# Guidance for Maintenance of an Investigator Site File

The Investigator Site File should contain the essential documents that permit an evaluation of the conduct of a research project. The contents of the Site File serve to demonstrate the compliance of the Investigator and the research team to the requirements of the Research Governance Framework for Health and Social Care and to standards of Good Clinical Practice.

The documents contained in the Site File are those that will be audited as part of the Research Governance process.

The Research Ethics Committee has provided guidance on the documentation to be contained in an Investigator Site File. This guidance is based closely on that provided by Sheffield Health and Social Research Consortium. You may find this guidance a useful checklist to develop and maintain an up-to-date Site File. Some items contained in the University's guidance may not apply to particular projects. If you are unsure whether a piece of documentation should be contained in your Site File, please contact Sheffield Hallam University Research Ethics Committee Secretary, 0114 225 4050, research support@shu.ac.uk.

#### Investigator Site File

|  |  |
| --- | --- |
| **Principal investigator:** |  |
| **Consortium Reference number:** |  |
| **Study Title:** |  |
| **REC name (where appropriate):**  |  |
| **REC registration number (where appropriate):**  |  |

# Investigator Site File Contents

## 1 Study Protocol 🗸 N/A

**1.1** A copy of the final approved protocol (version number and date) 🗆 🗆

**1.2** A copy of the final approved participant information sheet(s)

(version number and date) 🗆 🗆

**1.3** A copy of the final approved participant consent form

(version number and date) 🗆 🗆

* 1. A copy of any approved amendments to protocol, information sheet

or consent form (version number and date) 🗆 🗆

**1.5** Advert(s) for recruitment 🗆 🗆

**1.6** A copy of data collection tool(s) (questionnaire, diary, focus group

schedule, interview schedule etc) (version number and date) 🗆 🗆

**1.7** Information for GPs or consultants (version number and date) 🗆 🗆

**1.8** Letters of invitation to participants (version number and date) 🗆 🗆

### 2 Independent Scientific Review

**2.1** Evidence of independent scientific review 🗆 🗆

**2.2** Approval of amendment(s) 🗆 🗆

**2.3** Copies of the protocol and related documents (with version number and date)that were independently reviewed to assess scientific quality 🗆 🗆

**2.4** All correspondence with organisation giving the independent review 🗆 🗆

## 3 Ethics

**3.1** IRAS forms A-C and related documentation (with version number and

dates reviewed by the REC (final approved version and any previous

versions considered by the REC 🗆 🗆

**3.2**  The REC favourable opinion letter 🗆 🗆

**3.3** Site Specific Assessment 🗆 🗆

**3.4** Approval of amendment(s) 🗆 🗆

**3.5** All correspondence with the committee(s) 🗆 🗆

### 4 Regulatory Documents

 **4.1** Eudract Registration 🗆 🗆

**4.2** Appropriate Medicines and Healthcare Products Regulatory

 Agency (MHRA) certificate 🗆 🗆

**4.3**  Appropriate Administration of Radioactive Substances Advisory

 Committee (ARSAC) certificate 🗆 🗆

**4.4** Radiation Protection (IRMER) 🗆 🗆

**4.5** Section 60 Health and Social Care ACT 2001 🗆 🗆

**4.6** Home Office License for Animal Studies 🗆 🗆

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 **🗸 N/A**

### 5 Consortium Research Governance

**5.1** The Standard NHS R&D Application form (or Part D) 🗆 🗆

**5.2** The Consortium Research Governance approval letter 🗆 🗆

* 1. Evidence ofindemnity arrangements: Trust, university, trials

insurance, ABPI 🗆 🗆

* 1. Letter from Sponsor, confirming the acceptance of Sponsorship

responsibilities 🗆 🗆

**5.5** Data protection: arrangements for participant identifiable data 🗆 🗆

**5.6** Evidence ofappropriate health and safety requirements in place 🗆 🗆

**5.7** Evidence ofconsideration ofintellectual property rights 🗆 🗆

### 6 Financial Management

**6.1** Contract/financial agreement 🗆 🗆

**6.2** Confirmation of grant award 🗆 🗆

**6.3** Trust finance approval 🗆 🗆

**6.4** Financial tracking/budget statements 🗆 🗆

### 7 Investigator and Research Team

**7.1** Local Principal Investigator CV (signed and dated) 🗆 🗆

**7.2** Co-investigators’ CVs 🗆 🗆

**7.3** Signature log of all members of the research team 🗆 🗆

**7.4** Honorary Contracts and/or Letters of Authority 🗆 🗆

### 8 Project Management

**8.1** Membership of project steering group 🗆 🗆

**8.2** Data management arrangements/security of data storage/

list of personnel authorised to access data, electronic or paper 🗆 🗆

**8.3** Laboratory Accreditation certificate 🗆 🗆

**8.4** Normal laboratory values 🗆 🗆

### 9 Participant Information

**9.1** Originals of consent forms signed by participants and Investigator or

record of people informed for observational studies 🗆 🗆

**9.2** List of consenting research participants 🗆 🗆

**9.3** Record of retained body fluids/tissue samples 🗆 🗆

**9.4** Record of tapes and transcripts of interviews and/or focus groups 🗆 🗆

### 10 Pharmacy issues

**10.1** Pharmacy arrangements 🗆 🗆

 **10.2** Randomisation/treatment allocation procedures 🗆 🗆

**10.3** Code break procedures 🗆 🗆

**10.4** Prescribing/transcribing arrangements 🗆 🗆

**10.5** Dispensing log 🗆 🗆

**10.6** Drug accountability 🗆 🗆

###  🗸 N/A

### 11 Serious Adverse Events

**11.1** Serious Adverse Events Initial and Follow Up Reports 🗆 🗆

**11.2** Evidence of notification to Sponsor 🗆 🗆

**11.3** Evidence of notification to Ethics 🗆 🗆

## 12 Study Closure

**12.1** Recruitment summary 🗆 🗆

**12.2** Archiving arrangements 🗆 🗆

**12.3** Dissemination: plans for/record of 🗆 🗆

### 13 Monitoring and Auditing

**13.1** Record of internal monitoring 🗆 🗆

**13.2** Monitoring reports (supplied for example to Consortium, Ethics

Committee, funding organisation and Sponsor) 🗆 🗆

**13.3** Final Study Report 🗆 🗆

**13.4** Audit Self-completion form 🗆 🗆

### 14 Study Related Literature

**14.1** Study-related literature (e.g. conference papers, journal articles,

### newsletter items etc.) 🗆 🗆

**15 Miscellaneous project-related correspondence** 🗆 🗆