The Leeds Teaching Hospitals NHS
NHS Trust

RESEARCH AND INNOVATION

IRAS USER MANUAL

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INTRODUCTION TO THE IRAS SYSTEM

The Integrated Research Application System (IRAS) is a single system aimed at pursuing permissions and approvals for health and social care/community care research in the United Kingdom.

The IRAS System is designed to streamline the process of seeking relevant approvals. IRAS also enables information to be inserted once instead of duplicating information for separate application forms. It also uses filters so the questions are relevant to your type of study making the process less time consuming and efficient. Most importantly it helps meet regulatory and governance requirements.

This document is designed to support and guide researchers in completing the application process through the IRAS system.

Introduction to IRAS

Set up account-This only takes a few minutes and is done through the create account section of the website. Alternatively if you have in the past used NRES on line application you will be able to use your NRES log in details to access IRAS

E-learning module- New users are advised to use the free online training tool to familiarise themselves with the layout, functionality and navigation that is available in IRAS.

Project Filter- will help with the data according to the type of research project, importantly disabling sections which are not relevant

Project Data- contains the questions and sections that need completing for all of the forms that you need to submit. Please note you would need to submit separate application forms and not the integrated dataset. It is recommended to complete your data in the project data section as this will populate all your forms.

Submitting forms- Once a specific application form is selected, the tabs and questions shown on the right hand side of the navigation page will be specific to that particular application. This also includes the submission instructions and the checklist for that particular application

The **'Help section'** in IRAS contains all the guidance.
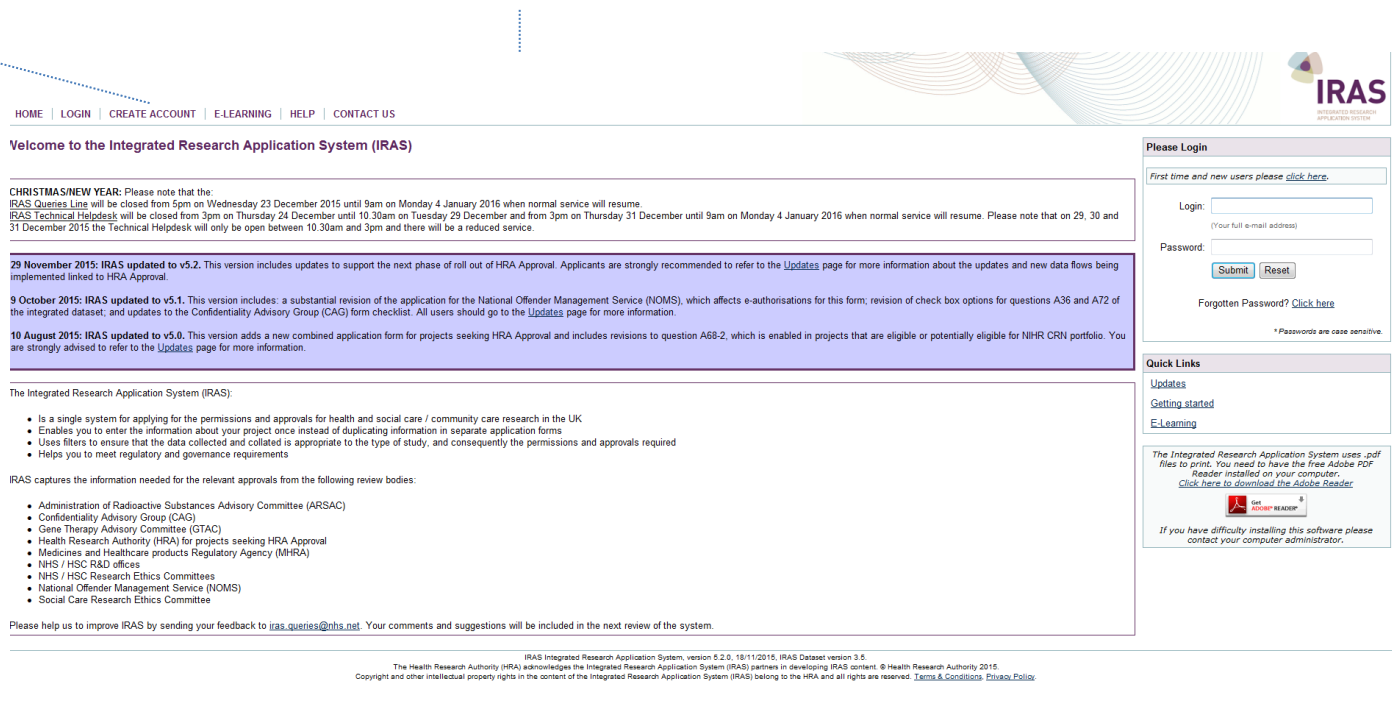
1. HOW DO I GET STARTED ON IRAS

