

## KCH Research Office

### IRAS Guidance

The Integrated Research Application System (IRAS) is an online tool which enables researchers to create a core data set and then to create the forms which they will need for applications to R&D, NHS Ethics Committees, the MHRA, and a number of other national bodies.

**All of the documents cited in this guidance can be found on the KCH website.**

#### Creating a new IRAS account

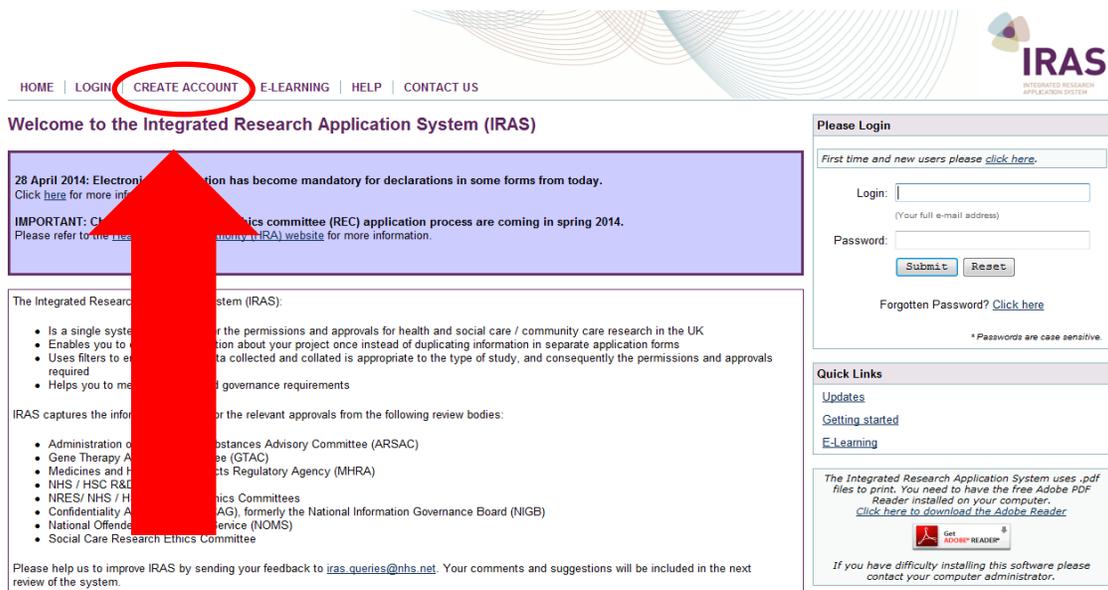
IRAS uses a system of electronic signatures for authorisations. As such anyone who will need to sign the forms will need to register with IRAS.

[www.myresearchproject.org.uk](http://www.myresearchproject.org.uk)

Use the link below to do some IRAS online training. It should take about an hour. The green  icon will bring up question-specific guidance to help you complete the forms.

[https://www.myresearchproject.org.uk/Elearning/IRAS\\_E\\_learning.htm](https://www.myresearchproject.org.uk/Elearning/IRAS_E_learning.htm).

If you can't find the information required in the help screens, IRAS queries can be sent to [iras.queries@nhs.net](mailto:iras.queries@nhs.net)



HOME | LOGIN | **CREATE ACCOUNT** | E-LEARNING | HELP | CONTACT US

Welcome to the Integrated Research Application System (IRAS)

28 April 2014: Electronic signature has become mandatory for declarations in some forms from today. Click [here](#) for more information.

IMPORTANT: Changes to the Research Ethics Committee (REC) application process are coming in spring 2014. Please refer to the [IRAS website](#) for more information.

