A User's Guide to IRAS

Integrated Research Application System

Accessing IRAS

www.myresearchproject.org.uk

- If you already have an account for the NRES website, you can use the same login details to access IRAS.
- If not, then click the 'Create Account' option on the IRAS main menu. After submitting your registration details you will receive an email containing with an activation code and a link to activate your account. **Use this activation link once only**!

Help

- **The IRAS Help Manual**.
- **Question Specific Guidance**. (also available by clicking icons within the application forms).
- **Example applications forms**: Read-only PDFs show typical data required for various research project types.
- Information on IRAS **version updates** .
- **IRAS question index** (includes references to old NRES form questions).
- An E-learning module.
- **Other guidance** (amendments, academic studies etc).
- Submission **checklists.**

IRAS Contacts

- IRAS has an integrated contacts database.
- You can either enter contact details into the contacts database and copy them instantly into a form - or enter contact details directly into a form and then save them to the contacts database for re-use. This helps to:
  - Reduce repetitious data entry.
  - Enhance accuracy.

My Projects

- A single project captures all of the information needed for the relevant approvals from all the review bodies that use IRAS.
- Each project you create will be listed on the My Projects page. The list displays the project's acronym or short title, date created and status. (e.g. 'Active', 'Transferred in' or 'Transferred out').
- To create a new project, click on the My Projects page of IRAS. You will be then be directed to the Project Filter Page.

The Project Filter

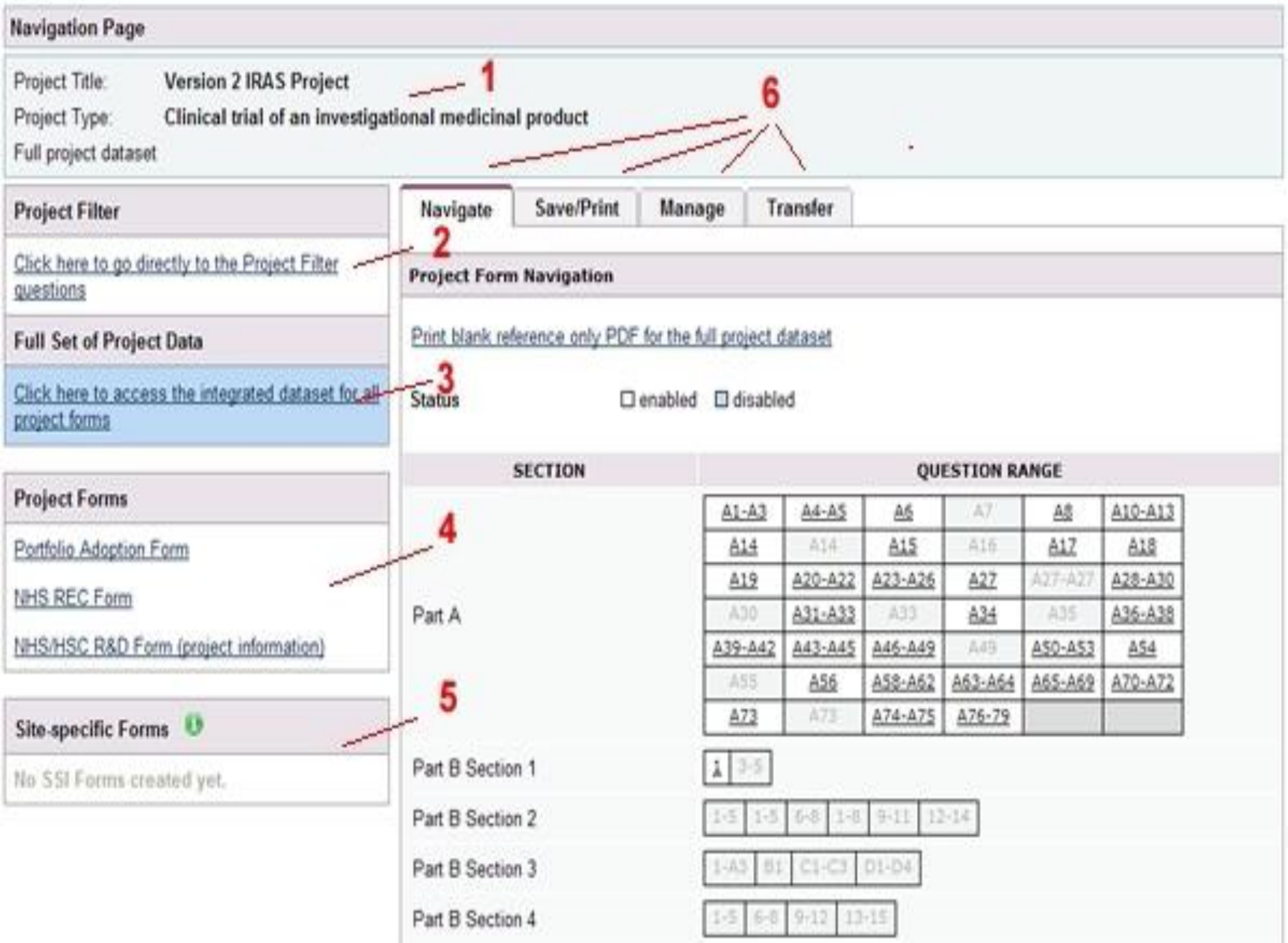
- When you create a new project you should begin by filling in the project filter page. (There is only **one** filter page per project).
- As you enter your answers into the filter, subsequent questions on the filter may change depending on your answers.
- Answers given on the project filter page define the forms and data raised for your project.
- When you have answered all of the filter questions click on the ‘Navigate’ button to go to the project navigation area.