IRAS can be accessed from the following website link: www.myresearchproject.org.uk

Once the above link is followed it should take you to the home page of IRAS as displayed below. In order to use IRAS you would need to register and open an account following the instructions below:

IRAS Home Page

1. If you do not already have an account with IRAS, Select the create account tab to create a new account on IRAS and begin using the system

2. Fill out the registration form and ensure all the information is entered thoroughly completing all the fields and press register.

Remember: Although the IRAS account will be created following completion of the registration process, it is important to activate your account. Check your email inbox (that you signed up with) and click the link in it to be taken to the activation page. Once you are at the activation page simply enter the activation code that has been emailed to you and press Submit.

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2. LOG IN PAGE

IRAS Home Page, log-in box (top-right corner of webpage)

If you would like to undertake e-learning training on IRAS this can be accessed from this link

If you have forgotten your password you can get a reminder by using the 'Forgotten Password' link that can be found just below the login input boxes.

3. NAVIGATING ON THE IRAS SYSTEM
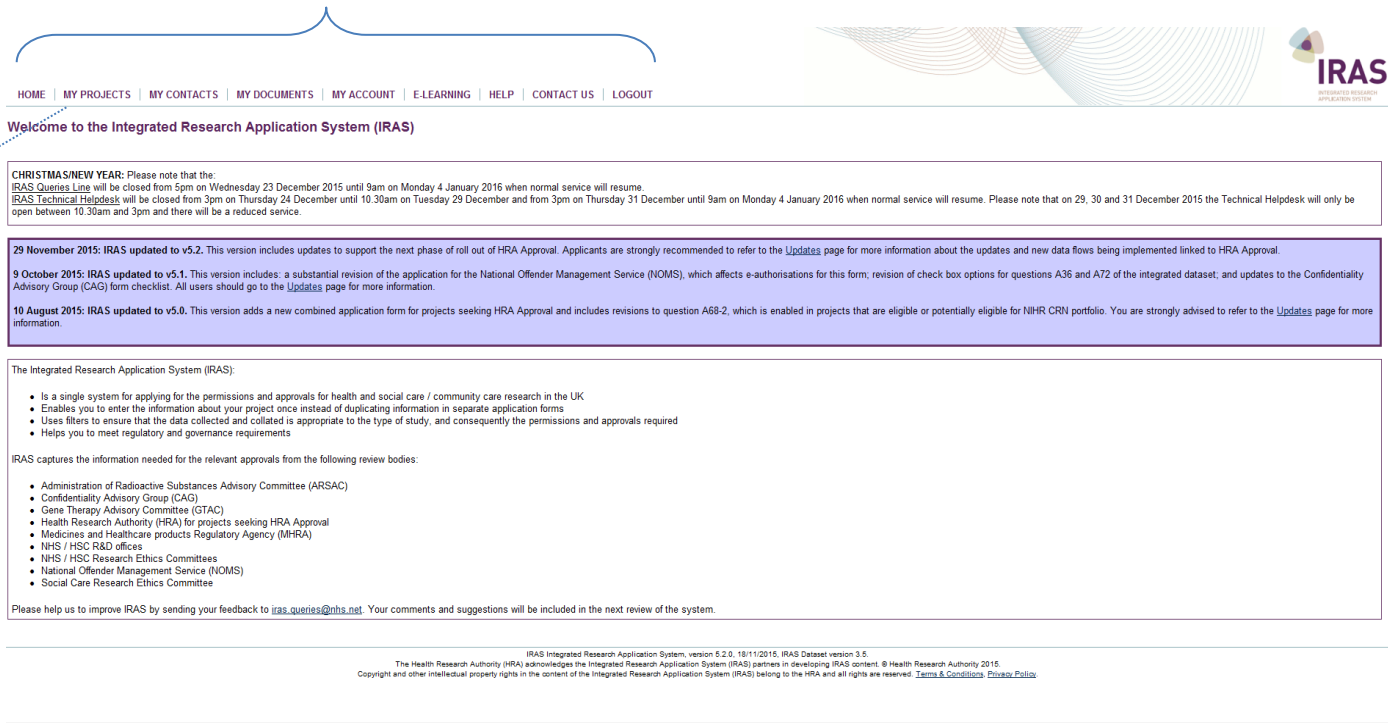
IRAS is a web based database and can be accessed via the following URL (web address): https://www.myresearchproject.org.uk/