The Integrated Research Application System (IRAS):

- Is a single system for the permissions and approvals for health and social care / community care research in the UK
- Enables you to submit information about your project once instead of duplicating information in separate application forms
- Uses filters to ensure that data collected and collated is appropriate to the type of study, and consequently the permissions and approvals required
- Helps you to meet all relevant governance requirements

IRAS captures the information for the relevant approvals from the following review bodies:

- Administration of Medicines (AMC), Medicines Division (MD), Medicines Division (GTAC)
- Gene Therapy Advisory Committee (GTAC)
- Medicines and Healthcare Products Regulatory Agency (MHRA)
- NHS / HSC Research Ethics Committees
- NRES/ NHS / HSC Research Ethics Committees
- Confidentiality Advisory Group (CAG), formerly the National Information Governance Board (NIGB)
- National Offender Management Service (NOMS)
- Social Care Research Ethics Committee

Please help us to improve IRAS by sending your feedback to [iras.queries@nhs.net](mailto:iras.queries@nhs.net). Your comments and suggestions will be included in the next review of the system.

Please Login

First time and new users please [click here](#).

Login:

(Your full e-mail address)

Password:

Forgotten Password? [Click here](#)

\* Passwords are case sensitive.

Quick Links

[Updates](#)

[Getting started](#)

[E-Learning](#)

The Integrated Research Application System uses .pdf files to print. You need to have the free Adobe PDF Reader installed on your computer. [Click here to download the Adobe Reader](#)

 Get ADOBE READER

If you have difficulty installing this software please contact your computer administrator.

## Complete the IRAS Project Filter Questions

The project filter questions create the IRAS form; depending on the responses you select, questions will either appear or disappear –so it’s important to make sure you get this right or you’ll end up not answering all of the questions you need too—or too many!

The form is divided into 3 main sections.

- Part A deals with the study as a whole
- Part B is legislation specific – there are different sections to deal with Tissue, CTIMPs, the Mental Capacity Act, Radiation and Information Security/Data.
- Part C relates to the various sites at which the study will be taking place.

Because the form has to cater for all types of research the questions are not always applicable to your project, so try to answer each question as best you can, with as much transparency as possible.

It’s also important to keep your audience in mind and ensure the form is completed in lay-language – the majority of those reviewing will not have medical/clinical knowledge and your applications must be easily understood by all reviewers.

## Project Filter questions

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IRAS  
INTEGRATED RESEARCH APPLICATION SYSTEM

Navigation Page (Get to this page from anywhere in your project by clicking on 'Navigate')

Project Title: **radiation test** IRAS Project ID: **154417**  
Project Type: **Research involving qualitative methods only**  
Full project dataset

Project Filter  
[Click here to go directly to the Project Filter questions](#)  
Full Set of Project Data (Select this dataset to answer all the questions for your project)  
[Click here to access the full dataset for all project forms](#)

Project submission, amendments and reports to get menus for  
NHS REC Form  
NHS/HSC R&D Form (for more information)

Site-specific Form questions for each site from the REC or NHS R&D Form  
1 NHS/HSC R&D Form to PI typed (No research organisation type)

Navigate | Manage | Transfer | Save/print

Project Form Navigation  
[Print blank reference only PDF for the full project dataset](#)

Status  enabled  disabled  completed

SECTION	QUESTION RANGE
<b>Part A: Core study information</b>	
Administrative details	Proj. Title-A1 A2 A3 A4-A5
Overview of the research	A6
Purpose and design of the research	A7 A8-A9 A10-A13 A14 14
Risks and ethical issues	A15 A16 A17
Research procedures, risks and benefits	A18 A19 A20 A21-A22 A23-A24 A25 A26
Recruitment and informed consent	A27 A28-A30 A31 A32 A33 A34 A35
Confidentiality	A36-A38 A39 A40-A42 A43-A45 A46-A49
Publication and dissemination	A50-A53
Scientific and Statistical Review	A54 A55-A57 A58 A59-A60 A61 A62
Management of the research	A63-A64 A65-A69 A70 A71-A72 A73-A74 A75 A76 A77 A78 A79 A80

If you get stuck you can access question-specific guidance by clicking the  icon to the top right of the question.

