Integrated Research Application System (IRAS)

Question-specific guidance

Site-specific information form (non-NHS sites)

This version of the guidance on the Site-Specific Information Form (SSIF) applies to non-NHS sites only. Separate guidance is available for NHS sites.

Content

1. Identifying the research site
2. General guidance on site-specific assessment (SSA)
3. General guidance on the SSI form
4. Question 1 – Name of trial site
5. Question 2 – Site Management Organisation
6. Question 3 – Management and monitoring
7. Question 4 – Accreditation
8. Question 5 – Principal Investigator
9. Question 6 – Identification of participants
10. Question 7 – Members of the local research team
11. Question 8 – Conflicts of interest
12. Question 9 – Local study dates
13. Questions 10–2 and 11–2 – Local variations in study procedures
14. Question 12 – Number of participants
15. Question 13 – Recruitment of participants
16. Question 14 – Obtaining informed consent
17. Question 15–1 – Adults with incapacity – CTIMPs
18. Question 15–2 – Adults with incapacity – research in England and Wales
19. Question 15–3 – Adults with incapacity – research in Scotland
20. Question 15–4 – Adults with incapacity – research in Northern Ireland
21. Question 16 – Emergency treatment
22. Question 17 – Complaints process
23. Question 18 – Independent contact point
24. Question 19 – Local version of the participant information sheet
25. Question 20 – Language issues
26. Question 21 – Information for professional carers
27. Question 22 – Facilities and staffing
28. Question 23 – Over-volunteering
29. Question 24 – Management and monitoring arrangements
30. Question 25 – ARSAC certificate
31. Question 26 – Insurance and indemnity
32. Declaration

Identifying the research site

• Whether a site is defined as NHS or non-NHS is not related to the physical location of research activities, but to the organisation that is responsible for the research activity. If a NHS organisation is accountable for the care of participants or the governance of tissue and data then NHS site should be
selected when creating the SSI Form. If not, the site should be treated as a non-NHS site.

- Research sites are organisations responsible for participant–related research procedures specified in the protocol – including recruitment and informed consent. Referral of a patient for assessment and possible recruitment is not part of the conduct of the study. The following are not considered to be research sites:

  Clinicians or clinical units making referrals to the research team.
  Research units undertaking support functions, e.g. project management, site monitoring, data analysis or report writing.

- Where "shared care" arrangements are in place between two or more organisations, each of which is responsible for the conduct of some protocol procedures, each organisation should be treated as a separate research site. A SSI Form should be completed for each site. Where facilities or equipment at a different location from the site are used, but the participant remains under the responsibility of the main site, then only one SSI Form needs to be completed. Details of protocol procedures conducted at other locations should be described in the SSI Form for the main site.


General guidance on site–specific assessment (SSA)

- Site–specific assessment is an assessment of the suitability of the local research site and investigator to conduct the research.

- For non–NHS sites, SSA will always be undertaken by a Research Ethics Committee (REC). This will normally be a local REC in the domain where the site is located. In some cases another REC may be assigned to undertake SSA (e.g. for specific types of research such as Phase 1 clinical trials). (For NHS sites, SSA will normally be undertaken by NHS R&D offices.)

- The REC undertaking SSA ("the SSA REC") will notify the main REC for the study within 25 days of receiving a valid application on the SSI Form whether or not it has any objection to the research going ahead at the site. The main REC will then confirm in writing to the Chief Investigator whether or not the site is ethically approved.

- SSA is always required as part of the ethical review where the application relates to:

  A clinical trial of an investigational medicinal product
  A clinical investigation of a medical device.
  Research involving adults unable to consent for themselves.

- For other types of interventional research taking place at non–NHS sites, application for SSA is at the discretion of the applicant. The NHS REC system will normally be happy to undertake SSA as part of the ethical review where requested.
• Where ethical approval is sought to comply with the Human Tissue Act 2004 and the research only involves use of tissue and/or data, applications for SSA should not be made.

• For further guidance on SSA procedures, see Section 4 of the NRES SOPs at standard operating procedures. A flowchart on SSA is available at http://www.nres.npsa.nhs.uk/applicants/guidance.

General guidance on the SSI form

• The Site–Specific Information (SSI) Form is an integrated form for use with both NHS and non–NHS sites. The answer to the filter question will determine whether the site is NHS or non–NHS and generate the appropriate dataset.

• The SSI Form should only be completed after the main study application form (Parts A–D) has been completed by the Chief Investigator and validated by the main REC. The CI will then forward the application to the PI to assist in completion of the SSI Form.