The image below is home page of IRAS and provides the user with a few options or categories to navigate. Generally whenever a user logs in to the system they will be taken to this page.

1. At the top of the Home page you will see a number of categories (tabs)

Once you have logged in you will be taken to the IRAS home page:

2. We will begin by clicking the My Projects tab

How do I create a new project? Once on the IRAS home page click my project tab this should take you to the new project section. In this section there will be a number of questions related to your project, the questions will depend on your answers and will be populated as you progress through the IRAS application. A typical example if your research is a CTIMP clinical Trial all the questions asked by the system will relate to a clinical trial.

2. Import | This button is used to import XML files if you press this tab it will take you to another page where it becomes possible to upload XML* files

***** An **.XML** file is a software- and hardware-independent tool for storing and transporting data. Once this file is uploaded on the R&D system it automatically populates general information which saves time and duplication

1. New Project | In order to create a new project you would need to click this tab which will lead to completing an IRAS form

3. Projects | If you go to this tab it will show your projects (title, date created etc.)

4. Project Search | All your projects can be searched by title and will be listed in this section

HOME | MY PROJECTS | MY CONTACTS | MY DOCUMENTS | MY ACCOUNT | E-LEARNING | HELP | CONTACT US | LOGOUT

My Projects

Project Categories	New Project	New Minimal Dataset	Import
New Projects (4)	Create new IRAS Project	Create minimal dataset for pre-IRAS project	Import IRAS or EudraCT Form XML

Manage Project Categories

Projects | Project Search | Requests for Authorisation (0) | Authorisation history

Project Title	IRAS Project ID ▼	Created On	Status	Last Opened
Not named yet	197194	01/12/2015	Active	01/12/2015
Not named yet	197193	01/12/2015	Active	01/12/2015
Not named yet	196942	27/11/2015	Active	01/12/2015
Not named yet	196936	27/11/2015	Active	27/11/2015