- Q2 Be sure you selected the most accurate description for your study. The first five are high-risk studies and will require full NHS REC review and the others are low-risk studies and may be eligible for by proportionate review. <http://www.hra.nhs.uk/documents/2013/09/no-material-ethical-issues-tool.pdf>
- Q3 Ensure all nations where there will be Research sites are selected.
- Q3a Ensure “England” is selected.
- Q4 Check options 1 and 3 (if applicable) as this automatically generates the NHS R&D and NHS REC forms, respectively. For studies involving NHS participants and sites both items 1 and 3 must be checked. Studies involving NHS Staff as participants do not require REC review. Studies that involve tissue and/or data only may also not require REC review. Guidance can be found here: <http://www.dt-toolkit.ac.uk/home.cfm>
- Q5a relates to funding from the NIHR BRC- if you are an NIHR Fellow please check Yes otherwise follow the guidance.
- Q5b relates to the UKCRN Portfolio. If your research has been funded as part of a grant awarded from an open National call, check Yes. For unfunded research check “No”. For those that select Yes, a Portfolio Application Form will need to be completed as part of the application.
- Q9 give a detailed list or description of your role in the study. For e.g. *“I will write the protocol, undertake the questionnaire design and all aspects of the data entry/data analysis”*. It is not sufficient to say “this is my MSc dissertation.”

### **Completing the Full Dataset**

This section of the form is crucial as it is used to populate the forms you generate for the various applications.

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IRAS  
INTEGRATED RESEARCH APPLICATION SYSTEM

Navigation Page (Get to this page from anywhere in your project by clicking on 'Navigate')

Project Title: radiation test IRAS Project ID: 154417  
Project Type: Research involving qualitative methods only  
Full project dataset

Project Filter: **Navigate** Manage Transfer Save/print

1 [Click here to access the integrated dataset for all project forms](#)

2 **Navigate**

Project Form Navigation

Print blank reference only PDF for the full project dataset

Status:  enabled  disabled  completed

SECTION	QUESTION RANGE
<b>Part A: Core study information</b>	
Administrative details	Proj. Title-A1 A2 A3 A4-A5
Overview of the research	A6
Purpose and design of the research	A7 A8-A9 A10-A13 A14 A14
Risks and ethical issues	A15 A16 A17
Research procedures, risks and benefits	A18 A19 A20 A21-A22 A23-A24 A25 A26
Recruitment and informed consent	A27 A28-A30 A31 A32 A33 A34 A35
Confidentiality	A36-A38 A39 A40-A42 A43-A45 A46-A49
Publication and dissemination	A50-A53
Scientific and Statistical Review	A54 A55-A57 A58 A59-A60 A61 A62
Management of the research	A63-A64 A65-A69 A70 A71-A72 A73-A74 A75 A76 A77 A78 A79 A80

Select Full Set of Project Data (1) and then Navigate (2) to open the IRAS full set of project data.

- A2-1 Students should insert their full university address and college email
- A3-1 Chief Investigator - Enter either the name of your academic supervisor or the person who is overall responsible for the study. Their substantive employer will act as the study Sponsor. For KCL/KCH Sponsorship guidance see appendix 1
- A4 See appendix 1
- A5-1 No need to enter any numbers into this section
- A6-1 This section is the introduction to your study. Simply describe the condition you're studying and what you hope to gain by studying it –that is, what your research is looking at and why it's important. This section is printed on the HRA website
- A6-2 We recommend that you think about the type of issues your study is likely to involve and list them as a series of titles in this section (tissue, incapacitated adults, data security, &c.). Under each heading describe briefly the nature of the problem and how you will address it. This section refers only to Ethical and Logistical issues, and is not intended to be another section of methodology.

