

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

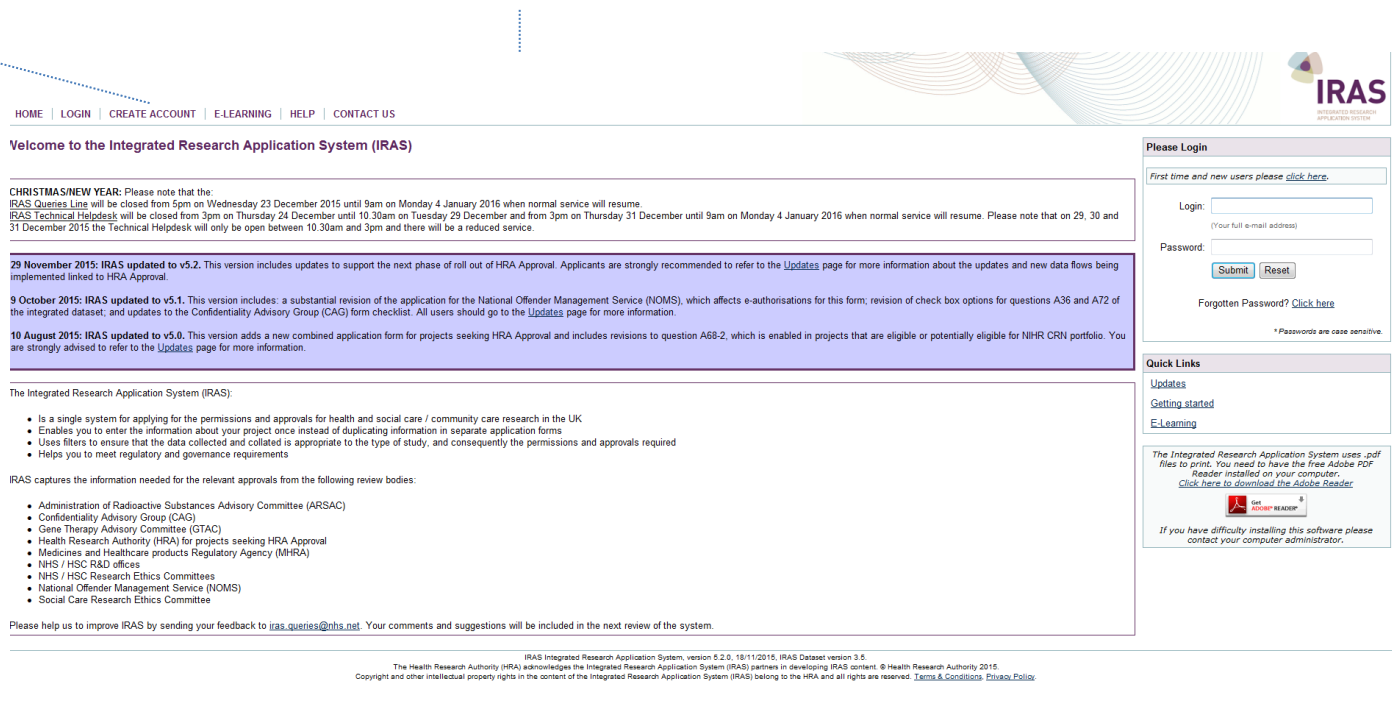
IRAS can be accessed from the following website link: www.myresearchproject.org.uk

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.



The screenshot shows the IRAS Home Page. At the top, there is a navigation bar with links: HOME | LOGIN | CREATE ACCOUNT | E-LEARNING | HELP | CONTACT US. Below this is a welcome message: "Welcome to the Integrated Research Application System (IRAS)".