◄◄ ◄ 1 ► ►◄   Page size: 20   4 items in 1 pages

5. Requests for authorization | In order to use electronic authorisation you would need to know the email of the person responsible for authorising. They would also need to have an IRAS account, you would need to use the email they registered on IRAS.
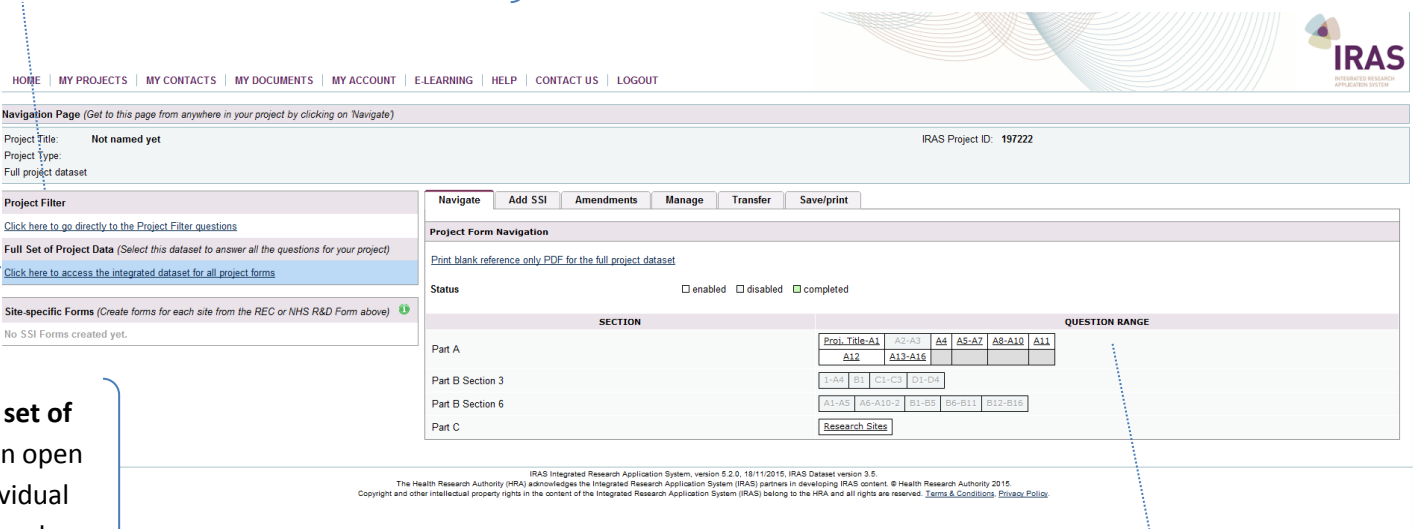
As you progress through the IRAS system and answer various questions related to your research project additional forms will be developed. These forms are automatically generated and then can be found in the full set of project data section.

1. The **project filter** questions determine which approvals are needed, what information you need to provide to complete all approval forms and finally determine which declarations are required to be signed and submitted

2. **Title and type** of project

3. This shows the **full set of project data***, you can open project filter and individual project data forms from here

*The **full set of project data** provides a single location where you can add all the project information and IRAS can populate all the necessary forms for you. Completing the project data will also help large part of the SSI Site Specific form to be completed which would need to be finalised at each research site.

4. **Question Range**| Here is where you will find all the questions that need to be answered for the full project

This section provides information on how to prepare and submit your application for HRA Approval. The Integrated Research Application System (IRAS) will be used when applying for HRA Approval. Research Studies which go through the HRA approval process will not require SSI forms. Further information for HRA Approval process can be obtained from: http://www.hra.nhs.uk/resources/hra-approval-applicant-guidance/applying-for-hra-approval/

1. At Question 4 in the Project Filter select the option for HRA Approval. Note when you select this option the remaining options for separate application forms for NHS R&D and NHS Research Ethics Committee will disappear.

2. When the project filter is completed, click on Navigate. You will notice that on the Navigation Page for your project in IRAS, under the Project Forms list, there is a form labelled 'IRAS Form'. This is the application form that you will need to electronically submit to apply for HRA Approval. There will be no separate REC and R&D application forms.

3. Complete your dataset and prepare your supporting documentation as usual. Your application to the HRA may need to include the Statement of Activities and Schedule of Events, for each type of site in your study. Where this is required, please include each document in a new row in the 'other' section of the Checklist by using the 'add new row' button.