- A14-1 'PPI' refers to the participation of public/patient groups in the actual design, analysis etc., of the research and not to participating in research as a subject. If a patient group was involved in your study e.g. young mothers designing and reviewing the questionnaire for example, then you can say "yes" and give this information. "None of the above" is fine to put here.
- A18 and A19 These cover details of non-clinical and Clinical intervention. This must be explicit in the PIS and protocol, and appropriate consent must be sought and obtained. Persons listed here should also appear in question A63-1. In Column 2 enter the how many of these interventions would have occurred during routine care. **Do not leave blank.** It is acceptable to enter 0 if all the interventions are part of the study. Column 4 –give the names of the persons and give the details of the location of the research activity.
- A31 should usually be a minimum of 24 hours to give participants enough time to consider their participation and ask any questions.
- A45 Enter: In accordance with Trust policy all personal and/or sensitive personal data (as defined by the Data Protection Act 1998) will be securely destroyed at the conclusion of the research. Non-identifiable data and other records not containing person identifiable data may be retained for a longer period at the discretion of the PI.
- A45 Enter: Any non-identifiable data (exempt from the requirements of the Data Protection Act 1998) retained by the PI will be stored appropriately to ensure its integrity, confidentiality and accessibility.
- A50-1 If you are aware of a suitable register or other method of publication, please give details. If not, you may indicate that no suitable register exists. It is only mandatory for Clinical Trials to register on a public database.
- A64-1 See Appendix 1
- A68 See Appendix 1
- A73-1 if you check "yes", please list all the Patient Identification Centre's (PICs ) you intend to use here in Part C. A PIC is a site that identifies patients and refers them to a Research site for possible recruitment. No research activity, including consent, can take place at a PIC.
- A74. **Please Enter:** The CI will be responsible for the day-to-day monitoring and management of the study. The Sponsor will monitor and conduct random audits on a selection studies in its clinical research portfolio. Monitoring and auditing will be conducted in accordance with the DoH's Research Governance Framework for Health & Social Care, and in accordance with the Sponsor's monitoring and audit policies and procedures.

- A76-1 KCH sponsored studies, tick “Yes”. Students should tick “No” to NHS indemnity scheme will apply (this applies to NHS sponsors only). Tick “Yes” Other insurance or indemnity arrangements will apply Enter: “The management of the research will be covered by (entre name of your university) insurance for negligent harm”.
- A76-2 KCH sponsored studies, tick “Yes”. Students should tick “No” to NHS indemnity scheme will apply (this applies to protocol authors with NHS contracts only). Tick “Yes” to Other insurance or indemnity arrangements will apply. Enter “KCL provides cover for negligent harm arising from the design of the research”
- A76-3 If your study involves NHS participation only tick “Yes” NHS indemnity scheme or professional indemnity will apply (this applies to participants recruited at NHS sites only) and make no response.

KCH do not provide secure storage for research records generated as a result of student research. Therefore any decisions around the archiving (‘retention’) period determined by the student should be pragmatic. The Trust strongly recommends that all person identifiable data (data subject to the requirements of the Data Protection Act 1998) is purged in its entirety at the end of the research to limit the risks of data loss. Any data generated during the trial in non-identifiable format may be retained indefinitely by the student.

The fact that all identifiable data will be purged at the end of the research should be indicated on the IRAS form and or consent form (as applicable).

### **Part C– over-view of research sites & Participant Identification Centres**

**A 72** Please list all the participatory NHS UK sites in this section of the IRAS form and complete NHS (SSI) site specific information Form in IRAS for each site.

A site is any location in which protocol activity is undertaken. Protocol activity includes: screening participants and or their records, recruiting, consenting, data generation, data recording, data handling, any intervention, observation, interviews, questionnaires, and focus groups (or any variation thereof).

PICs should be entered as per A73-1.

All Non- NHS sites will require REC review, this can be done at the same time as initial review or after Favourable Opinion is given. You will need to send a completed SSI to the main REC.

Note – To enter KCH as a site, use the postcode SE5 9RS in the search, as there are other sites with similar names, and it will not appear as a site if you search ‘King’s’:

## Reference Data Organisation Search

Please identify the site using the search options below.

For NHS sites, the host organisation is the NHS Trust (TRUST in 'Type' column). Where the research site is a primary care site, please seek advice from the Lead CLRN whether the host organisation is the PCT (PCT SITE in 'Type' column) or GP practice (PRACTICE in 'Type' column).