Navigation

Key areas:

1. **Project Information Bar** (displays the project short title, project type).
2. A link to the **Project Filter** page.
3. A link to the **Integrated Dataset** (which displays all the questions from all the forms in your project into a single unified set of data - excluding SSI form data).
4. **Project Forms** list.
5. **SSI Forms** list.
6. **Action Tabs**.

(diagram on next slide)


Navigation Page
Project Title: Version 2 IRAS Project
Project Type: Clinical trial of an investigational medicinal product
Full project dataset
1
6
Project Filter
Click here to go directly to the Project Filter questions
2
Full Set of Project Data
Click here to access the integrated dataset for all project forms
3
Project Forms
Portfolio Adoption Form
NHS REC Form
NHS/HSC R&D Form (project information)
4
Site-specific Forms
5
No SSI Forms created yet.
Navigate
Save/Print
Manage
Transfer
Project Form Navigation
Print blank reference only PDF for the full project dataset
Status
enabled
disabled
SECTION
QUESTION RANGE
Part A
A1-A3 A4-A5 A6 A7 A8 A10-A13
A14 A14 A15 A16 A17 A18
A19 A20-A22 A23-A26 A27 A27-A27 A28-A30
A30 A31-A33 A33 A34 A35 A36-A38
A39-A42 A43-A45 A46-A49 A49 A50-A53 A54
A55 A56 A58-A62 A63-A64 A65-A69 A70-A72
A73 A73 A74-A75 A76-79
Part B Section 1
1 3-5
Part B Section 2
1-5 1-5 6-8 1-8 9-11 12-14
Part B Section 3
1-A3 B1 C1-C3 D1-D4
Part B Section 4
1-5 6-8 9-12 13-15

The Integrated Dataset

- The integrated dataset comprises of 4 main sections:
  - Part A: Core study information
  - Part B: Additional information for specific study types
  - Part C: Site list
  - Part D: Declarations

(Refer to IRAS Help page for detailed question index)

Action Tabs

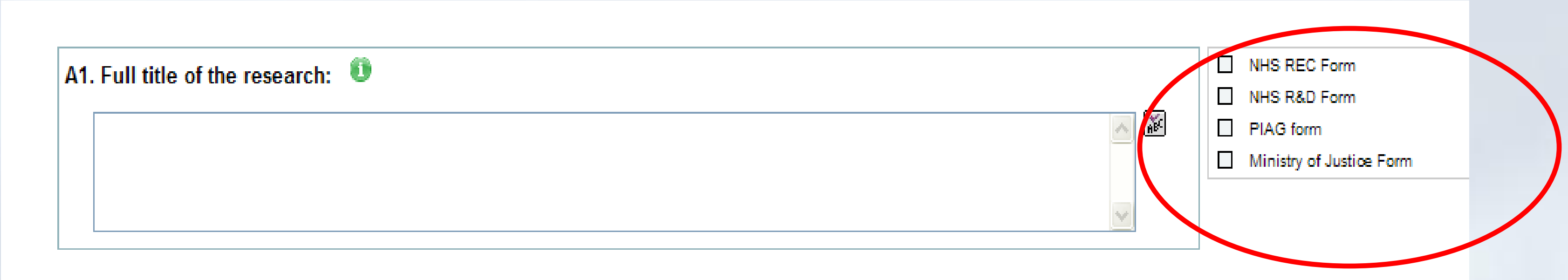
- Some or all of the following action tabs will be available in the navigation area - depending on which form is currently selected:
  - Navigate
  - Add SSI
  - Checklist
  - Authorisations
  - Save/Print
  - Submission
  - Progress
  - Amendment
  - Manage
  - Transfer