There are several news items and updates listed:

- CHRISTMAS/NEW YEAR:** Please note that the IRAS Queues Line will be closed from 5pm on Wednesday 23 December 2015 until 9am on Monday 4 January 2016 when normal service will resume. IRAS Technical Helpdesk will be closed from 3pm on Thursday 24 December until 10.30am on Tuesday 29 December and from 3pm on Thursday 31 December until 9am on Monday 4 January 2016 when normal service will resume. Please note that on 29, 30 and 31 December 2015 the Technical Helpdesk will only be open between 10.30am and 3pm and there will be a reduced service.
- 29 November 2015:** IRAS updated to v5.2. This version includes updates to support the next phase of roll out of HRA Approval. Applicants are strongly recommended to refer to the [Updates](#) page for more information about the updates and new data flows being implemented linked to HRA Approval.
- 9 October 2015:** IRAS updated to v5.1. This version includes: a substantial revision of the application for the National Offender Management Service (NOMS), which affects e-authorisations for this form; revision of check box options for questions A36 and A72 of the integrated dataset; and updates to the Confidentiality Advisory Group (CAG) form checklist. All users should go to the [Updates](#) page for more information.
- 10 August 2015:** IRAS updated to v5.0. This version adds a new combined application form for projects seeking HRA Approval and includes revisions to question A68-2, which is enabled in projects that are eligible or potentially eligible for NIHR CRN portfolio. You are strongly advised to refer to the [Updates](#) page for more information.

The Integrated Research Application System (IRAS):

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

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

- Administration of Radioactive Substances Advisory Committee (ARSAC)
- Confidentiality Advisory Group (CAG)
- Gene Therapy Advisory Committee (GTAC)
- Health Research Authority (HRA) for projects seeking HRA Approval
- Medicines and Healthcare products Regulatory Agency (MHRA)
- NHS / HSC R&D offices
- NHS / HSC Research Ethics Committees
- 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. Your comments and suggestions will be included in the next review of the system.

At the bottom, there is a footer with the following text:

IRAS Integrated Research Application System, version 5.2.0, 18/11/2015, IRAS Dataset version 3.5.
The Health Research Authority (HRA) acknowledges the Integrated Research Application System (IRAS) partners in developing IRAS content. © Health Research Authority 2015.
Copyright and other intellectual property rights in the content of the Integrated Research Application System (IRAS) belong to the HRA and all rights are reserved. [Terms & Conditions](#) [Privacy Policy](#)

On the right side of the page, there is a "Please Login" section with fields for "First time and new users please [click here](#).", "Login:" (with a note "(Your full e-mail address)"), and "Password:". There are "Submit" and "Reset" buttons. Below this is a link for "Forgotten Password? [Click here](#)". A note states: "* Passwords are case sensitive."

Below the login section is a "Quick Links" section with links for "Updates", "Getting started", and "E-Learning".

At the bottom right, there is a note: "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](#)." Below this is an Adobe Reader logo and a note: "If you have difficulty installing this software please contact your computer administrator."

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.

2. LOG IN PAGE

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



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.

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

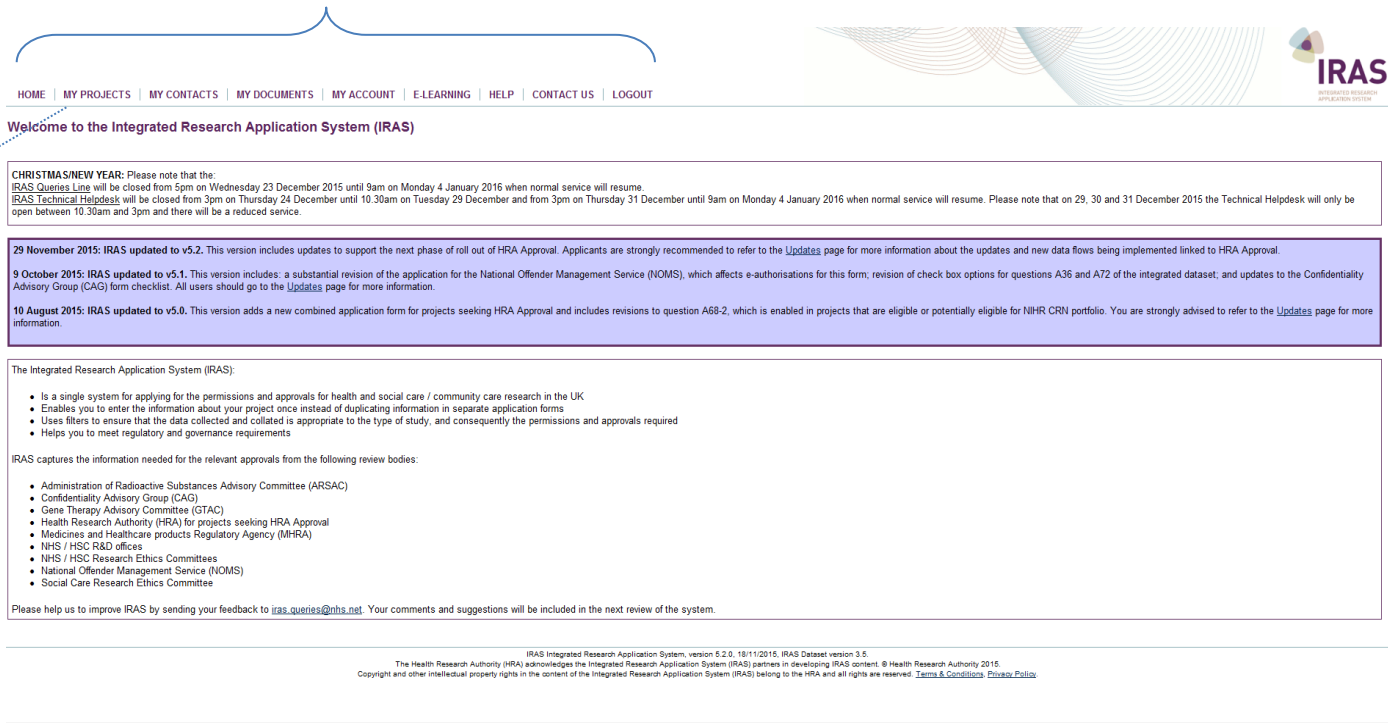
IRAS is a web based database and can be accessed via the following URL (web address): <https://www.myresearchproject.org.uk/>

