Welcome to the Integrated Research Application System

IRAS Project Filter

The integrated dataset required for your project will be created from the answers you give to the following questions. The system will generate only those questions and sections which (a) apply to your study type and (b) are required by the bodies reviewing your study. Please ensure you answer all the questions before proceeding with your applications.

Please enter a short title for this project (maximum 70 characters)

1. Is your project an audit or service evaluation?
   - Yes
   - No

2. Select one category from the list below:
   - Clinical trial of an investigational medicinal product
   - Clinical investigation or other study of a medical device
   - Combined trial of an investigational medicinal product and an investigational medical device
   - Other clinical trial or clinical investigation
   - Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology
   - Study involving qualitative methods only
   - Study limited to working with human tissue samples, other human biological samples and/or data (specific project only)
   - Research tissue bank
   - Research database

   If your work does not fit any of these categories, select the option below:
   - Other study

2b. Please answer the following question(s):
   a) Does the study involve the use of any ionising radiation?
      - Yes
      - No
   b) Will you be taking new human tissue samples (or other human biological samples)?
      - Yes
      - No
   c) Will you be using existing human tissue samples (or other human biological samples)?
      - Yes
      - No

3. In which countries of the UK will the research sites be located? (Tick all that apply)

   - England
   - Scotland
   - Wales
   - Northern Ireland
4. In completing this form, which bodies are you making an application to?

- NHS/HSC Research and Development offices
- Research Ethics Committee
- Patient Information Advisory Group (PIAG)
- Ministry of Justice (MoJ)

4a. Will you only be requesting data from Hospital Episode Statistics (HES) or the Secondary Uses Service (SUS)?

- Yes
- No

5. Will any research sites in this study be NHS organisations?

- Yes
- No

6. Do you plan to include any participants who are children?

- Yes
- No

7. Do you plan to include any participants who are adults unable to consent for themselves through physical or mental incapacity? *The guidance notes explain how an adult is defined for this purpose.*

- Yes
- No

8. Do you plan to include any participants who are prisoners or young offenders in the custody of HM Prison Service in England or Wales?

- Yes
- No

9. Is the study, or any part of the study, being undertaken as an educational project?

- Yes
- No

10. Will identifiable patient data be accessed outside the clinical care team without prior consent at any stage of the project (including identification of potential participants)?

- Yes
- No

Once you have completed the Project Filter, please go to Navigate to view your forms and navigate between questions and sections. From Navigate you can also download and print a Reference Only blank copy of the integrated dataset for your applications.
Research Application form

This application is for approval to:

- Gain access to and process identifiable data under Section 60 of the Health and Social Care Act 2001 (now Section 251 of the NHS Act 2006)
- Gain access to and process data held by NHS Connecting for Health’s Secondary Uses Service (SUS). This includes Hospital Episodes Statistics (HES) data, NSTS/PDS data etc.

This application therefore covers access to any identifiable data, as well as any SUS data (whether identifiable or not).

Most of the information required for this form is populated automatically from the Integrated Research Application System once relevant sections and questions are completed. Please check that all answers have been correctly generated and modify if necessary.

**Note on the Freedom of Information Act**

Apart from the Information Security Measures form (Part B Section 9 of IRAS), all parts of this application form may be published or put into the public domain.

It should be noted that all parts of the form are potentially disclosable under the Freedom of Information Act 2000. If you wish to submit information that needs to remain confidential, please include this as a confidential annex with a reference in the relevant places on the application form. The Information Security Measures form includes a tick box to indicate if you wish this part of the application to remain confidential.

### Section 1 Administrative details

| Short title and version number: (maximum 70 characters – this will be inserted as header on all forms) |
| Submission date: |

1. Is your project an audit or service evaluation?

   - Yes  
   - No  

2. Title of project

3. Chief Investigator:

<table>
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<tr>
<th>Title</th>
<th>Forename/Initials</th>
<th>Surname</th>
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<td>Qualifications</td>
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<td>Employer</td>
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<tr>
<td>Work Address</td>
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</tbody>
</table>
6. Project reference numbers. Please give any relevant references for your study:

