NIHR Leicester Cardiovascular Biomedical Research Unit

Work Instruction: GENVASC: Obtaining consent at the first point of contact

1. Only persons who have completed the GENVASC training 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: 18-74 yrs with no CVD or blood transmissible infection.
3. Explain to the patient what the GENVASC study is and give the patient a copy of the patient information leaflet for them to take home and read. 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, print 2 copies of the consent form off System 1. Ask the participant to initial in each of the boxes and sign, date and write their signature on both copies of the consent form in black ink. Having signed, dated and written your signature in black ink, give one copy to the participant and keep the other copy for scanning into the participants medical notes and filing in the site file. A copy of the consent form is to be printed out when required for the phlebotomist and attaching to the research samples.
5. Along with the patient copy of the consent form give the participant a withdrawal form to take home.
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.