Search by:

Name:  Address:  Postcode:

	Code ID	Type	Organisation Name	Postcode	
▶	RJZ	TRUST	KING'S COLLEGE HOSPITAL NHS FOUNDATION TRUST	SE5 9RS	<a href="#">Copy data</a>

Now you have generated the integrated dataset, check it against the Protocol, the PIS, and any other associated documentation for consistency

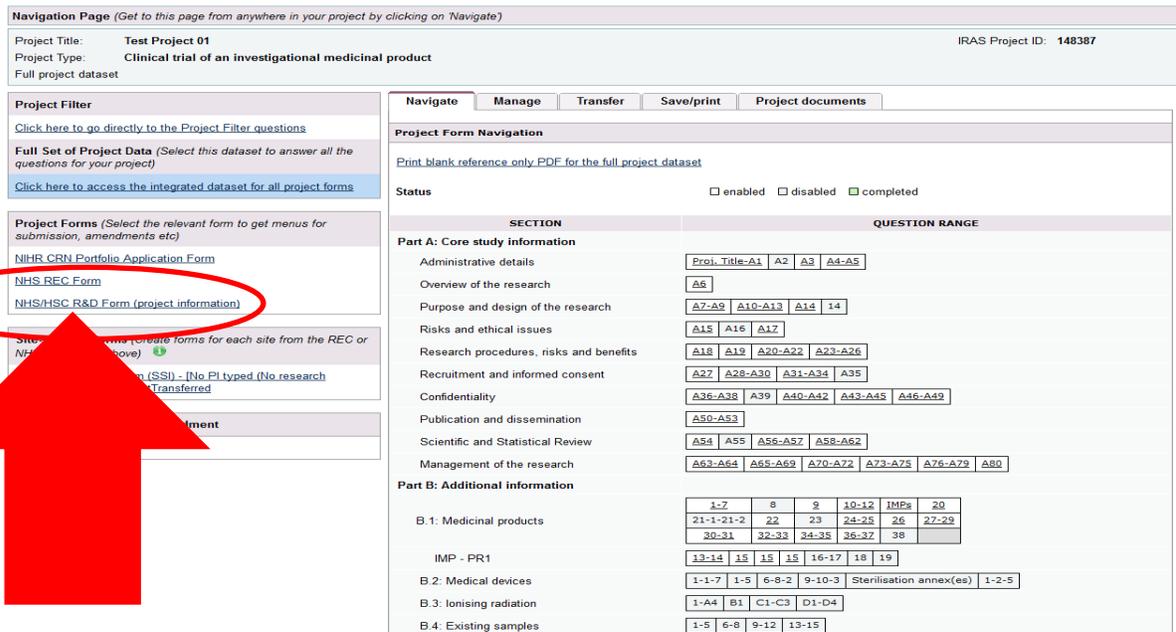
## Generating Draft REC & R&D forms

You will need to send through a copy of your REC and R&D form to the research office for review prior to making an application (See **guidance on Sponsorship, submitting to Ethics, and submitting to R&D**).

The Integrated Dataset that you have completed will have automatically filled in the relevant sections of both forms already.

To create draft copies of the forms:

- Select either the REC or R&D form from the list:



Navigation Page (Get to this page from anywhere in your project by clicking on 'Navigate')

Project Title: **Test Project 01** IRAS Project ID: **148387**  
Project Type: **Clinical trial of an investigational medicinal product**  
Full project dataset

**Project Filter**  
[Click here to go directly to the Project Filter questions](#)  
**Full Set of Project Data** (Select this dataset to answer all the questions for your project)  
[Click here to access the integrated dataset for all project forms](#)

**Project Forms** (Select the relevant form to get menus for submission, amendments etc)  
[NIHR CRN Portfolio Application Form](#)  
[NHS REC Form](#)  
[NHS/HSC R&D Form \(project information\)](#)  
[Site-specific forms \(create forms for each site from the REC or NHS/HSC R&D Form above\)](#)  
[Site-specific forms \(SSI\) - \[No PI typed \(No research transfered\)\]](#)