Applicant's/organisation's own reference number, e.g. R & D (if available):
Sponsor's/protocol number:
Funder's reference number:
International Standard Randomised Controlled Trial Number (ISRCTN):
European Clinical Trials Database (EudraCT) number:
Project website:

<table>
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<tr>
<th>Ref. Number</th>
<th>Description</th>
<th>Reference Number</th>
</tr>
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</table>

7. Will you be applying to a NHS Research Ethics Committee for ethical review of this project?

- [ ] Yes – application submitted
  - Name of REC:
    - REC reference number:
  - Yes – application not yet submitted
- [ ] No
Section 2: Purpose, design and methodology

Overview

8–1. Lay summary. Please provide a brief summary of the research (maximum 200 words). This will be used by lay reviewers and may also be provided by review bodies in response to any request for disclosure under the Freedom of Information Acts.

8–2. Summary of main issues. Please summarise the main ethical and design issues arising from the study and say how you have addressed them.

Purpose and design

9. Select the appropriate methodology description for this research. Please tick all that apply:

- Case series/ case note review
- Case control
- Cohort observation
- Controlled trial without randomisation
- Cross-sectional study
- Database analysis
- Epidemiology
- Feasibility/ pilot study
- Laboratory study
- Metaanalysis
- Qualitative research
- Questionnaire, interview or observation study
- Randomised controlled trial
- Other (please specify)

10. What is the principal research question/objective? Please put this in language comprehensible to a lay person.

11. What are the secondary research questions/objectives if applicable? Please put this in language comprehensible to a lay person.

12. What is the scientific justification for the research? Please put this in language comprehensible to a lay person.
13. Please give a full summary of your design and methodology. It should be clear exactly what will happen to the research participant, how many times and in what order. Please complete this section in language comprehensible to the lay person. Do not simply reproduce or refer to the protocol. Further guidance is available in the guidance notes.

14−1. In which aspects of the research process have you actively involved, or will you involve, patients, service users, or members of the public?

- [ ] Design of the research
- [ ] Management of the research
- [ ] Undertaking the research
- [ ] Analysis of results
- [ ] Dissemination of findings
- [ ] None of the above

Give details of involvement, or if none please justify the absence of involvement.

16. Please list the principal inclusion and exclusion criteria.

Risks and benefits

18. What are the potential risks and burdens for research participants and how will you minimise them?

For all studies, describe any potential adverse effects, pain, discomfort, distress, intrusion, inconvenience or changes to lifestyle. Only describe risks or burdens that could occur as a result of participation in the research. Say what steps would be taken to minimise risks and burdens as far as possible.

19. What is the potential for benefit to research participants?

Science

20. How has the scientific quality of the research been assessed? Tick as appropriate:

- [ ] Independent external review
- [ ] Review within a company
- [ ] Review within a multi–centre research group
- [ ] Review within the Chief Investigator’s institution or host organisation
- [ ] Review within the research team
- [ ] Review by educational supervisor
- [ ] Other

Justify and describe the review process and outcome. If the review has been undertaken but not seen by the researcher, give details of the body which has undertaken the review:

For all studies except non–doctoral student research, please enclose a copy of any available scientific critique reports, together with any related correspondence.
For non–doctoral student research, please enclose a copy of the assessment from your educational supervisor/ institution.
21. How have the statistical aspects of the research been reviewed? *Tick as appropriate:*

- Review by independent statistician commissioned by funder or sponsor
- Other review by independent statistician
- Review by company statistician
- Review by a statistician within the Chief Investigator’s institution
- Review by a statistician within the research team or multi-centre group
- Review by educational supervisor
- Other review by individual with relevant statistical expertise

*In all cases please give details below of the individual responsible for reviewing the statistical aspects. If advice has been provided in confidence, give details of the department and institution concerned.*

Title  Forename/Initials  Surname

Department
Institution
Work
Address

Post Code
Telephone
Fax
Mobile
E-mail

*Please enclose a copy of any available comments or reports from a statistician.*

22. What is the primary outcome measure for the study?

23. What are the secondary outcome measures? *(if any)*

24. What is the sample size for the research? *How many participants/samples/data records do you plan to study? If there is more than one group, state the sample size for each group. For international studies, say what the sample size will be in the UK and in total.*

Total UK sample size:
Total international sample size (including UK):

*Further details:*
### Section 3: Identification of cohort

25. How and by whom will potential participants, records or samples be identified?

26. Will this involve reviewing or screening identifiable personal information of potential participants or any other person?