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



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

Welcome to the Integrated Research Application System (IRAS)

CHRISTMAS/NEW YEAR: Please note that the IRAS Queries Line will be closed from 5pm on Wednesday 23 December 2015 until 9am on Monday 4 January 2016 when normal service will resume. IRAS Technical Helpdesk will be closed from 3pm on Thursday 24 December until 10.30am on Tuesday 29 December and from 3pm on Thursday 31 December until 9am on Monday 4 January 2016 when normal service will resume. Please note that on 29, 30 and 31 December 2015 the Technical Helpdesk will only be open between 10.30am and 3pm and there will be a reduced service.

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- Social Care Research Ethics Committee

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

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4. MY PROJECTS PAGE

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.

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

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

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

The screenshot shows the 'My Projects' page in the IRAS system. At the top, there is a navigation bar with links: HOME, MY PROJECTS, MY CONTACTS, MY DOCUMENTS, MY ACCOUNT, E-LEARNING, HELP, CONTACT US, and LOGOUT. Below this, the 'My Projects' section has three buttons: 'New Project' (Create new IRAS Project), 'New Minimal Dataset' (Create minimal dataset for pre-IRAS project), and 'Import' (Import IRAS or EudraCT Form XML). On the left, there is a 'Project Categories' sidebar with 'New Projects (4)' and a 'Manage Project Categories' link. The main area has tabs for 'Projects', 'Project Search', 'Requests for Authorisation (0)', and 'Authorisation history'. The 'Projects' tab is active, showing a table of projects. The table has columns: Project Title, IRAS Project ID, Created On, Status, and Last Opened. There are four rows of data, all with 'Not named yet' as the title. Below the table, there are navigation controls (back, forward, first, last) and a 'Page size: 20' dropdown. At the bottom right, it says '4 items in 1 pages'. At the very bottom, there is a footer with version information and copyright notices.

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

Page size: 20
4 items in 1 pages

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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.