**Navigation** | **Manage** | **Transfer** | **Save/print** | **Project documents**

**Project Form Navigation**  
[Print blank reference only PDF for the full project dataset](#)

Status:  enabled  disabled  completed

SECTION	QUESTION RANGE
<b>Part A: Core study information</b>	
Administrative details	<a href="#">Proj. Title-A1</a> <a href="#">A2</a> <a href="#">A3</a> <a href="#">A4-A5</a>
Overview of the research	<a href="#">A6</a>
Purpose and design of the research	<a href="#">A7-A9</a> <a href="#">A10-A13</a> <a href="#">A14</a> <a href="#">14</a>
Risks and ethical issues	<a href="#">A15</a> <a href="#">A16</a> <a href="#">A17</a>
Research procedures, risks and benefits	<a href="#">A18</a> <a href="#">A19</a> <a href="#">A20-A22</a> <a href="#">A23-A26</a>
Recruitment and informed consent	<a href="#">A27</a> <a href="#">A28-A30</a> <a href="#">A31-A34</a> <a href="#">A35</a>
Confidentiality	<a href="#">A36-A38</a> <a href="#">A39</a> <a href="#">A40-A42</a> <a href="#">A43-A45</a> <a href="#">A46-A49</a>
Publication and dissemination	<a href="#">A50-A53</a>
Scientific and Statistical Review	<a href="#">A54</a> <a href="#">A55</a> <a href="#">A56-A57</a> <a href="#">A58-A62</a>
Management of the research	<a href="#">A63-A64</a> <a href="#">A65-A69</a> <a href="#">A70-A72</a> <a href="#">A73-A75</a> <a href="#">A76-A79</a> <a href="#">A80</a>
<b>Part B: Additional information</b>	
B.1: Medicinal products	<a href="#">1-7</a> <a href="#">8</a> <a href="#">9</a> <a href="#">10-12</a> <a href="#">IMPs</a> <a href="#">20</a> <a href="#">21-1-21-2</a> <a href="#">22</a> <a href="#">23</a> <a href="#">24-25</a> <a href="#">26</a> <a href="#">27-29</a> <a href="#">30-31</a> <a href="#">32-33</a> <a href="#">34-35</a> <a href="#">36-37</a> <a href="#">38</a>
IMP - PR1	<a href="#">13-14</a> <a href="#">15</a> <a href="#">16</a> <a href="#">17</a> <a href="#">18</a> <a href="#">19</a>
B.2: Medical devices	<a href="#">1-1-7</a> <a href="#">1-5</a> <a href="#">6-8-2</a> <a href="#">9-10-3</a> <a href="#">Sterilisation annex(es)</a> <a href="#">1-2-5</a>
B.3: Ionising radiation	<a href="#">1-A4</a> <a href="#">B1</a> <a href="#">C1-C3</a> <a href="#">D1-D4</a>
B.4: Existing samples	<a href="#">1-5</a> <a href="#">6-8</a> <a href="#">9-12</a> <a href="#">13-15</a>

- Select the Save/Print option from the tabs along the top of the form:

Project Name: **test Project 01** IKAS PROJECT ID: 140307  
 Project Type: **Clinical trial of an investigational medicinal product**  
 Application to: **NHS/HSC Research and Development offices**

Project Filter

[Click here to go directly to the Project Filter questions](#)

**Full Set of Project Data** (Select this dataset to answer all the questions for your project)

[Click here to access the integrated dataset for all project forms](#)

Project Forms (Select the relevant form to get menus for submission, amendments etc)

Navigate Add SSI Checklist Transfer Authorisations **Save/print** E-Submission Draft E-Subri

NHS/HSC R&D Form Navigation

[Print blank reference only PDF for this form](#)

Status  enabled  disabled

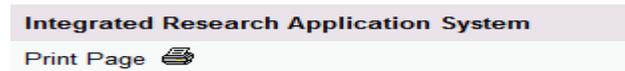
SECTION	PAGE					
Proj. Title	A1	A2	A3	A4-A5	A6	

- Select 'Print this form for review':

- **Print a form for review at any time while you are working on it.**

[Print this form for review](#)

- This will open a pop up box, shown below: (If you have a pop-up blocker installed on your browser this will open a message at the top of the window. Select this message, and click 'always allow pop-ups from this site'. Once selected, click on 'Print this form for review' again.