4. When you are ready to submit, select your IRAS Form and carefully review it to ensure that it is complete. Please note supporting documentation for your application is electronically submitted alongside your application form by uploading all the files to the relevant rows on the Checklist tab of your IRAS Form. Obtain the required electronic authorisations for the IRAS Form, by selecting the Authorisations tab for the form and following the instructions provided

5. Before electronically submitting your application for HRA Approval you need to contact the Central Booking Service (CBS). You need to complete this step for all studies applying for HRA Approval. You will receive an email confirming that your application has been booked for HRA Approval. You should enter the booking information on the first page of the IRAS Form.
   IMPORTANT NOTE: Do not amend any other part of the IRAS Form as this will invalidate your electronic authorisations.

6. On the E-submission tab for the IRAS Form you should click the button to electronically submit your application for HRA Approval. You are expected to do this the same day that you book your application via CBS. This will submit your IRAS Form and the supporting documentation you uploaded to the Checklist. Confirmation of your submission will appear in the Submission History area at the bottom of the E-submission tab.

The IRAS database allows you to transfer forms to other users that have registered accounts on the IRAS system.

1. In order to perform this task select a form and click on the 'Transfer' tab, insert the email address of the user you wish to transfer the IRAS form.

   Please note: the system cannot transfer to a person without an IRAS account as the form is not emailed – it is transferred securely within the IRAS system.

   Transfer this REC form to another user

   Please enter the recipient's e-mail address in the box below
   In order to transfer this form to an e-mail address the recipient must have an account on the system.

   [   ]   << Transfer To User

2. The person receiving the form will receive an email saying you are trying to transfer a form to them. When they log onto their account, they will see the form pending transfer in their form list.

   My Projects

   ◆ New Projects (3)   ◆ Archive (0)   ◆ Test Category (0)

   Manage Project Categories

   Create New Project   Import IRAS/EudraCT Form XML

Project Title	Created On	Status	Action
Version 2 IRAS Project	12/12/2008	NHS REC Form: Transferred In >> PENDING <<	Open Project
auth test	23/09/2008	Active	Open Project
Not named yet	29/01/2008	Active	Open Project

   Create New Project   Import IRAS/EudraCT Form XML

3. Once the transfer button is pressed a number of tabs will disappear, because you cannot edit a form unless you have full control over it. As an owner of the form you can always reclaim it by clicking on the transfer tab then clicking the 'Retrieve Application' button. This should immediately return the form to your control.

4. The user receiving the form will be given the option to either accept or reject the transfer after clicking on the open project link; if they reject the form it will be returned your control.

   In most cases forms can only be transferred by the original owner, if a form must go to more than one person the form should be returned to the original owner and then the owner can transfer to the next person.

   Transfer

   Accept REC form

   This form is being transferred to you by Rachel Cummings.

   >> Accept <<   /   Reject

MY PROJECTS | ELECTRONIC AUTHORISATION

1. On the main Navigation page select the relevant form that requires authorisation from the links under the **project forms** box
2. Select the **authorisation tab**; this will indicate all the authorisations that are required for that form for that particular project
3. Once the relevant authorisation has been decided press the request button
4. Following pressing the request button the applicant needs to enter email address of the authoriser and click 'Send Request'. The tab should now show the authorisation that has been requested. Please note that the authoriser MUST have an account on IRAS and you must use the e−mail address that they used to register their IRAS account.
5. The authoriser will receive an email from IRAS requesting they authorise the form, with a link to log in
6. When the authoriser logs into IRAS the main project page will now contain a 'Requests for Authorisation' section below any projects they own
7. Once the authoriser open's the request it will take them to main navigation page which will show the relevant form. Only the authorisation will be visible showing details of the authorisation required
8. The authoriser will review the form and grant authorisation, when authorise form is selected they would need to enter there user name and password which will allow an electronic signature
9. Once the above step has been completed by the Authoriser the applicant will receive an email from IRAS confirming authorisation. The declaration section will now contain the text: "This section was signed electronically by [name] on [date, time]". Alternatively the authoriser may decide to reject the request; the applicant will receive an email informing them the request was rejected.

