

GENVASC Site File

1. Practice Pack
2. Study Contacts
3. Protocol
4. Approval documents
5. Site Personnel: CV and Study Training / GCP Certificate
6. Site Personnel: Personnel Log
7. Deviation Log
8. Work Instructions and SOPs (Including ordering study information)
9. Current Study Materials
 - a. Sample Bag Labels
 - b. Participant Information Sheet
 - c. Abbreviated information sheet
 - d. Advert
 - e. Witnessed Consent Form
 - f. Un-witnessed Consent Form
 - g. Withdrawal Form
 - h. GP invitation letters
10. Local Consent Forms
11. Study Training
12. Site Initiation Check list
13. Study Related Correspondence
14. Monitoring