

WORK INSTRUCTIONS: DEVIATIONS FROM PROTOCOL

The processes and procedures of GENVASC have been approved by a Research Ethics Committee. It is important that they are followed closely. Sometimes deviations occur that are outside of your control and a record of the situations when you do not follow the protocol must be kept using the **GENVASC Protocol Deviation Log** situated in the **GENVASC Site File**. This is not a punitive exercise, and will be used to help develop practice and demonstrate transparency.

Minor breaches of protocol are defined as those that do not compromise the safety of the participant or the quality of the science.

Serious breaches of the protocol are those which do compromise the participant's safety or the quality of the science. If you think you have been involved in a serious breach of protocol please contact the Study Team immediately on 0116 204 4771/4738/4769.

Date: Please enter the date on which the deviation took place.

Name: Please enter the name of the person completing the report.

Description of the deviation: Explain what happened in sufficient detail for someone not familiar with the Practice to understand.

Action taken to prevent re-occurrence: Please detail what action was taken to prevent the same situation occurring again. If no action was taken please document that rather than leaving the section blank.

Details of notification of Main Site: Please contact the Study Team on 0116 204 4771/4738/4769, or email genvasc@le.ac.uk . Detail what information you provided, by what media, to whom and when.

Signature and date of signature: Please sign and date your signature. The date will usually be the same as the date of the deviation.