In order to submit your form, you will need to click on the "proceed to submission" button and follow the on-screen instructions. You also have the opportunity to check you have completed all the relevant sections of the form using the "check your form" button.

It is very important to answer the project filter questions correctly as this will determine which forms will be generated by IRAS. If you have any queries about the project filter please contact the R&D department.

Once you have clicked the "proceed to submission" button, you should have the option to **save the submitted form as a .PDF and .XML file.**

An easy way to obtain these is to scroll down to the bottom of the Submission page, where you will see links to "save as PDF" and "save as XML".

An .XML file is beneficial for the Research and Innovation department in addition to the .PDF as it is compatible with our database. Once we upload the file on our system it will automatically populate general information relating to your research project.

5. MY CONTACTS

In this section an opportunity has been given to insert a list of all your regular contacts. These contacts would only be useful if they have existing IRAS accounts. Once the SSI form is completed it can be transferred to the sponsor, principle investigator, chief investigator or any other authorised person to sign the declaration section.

1. My contacts, you can insert a list of all your regular contacts on this page

2. Additional contacts can be added using this button

3. The following link is used if the existing contacts list needs editing or updating
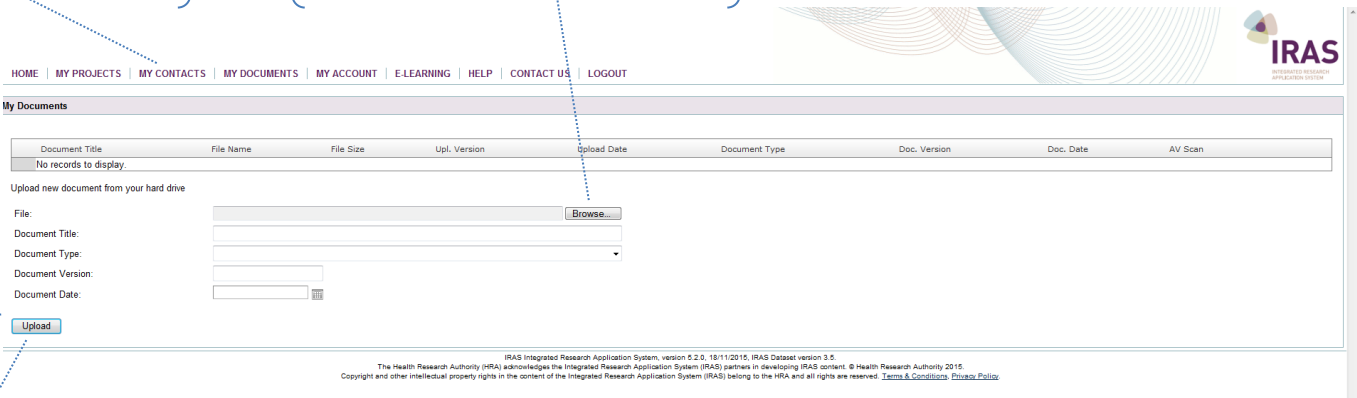
6. MY DOCUMENTS

Once documents have been uploaded on the IRAS system they can be seen by Chief investigator and the Research Ethics Committee. In order to upload documents you would need to go to my projects you will see a number of projects listed on the left hand side click the project in question there will be an import tab on the right hand side once this is clicked it will take you to Browser where documents can be uploaded with version numbers and dates

1. My Documents |This section is used to upload documents relating to your project

2. Browse | If you use the browser to locate documents these can then be uploaded

3. Documents can also be titled, dated and versioned

4. Remember to press the upload button once you have completed the necessary information

1. Amendments must be submitted electronically through IRAS. Go to the Navigation page for the R&D form, where you will find the checklist tab, ensuring the project title is associated with the Amendment application you are preparing for submission