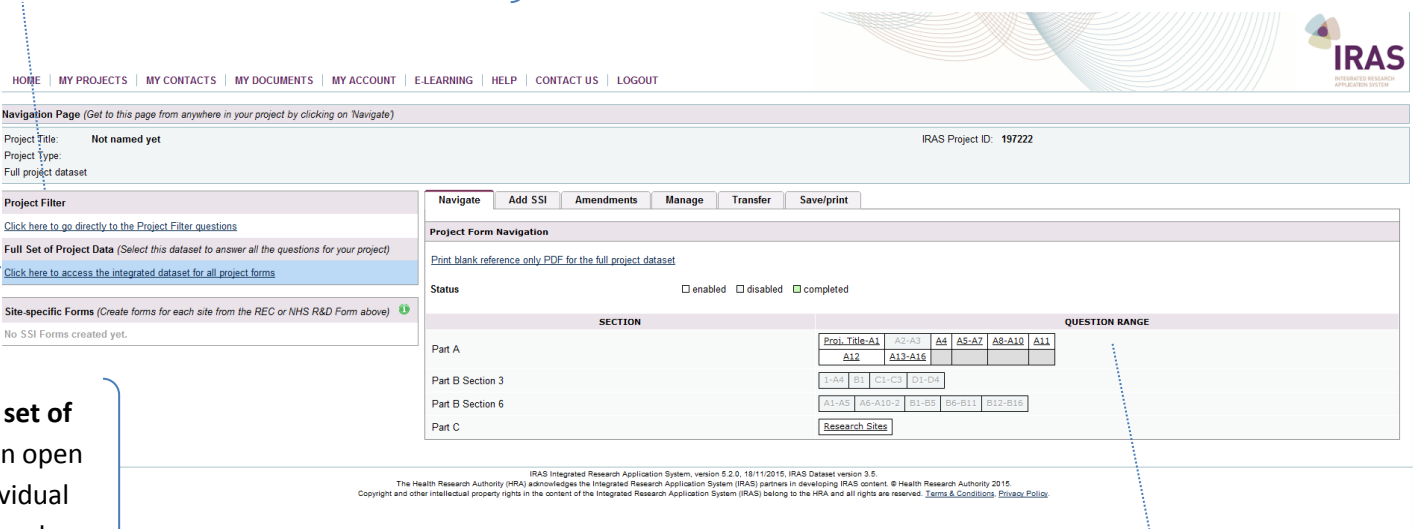
MY PROJECTS | PROJECT FILTER

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



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

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

Project Title: Not named yet IRAS Project ID: 197222


Project Type: 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](#)

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

No SSI Forms created yet.

Navigation Add SSI Amendments Manage Transfer Save/print

Project Form Navigation

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

Status ☐ enabled ☐ disabled ☒ completed

SECTION	QUESTION RANGE
Part A	Proj. Title-A1 A2-A3 A4 A5-A7 A8-A10 A11 A12 A13-A16
Part B Section 3	1-A4 B1 C1-C5 D1-D4
Part B Section 6	A1-A3 A5-A10-2 B1-B5 B6-B11 B12-B16
Part C	Research Sites

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

*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.

MY PROJECTS | HRA APPROVAL ROUTE

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.

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

☒ England
☒ Scotland
☒ Wales
☐ Northern Ireland

3a. In which country of the UK will the lead NHS R&D office be located:

☒ England
☐ Scotland
☐ Wales
☐ Northern Ireland
☐ This study does not involve the NHS

4. Which review bodies are you applying to?

☒ HRA Approval
☐ NHS/HSC Research and Development offices
☐ Social Care Research Ethics Committee
☐ Research Ethics Committee
☐ Medicines and Healthcare products Regulatory Agency (MHRA) – Medicines
☐ Gene Therapy Advisory Committee (GTAC)
☐ Confidentiality Advisory Group (CAG)
☐ National Offender Management Service (NOMS) (Prisons & Probation)

For NHS/HSC R&D offices, the CJ must create Site-Specific Information Forms for each site, in addition to the study-wide forms, and transfer them to the PIs or local collaborators.

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

☒ Yes ☐ No

5a. Are all the research costs and infrastructure costs for this study provided by an NIHR Biomedical Research Centre, NIHR Biomedical Research Unit, NIHR Collaboration for Leadership in Health Research and Care (CLAHRC) or NIHR Research Centre for Patient Safety & Service Quality in all study sites?

MY PROJECTS | HOW TO TRANSFER IRAS FORMS

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.

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.

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 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

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

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 opens 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 their 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.