- [ ] Yes
- [ ] No

*Please give details below:*

27. Please give details of how identification will be carried out and what resources will be used. *For example, using a disease register, computerised search of GP records, or review of medical records*

28. Will researchers or individuals other than the direct healthcare team have access to identifiable personal information of any potential participants?

- [ ] Yes
- [ ] No

*You have indicated in the Project Filter that you will not be processing identifiable data. Please return to the Project Filter and review your answers to question 2a.*

29. Has prior consent been obtained or will it be obtained for access to identifiable personal information?

- [ ] Yes
- [ ] No

*If Yes, please give details below. If No, application should be made to the Patient Information Advisory Group (PIAG) to process identifiable information of patients in England and Wales without consent – see guidance notes.*

31. How and by whom will potential participants first be approached?

33–1. Will you inform the participants’ General Practitioners (and/or any other health professional responsible for their care) that they are taking part in the study?

- [ ] Yes
- [ ] No

33–2. Will you seek permission from the research participants to inform their GP or other health professional?

- [ ] Yes
- [ ] No
## Section 4: Description of identifiable data

### 34. Do you plan to extract data from Hospital Episode Statistics (HES) or the Secondary Uses Service (SUS)?
- ☐ Yes
- ☐ No

Please complete Appendices A, B1 and B2.

*If Yes, please enclose Appendices A, B1 and B2 with this application*

### 35. Give a brief description of the confidential/sensitive patient information to be used.

*Please enclose the full dataset with this application.*

### 36. Please list each of the identifiers required for validation or linkage and say why each data item is required (i.e. the justification for this combination of data items).

- ☐ Name
- ☐ NHS number
- ☐ Hospital ID no.
- ☐ GP registration
- ☐ Date of birth
- ☐ Date of death
- ☐ Postcode
  - ☐ District level
  - ☐ Sector level
  - ☐ Sub-sector level
  - ☐ Unit level
- ☐ Other geographical identifiers (please specify)
- ☐ Other identifiers (please specify)

### 37. Which identifiers will be retained for analysis purposes?

- ☐ Name
- ☐ Date of birth
- ☐ Date of death
- ☐ Postcode
  - ☐ District level
  - ☐ Sector level
  - ☐ Sub-sector level
  - ☐ Unit level
- ☐ Other geographical identifiers (please specify)

- ☐ Purpose for which postcode/geographical identifiers required
38. If you need access to sensitive data items, please list them here and give a reason for requesting access to each item.

39. What is the justification for using patient identifiable data and/or HES restricted fields? Say why anonymised data would not be fit for purpose.
### Section 5: Processing of identifiable data

#### Sources of data

40. What are the sources of data?

41. Please provide an overview of the data flows. You may use or enclose a diagram to explain this if it is helpful. Stages of identifiability/de-identification should be specified and use of encryption for transfer or storage where applicable.

42. What is the frequency of the required extract?

- [ ] Monthly
- [ ] Quarterly
- [ ] Annual
- [ ] Not applicable

43. Describe what other data are held by the organisation, which might interact with the data requested to allow person identification. Will you be linking this data with data obtained with PIAG approval or HES data? If so for what purpose?

#### Storage and use of personal data during the study

44. Will you be undertaking any of the following activities at any stage (including in the identification of potential participants)? *(Tick as appropriate)*

- [ ] Access to medical records by those outside the direct healthcare team
- [ ] Electronic transfer by magnetic or optical media, email or computer networks
- [ ] Sharing of personal data with other organisations
- [ ] Export of personal data outside the EEA
- [ ] Use of personal addresses, postcodes, faxes, emails or telephone numbers
- [ ] Publication of direct quotations from respondents
- [ ] Publication of data that might allow identification of individuals
- [ ] Use of audio/visual recording devices
- [ ] Storage of personal data on any of the following:
  - [ ] Manual files including X-rays
  - [ ] NHS computers
  - [ ] Home or other personal computers
  - [ ] University computers
  - [ ] Private company computers
  - [ ] Laptop computers

*Further details:*
46. How will you ensure the confidentiality of personal data? Please provide a general statement of the policy for ensuring confidentiality, e.g. anonymisation or pseudonymisation of data.