Amendments:			
Notice of Substantial Amendment (signed/authorised)	nosa1	Yes	
Notice of Substantial Amendment XML file	nosa1xml	Yes	

2. Amendment documents should be attached to the relevant rows of the IRAS checklist. You must ensure correct document categories are selected

Document	Subtitle	Enclosed	Date	Version	Office Use	Reason not supplied		
Project Information: (All documents must be dated and/or have version numbers)								
Research protocol or project proposal		No						
Participant information sheet (PIS)		No						

3. To attach a file to the checklist, click on the paperclip symbol

Add Document

Browse for a file on your hard drive or select from your already uploaded documents

Add document from: ⦿ Hard drive ◯ My Documents ◯ Project Documents

File: (Choose File) no file selected

Document Title : _____

Document type: Research protocol or project proposal ▼

Document Version: _____

Document Date: _____ 🔲

(Upload document)

4. This will open a document window as below where you can select which document to upload and provide a description

Please note: Once the click upload button has been made a summary of details will be shown, an Anti-virus scan will run before you can click the close button and upload other documents.

You can import or export XML and PDF files into the system by clicking on the 'Import IRAS Form XML' button on the 'My Projects' page

1. Upload File | Once you reach this page you will need to select a file from your local file storage area. This file MUST be a valid IRAS XML export or the import will not succeed. You need to select the file by clicking the 'Browse' button and then using the file explorer box to find the target file.

2. Import Options | The next step will ask to verify what type of data you are importing. You have the option to import the main project information or a specific SSI. If you select to import the Project, a new Project will be created and inserted at the top of your Project list. If you select to import only SSI information, you will be asked which Project you wish to attach the SSI Form to.

3. Once you have completed this stage you will have one more chance to cancel the import before completing it.

4. The import process is complete.

9. EXPORTING PDF AND XML FILES

Export XML

IRAS will allow you to export your project data into XML for import into other systems so that data does not have to be re–typed when data is moved from system to system. There are a number of areas on the system where you can export your data:

1. Integrated Dataset: If you wish to export the full set of data for your project, this is best done from by selecting the Integrated Dataset. Then, on the Project Index/Navigation page, select the 'Manage' tab – and click the 'Export Project Data to XML' link. When exporting XML, you will then be able to choose which parts of your data to export. You can either export the main project data or the main project data and SSI data, or just the SSI data. If you do not have any SSI forms raised, you will not be able to select the SSI checkbox. Once you have selected the appropriate check boxes click 'Export' and the XML will be downloaded to your computer.
2. Form Submission Tab: When a form is submitted, a snapshot is created of the data at the time of submission. A list of these submissions, a print copy of the submission and a copy of the XML are all available. To get the XML for any specific submission simply click on the 'Save as XML' link in the appropriate row. You will have less export options when exporting from the submissions tab of a form – as the data relates specifically to that form and not the entire project.

During the download process you will be given the option to Open or Save the file. If you open it, it will open directly in your browser. If you are planning to send it to someone else, then you should save it to your hard drive and then send them the file. You should not edit this file by hand unless you know the full implications of doing so.

10. MY ACCOUNT

1. My Account |You will find all your personal information in this section

2. This information can also be edited or changed at any time

3. Ensure all the information is saved before you leave this page

E Learning

Help

Contact Us

Log Out

- There is an online training course on how to use the IRAS system

- The IRAS team can be contacted for help and queries

- The final tab is used to log out of the IRAS system

DOCUMENT VERSION CONTROL

Author/Editor	Version	Date	Details of changes made
Mohammed Khan	1.0	04/12/15	Original draft for R&I Consultation
Mohammed Khan	2.0	17/12/15	Additional information to each section
Mohammed Khan	3.0	27/01/16	Following consultation inserted additional information
Mohammed Khan	3.5	13/05/16	Included HRA Approval process
Mobeen Fazal	4.0	13/05/16	Edited formatting and some text