1-6 is mandatory in this study and if the participant declines any of these, they cannot be recruited into the study. The only field that is optional is number 7. The person witnessing consent then also needs to sign, date and write their name and job title in black ink. If any errors are made, they need to be corrected with one line through then initialled and dated. 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. Consent to or declining to take part in the study must also be recorded in the medical notes.

5. Along with the patient copy of the consent form give the participant a full information sheet and withdrawal form to take home (withdrawal form can be printed from SystMone/EMIS, along with the consent form).

6. 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.

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

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