• The name of the main REC and the REC reference number for the main application should appear automatically at the top of the form. The PI should then enter the name of the NHS REC responsible for the site–specific assessment.

Question 1 – Name of trial site

• The trial site may be:

  a private company or corporation (for example, a pharmaceutical or biotechnology company or a Site Management Organisation)
  a private hospital
  a private clinical practice

• You should also name any other locations at which trial procedures will be conducted (excluding the analysis of data produced by the trial and production of reports).

• The SSA REC may wish to consider issues such as:

  availability of necessary facilities and support services at these locations (taking into account information given at Questions 22 and 24)
  the capacity of the PI to supervise the research effectively across all locations
  whether research participants will have easy and safe access to the site.

Subsidiary sites

• Where procedures are sub–contracted to other organisations, for example a scanner centre, these
should be regarded as separate trial sites. If the procedures conducted at these "subsidiary sites" are routine procedures within the normal clinical competence of healthcare professionals at the site, there is no need to submit a separate SSI for site-specific assessment. However, the sponsor or Chief Investigator should provide the main REC with brief details of the subsidiary site, the activities to be conducted and the name of a Principal Investigator for the site. These may be sent by letter. The main REC will normally confirm approval for the site without any further process. For further guidance on this procedure, see paragraph 4.32 of the NRES SOPs.

Back to the top

Question 2 – Site Management Organisation

- The Site Management Organisation may be the sponsor company itself or a Contract Research Organisation which conducts the research on behalf of the sponsor. In some cases it could be the company responsible for a private hospital.

- If no Site Management Organisation is involved (for example, where the research is undertaken by a private clinical practice), state "None".

Back to the top

Question 3 – Management and monitoring

- The individual with responsibility for monitoring the research on behalf of the sponsor should be cited in all cases.

Back to the top

Question 4 – Accreditation

- Information about accreditation of Phase 1 trial sites by the Medicines and Healthcare products Regulatory Agency (MHRA) is available at http://www.mhra.gov.uk/.../nodeId=136

- Please consult the GCP Inspection Team at the MHRA for further guidance on the accreditation scheme and application process. Contact details are available at the link above.

- Where current accreditation is held, please enclose a copy of the accreditation certificate with the application to the SSA REC.

- Accreditation is not a legal requirement and is not a precondition for ethical approval for the site. However, where accreditation is held this will provide a robust assurance to the SSA REC of the general suitability of the site to conduct Phase 1 trials. Where the site is not accredited, the SSA REC may require further documentation in support of the application, and may wish to arrange its own visit to the site.

- Any significant changes at accredited sites, potentially affecting the accreditation status (e.g. changes in key personnel, facilities or emergency procedures), should be notified to the MHRA and SSA REC.
as soon as possible.

Back to the top

**Question 5 – Principal Investigator**

- The PI should submit a summary CV with information relevant to the current application. It is recommended that applicants use the CV template available in IRAS or, if not, the CV should include the areas of information in this template. For example, it should give evidence of previous research in the same field of study, and other relevant experience and training. The length should be a maximum of 2 pages of A4. The CV should be signed and dated prior to submission.

- The SSA will include assessment of whether the local PI has the necessary training and experience to undertake the research described in the proposal.

Back to the top

**Question 6 – Identification of participants**

- This question applies only where patients will be identified at NHS centres for referral for possible inclusion in the research.

Back to the top

**Question 7 – Members of the local research team**

- List other members of the research team who will have a significant research role (e.g. other clinical investigators, trial nurses, staff who will interview participants).

Back to the top

**Question 8 – Conflicts of interest**

- Any potential conflicts of interest should be raised here. The SSA REC will consider whether the issues raised pose any ethical concerns for the project.

Back to the top

**Question 9 – Local study dates**

- Give the proposed start date and the proposed end date for the research at this site. These may differ from the overall study dates. You may not know these dates exactly, but a rough estimate should be supplied.
• For CTIMPs, please give planned end dates both for the final clinical intervention (e.g. last administration of IMP) and the conclusion of all trial procedures (i.e. last data capture).

• For all other studies, the end date is the date on which all procedures specified in the protocol are concluded.

Questions 10–2 and 11–2 – Local variations in study procedures

• The tables have been populated with information from Part A, completed by the CI. Please insert details of the local members of the research team who will conduct procedures.

• If any variation is proposed in the interventions or procedures to be undertaken at this site, select Yes. This will allow you to make any alterations to the information in the table. The review will check that any variation is permitted within the terms of the protocol and the full application submitted to the main REC. If not, the PI should advise the CI to notify the main REC and seek ethical review of a protocol amendment applicable to the site and, if appropriate, the local version of the participant information sheet. SSA RECs do not have authority to approve such amendments.