48. Who will have access to participants' personal data during the study? Where access is by individuals outside the direct healthcare team, please justify and say whether consent will be sought.

Storage and use of data after the end of the study

51. How long will personal data be stored or accessed after the study has ended?

- Less than 3 months
- 3 – 6 months
- 6 – 12 months
- 12 months – 3 years
- Over 3 years

If longer than 12 months, please justify:

Publication and dissemination
55. Which class(es) of Section 60 support are you applying for? *Tick all that apply:*

- [ ] Specific support required (requires Regulations to be laid before Parliament)
- [ ] Support required under the Health Service (Control of Patient Information) Regulations 2002 for public health or cancer registry purposes
- [ ] Class 1 support: the process of extracting and anonymising the information
- [ ] Class 2 support: to obtain and use information about past or present geographical location
- [ ] Class 3 support: to select and contact patients to seek their consent
- [ ] Class 4 support: to link patient identifiable information obtained from more than one source
- [ ] Class 5 support: for auditing, monitoring and analysing patient care and treatment
- [ ] Class 6 support: to allow access to an authorised user for one or more of the above purposes
- [ ] Not applicable – only using HES/SUS data extract which is not identifiable

56. Please provide details of how you comply with each of the eight principles outlined in the Data Protection Act 1998.

<table>
<thead>
<tr>
<th>No</th>
<th>Principle</th>
</tr>
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<tbody>
<tr>
<td>1</td>
<td>Fair processing</td>
</tr>
<tr>
<td>2</td>
<td>Used for specified purposes</td>
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<td>3</td>
<td>Minimum necessary for the purpose</td>
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<td>4</td>
<td>Accuracy</td>
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<td>5</td>
<td>Kept for minimum time necessary</td>
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<tr>
<td>6</td>
<td>In accordance with rights of data subject</td>
</tr>
<tr>
<td>7</td>
<td>Security and confidentiality protection</td>
</tr>
<tr>
<td>8</td>
<td>Not disclosed outside the EU</td>
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</table>

57. Have you undertaken a self-assessment using the NHS Information Governance toolkit?

- [ ] Yes  - [ ] No

*If Yes, please provide details of your scoring and a summary of the actions to be taken as a result:*

58. Who will act as Information Guardian for any health records or other personal information used by the research team during the study?
59. Do you have anything to add in support of the application, which is not included elsewhere on the form?
### Section 7: Management of the research

#### 60. Other key investigators/collaborators

Please include all grant co-applicants, protocol co-authors and other key members of the Chief Investigator’s team, including non-doctoral student researchers not listed above.

#### 62. Details of research sponsor(s)

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<thead>
<tr>
<th>61–1. Lead sponsor <em>(must be completed in all cases)</em></th>
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<tr>
<td>Name of organisation which will act as the lead sponsor for the research:</td>
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<td>Status:</td>
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<tr>
<td>〇 NHS or HSC care organisation  〇 Academic  〇 Pharmaceutical industry  〇 Medical device industry  〇 Other</td>
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<td>If Other, please specify:</td>
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<td>Address</td>
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<td>E-mail</td>
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<tr>
<th>61–2. Sponsor’s UK contact point for correspondence <em>(must be completed in all cases)</em></th>
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<td>Title  Forename/Initials  Surname</td>
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<td>E-mail</td>
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<tr>
<th>61–3. Are there any co-sponsors for this research?</th>
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<tbody>
<tr>
<td>〇 Yes  〇 No</td>
</tr>
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*Give details of all co-sponsors:*
64. How long do you expect the study to last?