- Although the Pop-up states that the form is being printed, it is actually downloading a copy to the computer instead. Once finished a small pop up box will appear in the top of the box. Right click on this to open the .pdf version of the form.
- You will now have a .pdf copy of the form, with a Draft watermark on each page. This can be saved and printed as required.

### Site Specific Information (SSI)

Each site listed in Part C will require an SSI form. The SSI provides information about the resources and capacity to undertake the research at a particular site. Some of the SSI form will have been pre-populated with the responses from the integrated dataset.

- To create an SSI enter section C of the Integrated Dataset to where you have already entered your site details, as previously shown.
- Select 'Create NHS SSI Form':

Investigator identifier	Research site	Investigator Name	
IN1	<input checked="" type="radio"/> NHS site <input type="radio"/> Non-NHS site Country: <input type="text" value="England"/> * Please use the Organisation Search button to fill the fields below. <input type="button" value="Organisation Search"/> Organisation name: <input type="text" value="KING'S COLLEGE HOSPITAL NHS FO"/> Address: <input type="text" value="DENMARK HILL"/> <input type="text" value="LONDON GREATER LONDON"/> Post Code: <input type="text" value="SE5 9RS"/>	<input type="button" value="Create NHS SSI Form"/> Forename: <input type="text"/> Middle name: <input type="text"/> Family name: <input type="text"/> Email: <input type="text"/> Qualification (MD...): <input type="text"/> Country: <input type="text"/>	<input type="button" value="↑"/> <input type="button" value="↓"/> <input type="button" value="🗑️"/>

- Return to the Navigate tab, where the SSI will now be listed on the left of the screen, below the R&D & REC forms. Select the correct form for the site which you'd like to complete:

**Project Filter**

[Click here to go directly to the Project Filter questions](#)

**Full Set of Project Data** (Select this dataset to answer all the questions for your project)

[Click here to access the integrated dataset for all project forms](#)

**Project Forms** (Select the relevant form to get menus for submission, amendments etc)

[NIHR CRN Portfolio Application Form](#)

[NHS REC Form](#)

[NHS/HSC R&D Form \(project information\)](#)

**Site-specific Forms** (Create forms for each site from the REC or NHS R&D Form above) i

[1. NHS/HSC R&D Form \(SSI\) - \[No PI typed \(No research organisation typed\)\] / NotTransferred](#)

[2. NHS/HSC R&D Form \(SSI\) - \[No PI typed \(KING'S COLLEGE HOSPITAL NHS FO...\)\] / NotTransferred](#)

**Notices of Substantial Amendment**

[\(no number\)](#)

This will open the Navigate page of the SSI. Select the 1<sup>st</sup> question from the right hand of the page, and work through the questions as follows:

- 1-2 Will already have been populated with the Site name.
- 1-3 Should be selected to the correct Country.
- 1-4 If Site is a GP or Primary Care centre select Yes, and enter the site name in the pop-up box below.
- 2 Enter the full details of the PI or Local Collaborator. A Whole Time Equivalent showing how much time they will spend working on the study must be entered in section a). Section b) should only be ticked Yes if the PI already has access arrangements in place.
- 3 List all locations within the Site where activity will take place, such as 'Dental Clinic', and what will happen there. For Trusts such as KCH that are split over multiple sites ensure that details of which campus the location is on are clearly entered.
- 5 Add all research team members that will be working at this site, other than the PI, in the same way as information was entered for question 2.
- 6 If Yes, enter information in the pop-up box below.
- 7 Enter the specific start and end dates for this site. These may be different from the overall timescale entered in the previous forms.
- 8-1 & 9-1 should be populated already as per the A18 & A19 in the Integrated Dataset, other than Column 5. Enter the details in Column 5 of the specific members of staff that will be performing this intervention.
- 8-2 & 9-2 are used for when an intervention is not happening at this Site, or when there are variations to how it will be happening across sites. Selecting Yes to this question will allow Column's 1-4 of questions 8-1 & 9-1 to be edited. Enter details of the changes within the text box provided.
- 10 Enter the number of participants expected. For studies not prospectively recruiting this can be marked as N/A, as can the following recruitment related questions.
- 11 Enter Site specific details on how participants will be recruited.
- 12 Enter the names from question 5 that will be responsible for recruitment, along with details of their experience. If there is no prospective recruitment this can be left blank.
- 15-1 For KCH (and most other Trusts) this is the Patient Advice & Liaison Service (PALS). Details can be found here: <http://www.kch.nhs.uk/patientsvisitors/help-and-support/pals>.

