

Trial Master File / Investigator Site File Index

Title: GENVASC

Genetics and the Vascular Health Check Programme

REC: 12/EM/0208

R&I/EDGE: 13350

UoL: 0330

SECTION	TITLE	DOCUMENTS
1.	Site File Index	GENVASC Site File Index
2.	Protocol	Current Protocol signed and dated by PI Protocol Deviation Log/File Notes File Note Template
3.	Ethics Committee	Letter of Favourable Opinion (REC Approval)
4.	HRA	Letter of Favourable Opinion
5.	Amendments	Substantial and Non Substantial Amendments
6.	Study Documentation	Template of all current approved Participant Information Sheets and Informed Consent Forms- approved versions printed on Host Institution headed paper (make sure the version number and date is entered) Any other study related material e.g. invitation letters, posters questionnaires
7.	SOP's & Work Instructions	Link to current University of Leicester Standard Operating Procedures
8.	Informed Consent	Copies of all completed consent forms
9.	Financial / Legal	ISA Collaboration Agreement (Practice Study Pack) Insurance and Indemnity Statement for all investigators
10.	Sponsor	Authorisations and Green Light
11.	Monitoring	Monitoring Documentation – Site Visit reports and responses
12.	Correspondence	General Correspondence