

****GENVASC minimum paper document set for site files in
accordance with University of Leicester Sponsor
17th March 2017**

*All documents can be printed out from the GENVASC Portal site file documents folder
Ring binder folders and dividers provided by core GENVASC team*

- **Local Study contacts page:** Study Admin (number 2)
Please localise and file
- ****Protocol:** Protocol SOPs, Work instructions and deviation from protocol log (number 1&1A)
- ****Sponsor approval & agreements:** Approval documents (numbers 1, 2, 23 & 24)
- **Study Specific SOP & WI:** Protocol, SOP's, & Deviation Log (File note signposting to the Portal)
(number 11 and 11a)
- ****Consent Forms:** Study Documents (Witnessed, Unwitnessed & Withdrawal Form)
(numbers 17, 16 & 8)
- ****Practice Personnel & Training Log:** Practice Personnel Log, CV s' & Study Training (number 3)
To be completed and filed locally
- ****CV's:** Practice Personnel Log, CV s' & Study Training (number 2)
CV's to be completed and filed locally
- ****Training Certificates**
To be filed locally
- **Site initiation Checklist:** Study Admin (number 4)
To be completed and filed locally