Navigating a Form

- The Navigate tab in the navigation area shows active and inactive questions on the selected form (dependant on your answers given in the project filter and within the form itself).
- Click on an active question to go to that question.
- Navigation buttons are also available at the top and bottom of all form pages: ‘Next’, ‘Previous’ or ‘Navigate’.

Cross Population of Data

- To the right side of each question (when filling in the Integrated Dataset or any project form) there is a list of all forms where that question appears. The answer you give will automatically cross populate all appropriate forms.



- Hover over a form's name to see whether that form is active or has been submitted. (Forms which have been submitted are shaded grey).

Adding SSI Forms

- The ‘Add SSI’ tab is only available when either the REC, R&D or GTAC form is selected in the navigation area.
- There are options to add either NHS or Non-NHS SSI forms.
- **Most of the questions in the SSI form must be filled in separately as there is little cross population.**
- **SSI forms are listed under the Project Forms on the Navigation page.**
- To duplicate an SSI form, select the SSI form in the navigation area, then use the duplicate option on the Manage tab.

ARSAC Forms

- In order to add an ARSAC form for that site, you will need to select an SSI form from the Project List.
- The 'Add ARSAC' tab is only available if you have indicated on the project filter that the study involves ionising radiation (Q2c. a.)
- The fields in the ARSAC form requiring completion by the certificate holder are Sections B4, Q1 (Name of certificate holder) and Section A, QA1 ('Details of the radioactive materials'). **All other fields in the ARSAC form are populated in read–only format from data already entered in Parts A and B of the integrated dataset.**

Form Checklists

- Checklists of all supporting documentation to be submitted are available in IRAS for the following forms:
  - NHS REC form
  - SCREC form
  - R&D form
  - PIAG form
  - SSI form
  - GTAC form
  - Research Database form
  - Research Tissue Bank form

Transferring a Form

- IRAS allows you to transfer a form to another IRAS user.
- **Ensure you have selected the appropriate form** in the project list on the navigation area before selecting the Transfer tab.
- The email address that you enter must match the recipient's IRAS username.
- The recipient will receive an automated email notifying them of the transfer – they can then log into their account and either accept or reject the form.

Transferred Forms

- Once a transferred form has been accepted, the recipient will have access to a limited range of tabs/actions:
- **Navigate** (access to the project filter is Read-Only).
- **Checklist.**
- **Submission** (including 'Print for submission').
- **Manage** ('Export as xml' option only). Transferred forms cannot be deleted or duplicated.
- **Transfer** (The recipient can send the form back to the owner, but <u>cannot</u> transfer it on to another IRAS account).
- **Add ARSAC Form** (only available against SSI forms).
- **Amendments.**

Transferred Forms

- If an SSI form is transferred to another IRAS account, the recipient has access to the tab to 'Add ARSAC Form'.
- If a REC, GTAC or R&D Form is transferred to another IRAS account ,the recipient is **not** able to add SSI forms. This can only be done by the project owner.
- The project owner can add SSI forms at any time - even if the REC and/or GTAC and/or R&D form is transferred to another IRAS account.

Transferring a Project

- If you wish to transfer an entire project to another IRAS user, select the integrated dataset, then use the transfer option on the Transfer tab.
- When you transfer the integrated dataset, the recipient has access to all forms within the project and <u>has write-access to the Project Filter</u>.
- Once the recipient has accepted the project, the owner can then choose to <u>permanently transfer</u> the project to them (again, this is done via the Transfer tab).