Question 12 – Number of participants

• If there is more than one group, state how many participants will be recruited in each group.

• "Participants" may include patients who are not approached but whose records or samples are to be studied.

Question 13 – Recruitment of participants

• Explain how potential participants will be identified and approached. Who will review registers, lists or medical records to identify participants? Who will write to potential participants inviting them to take part? Will potential participants be referred from one organisation to another?

Question 14 – Obtaining informed consent

• The review will check that the person(s) taking informed consent locally are appropriate for the task. They should be fully informed about the nature of the study. They should be aware of the process of taking consent, including any specific issues relating to consent with the potential participant population, and familiar with "best practice". Any specific training received should be described.
• This person should have sufficient time and expertise to answer questions that might be raised by the research participants.

Back to the top

**Question 15–1 – Adults with incapacity – CTIMPs**

• Explain what local arrangements will be made to seek consent from a legal representative for the inclusion of adults unable to consent for themselves.

Back to the top

**Question 15–2 – Adults with incapacity – research in England and Wales**

• Explain what local arrangements will be made to seek advice from a consultee before including adults unable to consent for themselves in the research.

• This question applies only to conduct of the research at sites in England and Wales.

Back to the top

**Question 15–3 – Adults with incapacity – research in Scotland**

• Explain what local arrangements will be made to seek consent from a guardian or welfare attorney, or the adult's nearest relative, before including adults unable to consent for themselves in the research.

• This question applies only to conduct of the research at sites in Scotland.

Back to the top

**Question 15–4 – Adults with incapacity – research in Northern Ireland**

• Explain what local arrangements will be made to seek assent from a close relative or other person before including adults unable to consent for themselves in the research.

• This question applies only to conduct of the research at sites in Northern Ireland.

Back to the top

**Question 16 – Emergency treatment**

• Explain what local arrangements will be made to recruit participants requiring urgent treatment as part of the research. Say who will be responsible for making decisions on their inclusion in the research.

• Following the initial emergency, steps should be taken as soon as reasonably practicable to seek:
informed consent from the participant (if capacity to consent has been recovered)

or, if the participant has not recovered capacity,

informed consent from a legal representative (CTIMPs; non–CTIMPs at sites in Scotland)
advice from a consultee under the Mental Capacity Act (non–CTIMPs at sites in England and Wales)
assent from a close relative or friend (non–CTIMPs at sites in Northern Ireland).

• General provision to seek consent/advice/assent should be set out in the protocol. Say what local arrangements will be made at this site.

Back to the top

Question 17 – Complaints process

• Participants should be informed how they may make a complaint, if necessary, about the way they have been approached or treated in the course of the research. The REC will wish to know what contact point for complaints will be given on the participant information sheet to be used at the site.

Back to the top

Question 18 – Independent contact point

• It is good research practice to inform potential participants where they may obtain either independent information or advice about their rights as research subjects or about being involved in this particular research study. This may already be included in the generic information sheet. However, if there is an appropriate local source this should be cited here and added to the information sheet locally.

• Question 15–1 asks about provision for independent advice about taking part in research generally. The role of the independent advisor is to enable the participant to weigh up the decision whether or not to participate, taking into account the information provided about the study. Possible sources of advice include the following:
  Another clinician or manager not involved in the conduct of the research
  An information/support centre based at the site
  An organisation specialising in support for patients in the relevant field.

• Members of the research team should not be named as sources of independent advice.

• RECs should not be cited here. It is not the role of the REC to give direct advice or support to participants in this way.

• Question 15–2 asks about contacts who can provide more details about the study. You should explain whether or not the contact indicated in your response is independent of the research team. Having an independent source of advice about the study can be helpful to potential participants.

• If there is no appropriate individual or agency, please answer "No".
Question 19 – Local version of the participant information sheet

- The generic content of the participant information sheet is the responsibility of the REC undertaking the main ethical review. Any variation to the generic content must be approved by the main REC. Where the protocol allows variation between sites (for example, a choice of standard treatment in the control arm or imaging modality), the main REC may approve options in the participant information sheet to be selected by the local PI in consultation with the CI.

- If you consider that changes should be made to the generic content of the information sheet to reflect site-specific issues in the conduct of the study, please give details. A substantial amendment may need to be discussed with the Chief Investigator and submitted to the main REC.

- The SSA REC may not request changes to the generic content. However, it will check that relevant site-specific information has been included in the local version to make it suitable for local participants.