Planned start date:
Planned end date:
Planned end date (clinical interventions):
Planned end date (all trial procedures):
Total Duration:
Years:
Months:

65. What host organisations (NHS or other) in the UK will be responsible for the research sites? Please indicate the type of organisation by ticking the box and give approximate numbers of planned research sites:

- [ ] NHS organisations in England
- [ ] NHS organisations in Wales
- [ ] NHS organisations in Scotland
- [ ] HSC organisations in Northern Ireland
- [ ] GP practices in England 0
- [ ] GP practices in Wales 0
- [ ] GP practices in Scotland 0
- [ ] GP practices in Northern Ireland 0
- [ ] Social care organisations 0
- [ ] Phase 1 trial units 0
- [ ] Prison establishments 0
- [ ] Probation areas 0
- [ ] Independent hospitals 0
- [ ] Educational establishments 0
- [ ] Independent research units 0
- [ ] Other (give details) 0

Total UK sites in study

* Total number will be calculated automatically when you save.
Declaration by Chief Investigator

1. The information in this form is accurate to the best of my knowledge and belief and I take full responsibility for it.

2. I undertake to abide by the ethical principles underlying the Declaration of Helsinki and good practice guidelines on the proper conduct of research.

3. If the research is approved I undertake to adhere to the study protocol, the terms of the full application as approved and any conditions set out by review bodies in giving approval.

4. I undertake to notify review bodies of substantial amendments to the protocol or the terms of the approved application, and to seek a favourable opinion from the main REC before implementing the amendment.

5. I undertake to submit annual progress reports setting out the progress of the research, as required by review bodies.

6. I am aware of my responsibility to be up to date and comply with the requirements of the law and relevant guidelines relating to security and confidentiality of patient or other personal data, including the need to register when necessary with the appropriate Data Protection Officer, I understand that I am not permitted to disclose identifiable data to third parties unless the disclosure has the consent of the data subject or, in the case of patient data in England and Wales, the disclosure is covered by the terms of an approval under Section 251 of the NHS Act 2006.

7. I understand that research records/data may be subject to inspection by review bodies for audit purposes if required.

8. I understand that any personal data in this application will be held by review bodies and their operational managers and that this will be managed according to the principles established in the Data Protection Act 1998.

9. I understand that the information contained in this application, any supporting documentation and all correspondence with review bodies or their operational managers relating to the application:
   - Will be held by the main REC or the GTAC (as applicable) until at least 3 years after the end of the study; and by NHS R&D offices (where the research requires NHS management permission) in accordance with the NHS Code of Practice on Records Management.
   - May be disclosed to the operational managers of review bodies, or the appointing authority for the main REC, in order to check that the application has been processed correctly or to investigate any complaint.
   - May be seen by auditors appointed to undertake accreditation of RECs.
   - Will be subject to the provisions of the Freedom of Information Acts and may be disclosed in response to requests made under the Acts except where statutory exemptions apply.

10. I understand that information relating to this research, including the contact details on this application, may be held on national research information systems, and that this will be managed according to the principles established in the Data Protection Act 1998.

11. I understand that the main REC or its operational managers may share information in this application or supporting documentation with the Medicines and Healthcare products Regulatory Agency (MHRA) where it is relevant to the Agency’s statutory responsibilities.

Optional – please tick as appropriate:

☐ I would be content for members of other RECs to have access to the information in the application in confidence for training purposes. All personal identifiers and references to sponsors, funders and research units would be removed.
Declaration by the sponsor’s representative

If there is more than one sponsor, this declaration should be signed on behalf of the co-sponsors by a representative of the lead sponsor named at A64–1.

I confirm that:

1. This research proposal has been discussed with the Chief Investigator and agreement in principle to sponsor the research is in place.

2. An appropriate process of scientific critique has demonstrated that this research proposal is worthwhile and of high scientific quality.

3. Arrangements will be in place before the study starts for the research team to access resources and support to deliver the research as proposed.

4. Arrangements to allocate responsibilities for the management, monitoring and reporting of the research will be in place before the research starts.

5. The duties of sponsors set out in the NHS Research Governance Framework for Health and Social Care will be undertaken in relation to this research.

6. The statutory responsibilities of sponsors set out in the Medicines for Human Use (Clinical Trials) Regulations 2004 will be undertaken in relation to this trial.

Signature: .................
Print Name: 
Post: 
Organisation: 
Date: (dd/mm/yyyy)

Declaration by Information Guardian

1. I have read and approved the application to the Patient Information Advisory Group.

2. I undertake to fulfil the responsibilities of Information Guardian in line with PIAG guidance in relation to the personal data to be processed in this project.