Navigation Page

Project Title: Electronic authorisation test
Project Type: Other clinical trial or investigation
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

Click here to access the integrated dataset for this project

Project Forms

NHS REC Form

NHS RAD Form

Navigation: Add SSI Checklist **Authorisations** Submission Amendments Transfer

Gather electronic authorisations for this NHS/HSC R&D form

The following electronic authorisations are available for this form type

Authorisation Type	Status	Signing User	Action
Sponsor's representative	Not requested		Request Sign
Chief Investigator	Not requested		Request Sign

Navigation Page

Project Title: Electronic authorisations test
Project Type: Clinical trial of an investigational medicinal product
Application to: Research Ethics Committee

Project Filter

Click here to go directly to the Project Filter questions

Project Forms

NHS REC Form

NHS RAD Form

SSI Forms

12HS SSI - 1343 (No PI typed /No research organisation typed)

Navigation: **Authorisations**

Electronic authorisations requested for this REC form

A request for authorisation was sent by [Iras Testing Account](#) on 08/05/2008 06:09 that you sign this form as Sponsor's representative

[Sign data](#) [Reject Request](#)

IRAS Integrated Research Application System, version 1.0.0

MY PROJECTS | SUBMISSION

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.

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

Title: VX14-806-109 Cystic Fibrosis
Type: Clinical trial of an investigational medicinal product
App to: NHS/HSC R&D Office
IRAS Project ID: 182411

Navigation: Navigate | Checklist | **Submission** | Manage | Transfer | Authorisations | Save/print

Submission of SSI Form

Check your form
Please use the button below to check whether all questions in your form are answered and marked as complete.
[Check your form](#)

Obtain electronic authorisations
If you wish to use the [electronic authorisation](#) functionality as an alternative to ink signature, you must obtain the authorisation(s) before you click on the Proceed to Submission button below. A record of the authorisation(s) will then be visible on the application form.

Proceed to submission
Now click on the button below to save and print your form for submission. This final version will have a unique submission code added to the footer. A copy of the form will be saved in your submission history at the foot of this page.
Clicking the button does not send your form electronically. Please read the instructions below the button for guidance on sending your application to R&D offices.
[Proceed to submission](#)

Submitting applications to NHS R&D offices
The SSI Form should be included with all applications to R&D offices for management permission for research.
Applications should be made to NHS R&D offices at each site in the research. Contact details for R&D offices are available at <http://www.crforum.nhs.uk>.
Please send a disk to the R&D office containing one file for each document. Application form files should be saved in both pdf and XML format.
Where signed documents are required, please send either a hard copy, a faxed copy or a scanned electronic file. Check that the submission code appears at the foot of each page of the application form before sending. It is acceptable to send hard copies of signature pages separately, as long as the submission code is the same as on the electronic version.
All letters must be dated. All other accompanying documents must bear version numbers and dates.
When sending hard copies, please do NOT staple documents as they may need to be photocopied.
[Open the checklist for this application](#)

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

Forms (read-only)
[SC Form](#)
[SC R&D Form \(project information\)](#)
[Electronic Forms](#)
[NHS R&D Form \(SSI\) - Dr Timothy Lee \(Leeds General Infirmary\)](#)

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

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

IRAS

INTEGRATED RESEARCH APPLICATION SYSTEM

My Contacts

Sorting by Last Name | Show All contacts | or starting with A B C D E F G H I J K L M N O P Q R S T U V W X Y Z

or Search for: | in All

Contact List

Title	First Name	Last Name	Research Role	Organisation	Position	E-mail
No records to display.						

Add contact

Legend: Edit Contact details Expand row

IRAS Integrated Research Application System, version 5.2.0, 18/11/2015, IRAS Dataset version 3.5.

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2. Additional contacts can be added using this button