- It is a requirement of Good Clinical Practice that participants should be able to find out more information about the proposed research should they wish to do so. Details must be included in the local version submitted for review.

- Participants should be informed how they may make a complaint, if necessary, about the way they have been approached or treated in the course of the research. The contact point for complaints must be included on the local version.

- It is important that the participant information sheet and any other correspondence should be on "official" headed paper (e.g. of the Site Management Organisation or private practice). Private (personal) headed paper is not sufficient.

Question 20 – Language issues

- Whether or not potential participants who may have difficulty understanding English are (or are not) to be recruited is a general ethical issue for the main REC.

- If such participants are to be recruited, the minimum arrangements to be made locally for provision of interpreters and information in other languages are an issue for the main REC.

- The local Principal Investigator should describe here how he/she will implement those approved generic arrangements locally.

- The Chief Investigator should have informed the PI of the availability of written information for potential participants in other languages. It is the PI’s role to ensure that these are available as appropriate to his/her site.

- Where use of interpreters is desirable, the PI should describe the proposed local arrangements for their availability.
For research sites in Wales, please consult the guidance on question A33-1 in Part A of IRAS for meeting the requirements of the Welsh Language Act 1993.

Question 21 – Information for professional carers

- The review will check that those responsible for the professional care of a participant are told of their involvement in the research. Sufficient details should also be recorded in the patient's medical records, to ensure that the future treatment of the patient is compatible with their involvement in the study.

Question 22 – Facilities and staffing

- The SSA REC will check that the local facilities and staff are adequate for the research to be undertaken safely, taking into account the specific procedures to be undertaken and the potential risks.

- Describe the standard systems in place to protect the safety of participants.

- Describe any potential risks that could arise, and what arrangements have been made to deal with these potential risks, to minimise harm to participants and to respond to emergencies.

- Where the research has the potential to cause significant distress or discomfort to participants, describe any extra support that will be provided.

- For phase 1 clinical trials and clinical investigations of medical devices, describe the arrangements for medical care of participants.

Question 23 – Over-volunteering

- Describe what procedures are in place to check the previous and current involvement of potential participants in other research, for example use of The Over-Volunteering Protection System (TOPS). Further information about TOPS is available at www.tops.org.uk.

Question 24 – Management and monitoring arrangements

- The SSA REC will wish to be assured that adequate arrangements are in place to ensure the quality of the conduct of the research and monitor the safety of participants.
Question 25 – ARSAC certificate

• This question is only applicable to research involving administration of radioactive materials additional to normal care.

• A research certificate from the Administration of Radioactive Substances Advisory Committee (ARSAC) at the Department of Health will be required by the nuclear medicine professional at each research site where the study involves exposures that are additional to normal care. Most of the information required for the ARSAC application can be generated from IRAS.

• The ARSAC research application form can be launched either from the button at Question 25 or by selecting the ARSAC tab. The form will be automatically populated with relevant information from the SSI Form and Parts A–B of IRAS once completed. The form should be transferred to the relevant nuclear medicine professional at the research site, who will complete the remainder of the form and submit it to the ARSAC Support Unit.

• Where the only administration of radioactive materials is in accordance with normal care at the site, this will be covered by the certificate holder's normal ARSAC certification.

• Further guidance about ARSAC applications is available at http://www.arsac.org.uk/.

• Guidance on arrangements for use of ionising radiation in research is available at http://www.nres.npsa.nhs.uk/applicants/guidance/.

Question 26 – Insurance and indemnity

• Describe the insurance or indemnity arrangements which will be in place to meet any potential liabilities arising for the Principal Investigator, the Site Management Organisation and other members of the research team arising from this research.

• Where cover is arranged by the Site Management Organisation, please provide a summary statement explaining what the policy provides and for whom, and how the extent of the cover has been determined. Please confirm that the policy will cover this particular research. Highlight any exclusions in the policy which may limit the cover available. A copy of the insurance policy or certificate should be provided.

• It is not acceptable for the Site Management Organisation to provide an undertaking to "self−insure" against the potential liability from its own funds. The insurance or indemnity must be provided by another legal entity. It is acceptable for the insurer to be another company within the same corporate group provided it is a separate legal entity.

• Where cover for the Principal Investigator is arranged through professional indemnity insurance, a copy of the policy should be enclosed. Please confirm that the insurance covers the conduct of this research as well as the PI's normal clinical practice.
Declaration

• Please read the declaration carefully. By signing this, the Principal Investigator is legally agreeing to its contents.