3. I undertake to monitor the progress of the project to ensure it complies with PIAG conditions of approval and advise the applicant of any shortcomings and how these may be remedied.

4. I agree to report any serious failures to comply with conditions of approval to the PIAG Secretariat.

Signature: .................
Print Name:
Post: 

Organisation: 

Date: (dd/mm/yyyy)

Please return completed application to: 
PIAG Secretariat, 2nd Floor, West Wing, Princes Exchange, Princes Square, Leeds LS1 4HY
Information Security Measures

Note on the Freedom of Information Act

While the Patient Information Advisory Group (PIAG) has no plans to publish any of the information contained in this section, as a public body PIAG is required to comply with the Freedom of Information Act 2000 (FOIA). All information included in applications is therefore potentially disclosable. While the FOIA provides exemptions, which would in most instances cover the security information in this form, the presumption is in favour of disclosure and the PIAG Secretariat would be required to evaluate each request for disclosure on a case by case basis and provide justification why information had not been disclosed. One exemption is where information has been provided in confidence. If you want assurance, therefore, that this document will be treated in confidence, please tick the box below.

☐ I request that the information contained in this form is treated in confidence by the Patient Information Advisory Group and its security advisers within the Department of Health

Questions 1–7 should be answered in relation to each organisation receiving and processing identifiable data. Please open a separate set of the questions for each organisation.

Organisation 1

Please give the name of the organisation.

What security and audit measures have been implemented to secure access to, and limit use of, patient identifiable information within this organisation?

Please provide an assessment of how the organisation’s CSP complies with the principles of the management and control guidelines contained in ISO 27002 (formerly ISO 17799:2005) and ISO 27001:2005 (both formerly parts 1 and 2 of BS7799 “Code of practice for information security management”). Confirm that the policy or policies have been formally adopted by the organisation and are fully implemented.

Please provide an electronic reference copy of the CSP.

Who is responsible for the implementation of the CSP?

Title  Forename/Initials  Surname

Post
Qualifications
Employer
Work Address

Post Code
Work Email
Work Telephone
Fax
**What is the Data Protection Registration Number for this organisation?**

**Does the registration specify research as one of the purposes of processing and include confidential patient information in the classes of data processed?**

- [ ] Yes
- [ ] No

*Further details:*

*Please provide a copy of the Data Protection Registration(s).*

Please describe the physical security arrangements for the location(s) where patient identifiable data is to be (a) processed and (b) stored (if these are different).

**System–level security policy (SLSP)**

Ordinarily there should be one over–arching SLSP for the study which covers the processing by all partner organisations. Occasionally there may be one or two variations where more than one organisation is involved in holding and processing data. Where this applies, questions 8–14 should be answered in relation to each organisation’s computer system to be used for processing patient identifiable data. Please open a separate set of the questions for each system.

**System 1**

Please identify the type of computer system and application to be used for information processing including product version numbers where known (e.g. desktop PC, Laptop PC, MS Access, etc).

Will the system be (a) entirely standalone, or (b) connected (either temporarily or permanently) to a LAN or WAN network or be otherwise accessible remotely by another means such as dial–up modem? If connected, please confirm which networks these are and what they are used for, and provide a copy of the Network Security Policy.

Please provide details of access and/or firewall controls implemented on (a) this system and (b) any LAN or WAN to which it is connected. State who is responsible for the management of these arrangements.

**Is there a system level security policy (SLSP) for this system?**

- [ ] Yes
- [ ] No

*If Yes, please provide an electronic reference copy of the SLSP.*
Who is responsible for the management of the SLSP?

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<tr>
<td>Post</td>
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<th>Work Email</th>
<th>Work Telephone</th>
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Has the system ever been the subject of a security risk review?

- [ ] Yes
- [ ] No

*If Yes, please provide details and confirm whether all the necessary recommendations have been implemented:*

Please provide details of the arrangements you have implemented to routinely monitor and audit the security of this system for potential misuse or abuse.

Will encryption be used?

- [ ] Yes
- [ ] No

*If Yes, please indicate which software package you propose to use and confirm that it is to industry standard (128 bit):*

Data destruction

16. Please describe the method of data destruction you will employ when you have completed your work using patient identifiable data.