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

Page | 12

v4.0, 13 May 2016

6. MY DOCUMENTS

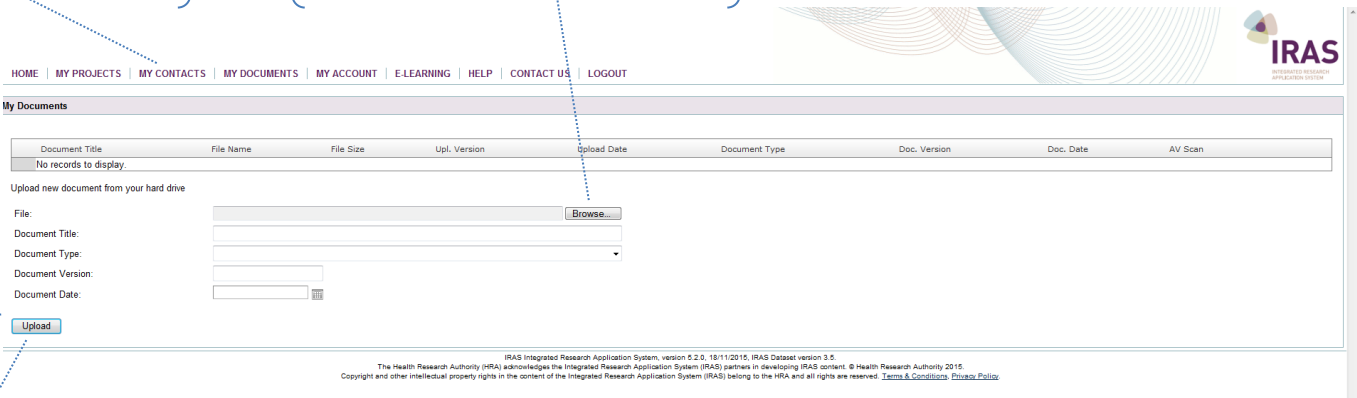
Once documents have been uploaded on the IRAS system they can be seen by Chief investigator and the Research Ethics Committee. In order to upload documents you would need to go to my projects you will see a number of projects listed on the left hand side click the project in question there will be an 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



7. SUBMITTING AMENDMENTS VIA IRAS

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

Project Title: **Demo**
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](#)

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

NHS/HSC R&D Form Navigation

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

Project Title: **Demo**
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)

[NHS REC Form](#)

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


Navigate **Add SSI** **Checklist**

NHS/HSC R&D submission checklist



IMPORTANT: This checklist supports an application from IRAS to the review body.

You must attach your supporting document






Instructions for attaching files:

1. Click on the file upload symbol  in the **Supporting Document** section where you can select the document to upload.
2. Select where you want to upload the document and click the button immediately below to open your file explorer.

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	nosa1.xml	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.

8. IMPORTING PDF AND XML FILES

HOME | MY PROJECTS | MY CONTACTS | MY ACCOUNT | LOGOUT | HELP | CONTACT US

My Projects

New Projects (3) | My Archived Projects (0)

Create New Project | **Import IRAS/EudraCT Form XML** | Manage Project Categories

Project Title	Created On	Status	Action
Version 2 IRAS Project	12/12/2008	Active	Open Project
CSP Test	13/06/2008	Active	Open Project
My PA Research Project	14/03/2008	Active	Open Project

Create New Project | Import IRAS/EudraCT Form XML

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

XML Data Import

STEP 1 - Upload File

Browse for an IRAS/EudraCT Form XML file and then press the "Upload" button.

Browse...

Upload Cancel

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.

Xml Import

STEP 2 - Import Options

File Name: IRAS_Export.xml
Import Type: IRAS xml import
Project Title: Version 2 IRAS Project
SSA Form - 1: No PI typed (No research organisation typed)

☒ The xml data will be imported as a new IRAS project and will appear at the top of the list
☐ Select one or more site-specific forms to add to an existing IRAS project

Next Step Cancel Import

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.

Xml Import

STEP 2 - Import Options

File Name:	IRAS_Export.xml
Import Type:	IRAS xml import
Project Title:	Version 2 IRAS Project
SSA Form - 1	No PI typed (No research organisation typed)

☐ The xml data will be imported as a new IRAS project and will appear at the top of the list.
☒ Select one or more site-specific forms to add to an existing IRAS project

Choose one or more SSA forms to add to a form
☒ No PI typed (No research organisation typed)

Choose a form

Version 2 IRAS Project
Version 2 IRAS Project
USP Test
My PA Research Project

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

Xml Import

STEP 3 - Import

File Name:	IRAS_Export.xml
Import Type:	IRAS xml import
Project Title:	Version 2 IRAS Project
SSA Form - 1	No PI typed (No research organisation typed)

The following actions will be performed:
Import the xml data as a new IRAS project.

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

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

My Account Information

[Edit Account](#)
[Edit CV](#)
[Edit Preferences](#)

Title

Forename

Surname

Organisation

E-mail Address (User Login)

New Password

Confirm Password

* Password must be at least 8 characters.

Strength:

Mailing address

Town

County

Postcode

Country

Telephone Number

34 Hyde Terrace,

Leeds

West Yorkshire

LS2 9LN

United Kingdom

01133920158

* County is applicable for UK residents only.

[Save](#)

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