- 15-2 Enter that contact details of the study team will be provided on the Patient Information Sheet.
- 16 This question can be left as N/A unless changes are required at this site as the study is being run in a different way (as per 8-2 & 9-2).
- 17 If translators aren't available, it is OK to state that only those who understand the English language will be able to participate.
- 18 Enter details of how (if required) GPs will be informed.
- 19 How will the safety of the Research be ensured at this site?
- 21 Enter site specific funding details. How much will be going to this site, and where will it be transferred to?
- 23 This will need to be populated with the contact within the R&D department who is helping to process the application. For KCH this would be the Facilitator who will be reviewing the form pre-submission.

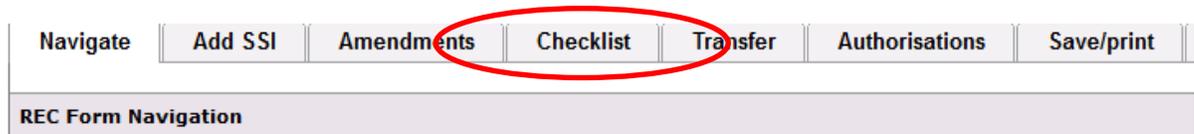
### **Adding Documents to the Checklist:**

The Checklist is where you should list all the documents that form part of the submission. There is a checklist for the REC form, R&D form and each SSI.

Electronic submissions (for REC forms and for all Portfolio studies) also allow you to attach the documents, so that they are submitted automatically along with the forms.

To complete the checklist:

- Select the Checklist tab from the navigation bar:



- This will open the Checklist screen:

Document	Subtitle	Enclosed	Date	Version	Office Use	Reason not supplied	
Covering letter on headed paper		No					<b>2</b> <b>3</b>
Research protocol or project proposal		Mandatory					
Investigator's brochure / IMP Dossier		No					
Summary of product characteristics (SmPC)		No					
Summary CV for Chief Investigator (CI)		Mandatory					
Participant information sheet (PIS)		Mandatory					
Participant consent form		Mandatory					
Letters of invitation to participant		No					
GP/consultant information sheets or letters		No					
Evidence of Sponsor insurance or indemnity (non-NHS Sponsors only)		Mandatory					
Letter from sponsor		No					
Letter from statistician		No					
Referee's report or other scientific critique report		No					
Summary, synopsis or diagram (flowchart) of protocol in non-technical language		No					
Details of any Data Monitoring Committee		No					
Sample diary card/patient card		No					
Validated questionnaire		No					
Non-validated questionnaire		No					
Copies of advertisement materials for research participants		No					
<b>Other documents</b>							
Other (please specify)		No					

**1** **4**

- Not each row will need to be completed if it is not relevant for the study (for e.g. if the study is not using a GP letter then this can be left as reading 'no'. Additional documents that are not included in the standard list (which is different for each form) can be added by selecting 'Add new row' from the bottom of the screen (1).
- To enter the details about a document select the pencil and paper icon on the right (2). The paperclip icon (3) is only available for forms where electronic submission is available (3). Select this to attach the document.
- A .pdf of the Checklist can be created using the print button at the bottom of the screen (4).

***All of the documents cited in this guidance can be found on the KCH website.***