IRAS and EudraCT

- The whole of the EudraCT dataset is now available in IRAS. Once a EudraCT number has been obtained (go to http://eudract.emea.europa.eu) it is possible to use IRAS to complete the whole EudraCT dataset and to save the application in the format required for submission to MHRA.
- Alternatively, sponsors may choose to use the EudraCT website to make their application to MHRA Medicines, in which case, the information on the IMP(s) may be imported into IRAS to form part of the REC and R&D applications.

Import Data from EudraCT to a New IRAS Project

1. Go the EudraCT database at http://eudract.emea.europa.eu and complete your Clinical Trial Application (CTA) as usual.
2. Save the application as a (full) XML file to your computer or disk.
3. To import the data to a new IRAS project, click the 'Import' button at the top of the My Projects page. Browse and upload the EudraCT xml file from the relevant directory.

Import Data from EudraCT to an Existing IRAS Project

1. Go to http://eudract.emea.europa.eu and complete your Clinical Trial Application.
2. Save the CTA as a (full) XML file to your computer.
3. Open the existing project that you wish to import the data to and select the MHRA Medicines (EudraCT Application Form) from the Projects List on the Navigation page.
4. Select the Import/Export tab and click 'How to Import' button. In the new window that opens up, click the 'Import from EudraCT XML' button.
5. Follow the instructions on screen.

Print Options in IRAS

- To print a draft copy of an application form for review prior to submission, use the print option within the form itself (you will be given the option to print either the current page or the whole form) or select the ‘print for review’ option on the Save/Print tab in the navigation area.
- To print a blank, reference only copy of an application form or the integrated dataset, use the link on either the Navigate tab or Save/Print tab.
- To print for submission – see later slides.

Electronic Authorisation

- It is now possible to obtain electronic authorisations as an alternative to ink signatures for most declarations required in IRAS, although some departments in CHS do not use these yet.
- Use of electronic authorisation is not mandatory and users may continue to arrange for ink signatures to be provided if preferred. There is no need to obtain both ink signature and electronic authorisation.
- Applicants must obtain electronic authorisations before proceeding to the submission stage.
- Authorisers must have an existing IRAS account in order to access the form and record their authorisation.

Electronic Authorisation

- On the Authorisations tab for the selected form, the applicant has the option to **Sign** the CI Declaration or **Request** authorisation from someone else.
- The authoriser accepts the form into their IRAS account and can review it in read-only format. They then select the option to either **authorise** or **reject** and the form is automatically returned to the owner.
- IRAS keeps a log of what has been authorised and by who, for audit purposes.

Submissions

- The Submission tab details the information and process to submit the selected form to the appropriate regulatory body.
- When you are ready to submit the completed form, click the ‘Print for Submission’ button to generate a PDF copy of the form.
- The form will be stamped with a ‘Submission Code’ on the bottom right hand corner of every page (see next slide).

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Submission History

- A list of past submissions for the selected form is shown at the bottom of the Submissions page. The most recent submission is always displayed at the top of the list.
- The History table displays the submission code and the date & time the submission was generated.
- Next to each submission are options to ‘Print as PDF’ and ‘Save as XML’.

Re-submitting a form

- Unlike the old NRES form, application forms created in IRAS are never 'locked'.
- If you make changes to the project dataset after submission, you will be prompted to consider whether review bodies need to be notified of the change.
- If you wish to re-submit a form, click once again on the 'Proceed to Submission' button on the Submission tab. The latest version for submission will appear in the submission history table with a new submission code, and options to generate PDF and XML files for that submission version.

Monitor Progress

- Where an organisation processing your application has a direct link to IRAS, you will be able to monitor the process of your application through this tab. This tab is specific to each form:
  - The progress of the ethical review at the Research Ethics Committee (REC) can be monitored via the Progress page of the REC form:
    - Application Checked in
    - Application Marked Valid
    - Application Clock Started
    - Added to Meeting
    - Clock Stopped

Amendments

- The Amendment tab provides details on the arrangements for giving notice of amendments to appropriate bodies.
- The button to 'Create Notice of Substantial Amendment' will only be available if the study is **NOT** a CTIMP.
- Substantial amendments to CTIMPs should be submitted to the REC (and MHRA) using the European Commission Amendment form (a link to the EudraCT amendment form is available on the Amendment page in IRAS).

Duplicating Projects and Forms

- IRAS allows the user to take any number of ‘snapshots’ of a form, so it is no longer necessary to duplicate a form in order to make changes to it post-submission.
- To duplicate an entire project, select the Integrated Dataset on the Navigation page, and then select the duplicate option on the Manage tab.
- The duplicated project is entirely separate from the original.
- It is also possible to duplicate a specific SSI form. Select the SSI form in the navigation area, then use the duplicate option on the Manage tab.

Deleting Projects and Forms

- Select the integrated dataset on the navigation area, then go to the Manage tab to '**Delete Project**'. (only available if none of the forms within the project have been submitted).
- Select an **SSI or ARSAC** form then go to the Manage tab to delete it. (If you delete an SSI form that has an ARSAC form associated with it, the ARSAC form, will also be deleted).
- An SSI or ARSAC form cannot be deleted if it has been submitted.
- Other forms cannot be deleted; instead ,forms may be added/removed from the project by altering the responses given on the Project Filter page.

Project Categories

- Click the Manage Project Categories link on the left of the My Projects page to create additional project categories and to move your projects into the desired categories.
- Categories can only be deleted if they do not contain any projects.
- Select a category on the left side of the My Projects page to view contents on the right side of the page.

Submission to NIHR CSP

- The National Institute for Health Research Coordinated System for gaining NHS Permission (NIHR CSP) came into effect on 18 November 2008 for NIHR Clinical Research Network Portfolio studies in England.

Creating an NIHR-CSP Application Form

- The NIHR CSP Application Form is raised according to your answers in the project filter. (The lead R&D office has to be based in England in order for the study to be eligible for inclusion in the portfolio):

  Q3 : 'In which country in the UK will the lead R&D office be located?

  Q5a 'Do you want your application to be processed through the NHIR CSP?'

- The NIHR CSP Application Form is accessed via the project's navigation area, and must be submitted before submission of other application forms.

Submitting an NIHR CSP Application Form

- The applicant must select the CLRN that covers the region where they are based. The CLRN will support them with their application to CSP. A list of which trusts belong to which CLRN is available on the NIHR website. The NIHR CSP Application Forms are submitted to a UKCRN Portfolio Adoption Team who assess the eligibility of studies for inclusion into the NIHR portfolio.

Eligible Studies

- If the study is potentially eligible, the R&D form can be submitted to CSP - via the R&D Submission page.
- Once the R&D form is validated, study documents can be emailed to the Lead CLRN.
- The SSI forms can then be submitted via the appropriate SSI form Submission pages.

Create a ‘Minimal Dataset’

- **From 1 September 2009, the NRES form system is no longer available to create or submit any types of application form.**
- Where application forms for ethical review were completed in the NRES form system or prior paper-based systems, IRAS now includes the facility to create a ‘minimal dataset’ with sufficient data to enable SSI Forms, amendment forms and ARSAC forms to be created for ongoing studies.

Create SSI Forms using the Minimal Dataset

- Create a minimal dataset study and fill in the project filter.
- Complete Part A of the minimum dataset ***only.***
- If you will also need to create an ARSAC form for the new site, complete Part B Section 3 as well.
- Select the Add SSI tab, visible on the right side of the screen and create the required number of SSI forms.

Create ARSAC Forms using the Minimum Dataset

- You must first create and complete an SSI form for the minimal dataset. (See previous slide).
- In the Navigation area, ensure the SSI form is selected, then select the Add ARSAC tab on the right of the screen.
- The ARSAC Form is displayed in the 'Site Specific Forms' area of the Navigation page - complete the open fields in the form.

Create Amendment Forms using the Minimal Dataset

- Create a minimal dataset study and fill in the project filter ***only.***
- Select the minimal dataset in the main Navigation page. (Do not complete any sections of the minimal dataset).
- Select the Amendments tab and click on Create Notice of Substantial Amendment.
- Select the Amendment Form in the main Navigation page and complete ***all*** sections of the amendment form that are enabled.

Any queries?

- If you'd like any help with a Portfolio study submission, then contact:
- Alex.thorpe@chs.northy.nhs.uk or
- Tina.carlisle@chs.northy.nhs.uk
- Extension 42143.
- Thanks.