

A step by step guide to using IRAS to apply to conduct research in or through the NHS/HSC.

28 June 2018

Summary

All project-based research conducted in or through the NHS/HSC in England, Northern Ireland, Scotland and/or Wales use the 'IRAS Form' to seek:

- HRA and HCRW Approval for research led from England or Wales.
- NHS/HSC R&D Permission and NHS REC review (where required) for research led from Northern Ireland or Scotland.

! Project-based research includes research that fits any of the IRAS Filter Question 2 categories *except* Research Tissue Banks and Research Databases.

! The IRAS Form and information in this guide only applies to research conducted in or through the NHS/HSC.

IMPORTANT NOTE: From 28 June 2018 the process for submitting the IRAS Form is the same regardless of whether or not your project needs NHS REC review or which of the UK nations the lead NHS/HSC R&D office is in. From this date all applications using the IRAS Form use a single electronic submission.

If you created your project in IRAS prior to 28 June 2018 you may need to follow slightly different instructions; please refer to the section provided for more information.

This step by step guide is divided into sections. Please refer to the section that applies to your project:

- **Research led from England, Northern Ireland, Scotland or Wales: Using the IRAS Form**
- **Projects created prior to 28 June 2018**

Research led from England, Northern Ireland, Scotland or Wales: single electronic submission of the IRAS Form

Prepare your application:

! Your application must be prepared in [IRAS](#).

1. Fully complete your project filter in IRAS.

- At filter question 3 tick the boxes to indicate all countries where the research sites will be located and in question 3a click the radio button to indicate where the lead NHS/HSC R&D office will be located.

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

- At filter question 4 ensure you select the option for “IRAS Form”. You should also select any other applications that are needed for your research project.

4. Which applications do you require?

 IRAS Form 
 Medicines and Healthcare products Regulatory Agency (MHRA) – Medicines 
 Confidentiality Advisory Group (CAG) 
 Her Majesty's Prison and Probation Service (HMPPS) 

- At filter question 5 confirm NHS/HSC involvement in your project by selecting ‘yes’.

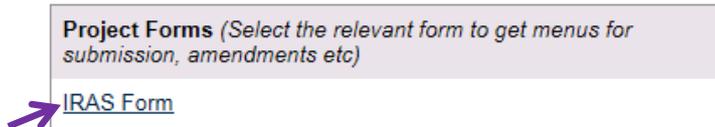
5. Will any research sites in this study be NHS organisations? 

 Yes No

Tip >> When you select ‘IRAS Form’ the options for separate applications to ‘NHS/HSC Research and Development’ and ‘Research Ethics Committee’ will be disabled if they were initially available for selection.

Tip >> Ensure that you complete all the filter questions as accurately as possible for your study. This will ensure you enable appropriate further options and forms. Please refer to the question specific guidance (click the  icons) for further information and to help you select appropriate options and complete your dataset.

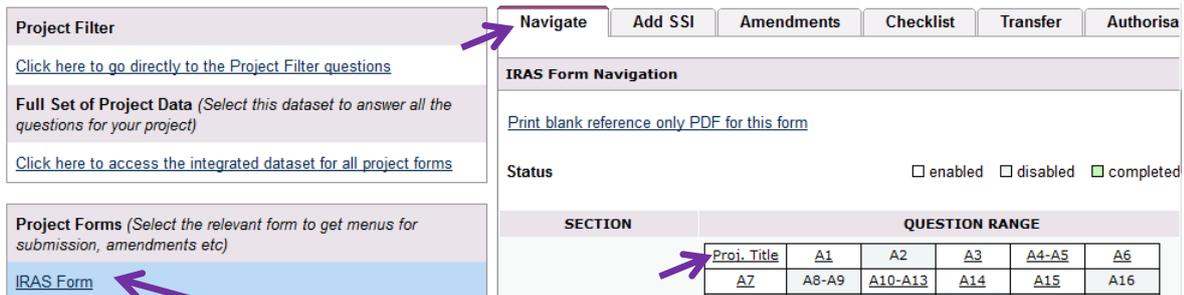
2. When you go to the Navigation Page, your application will appear in the Project Forms list labelled as “IRAS Form”.



Tip >> Remember when you use the IRAS Form you will not have separate NHS R&D and NHS REC Form applications.

3. Complete your dataset

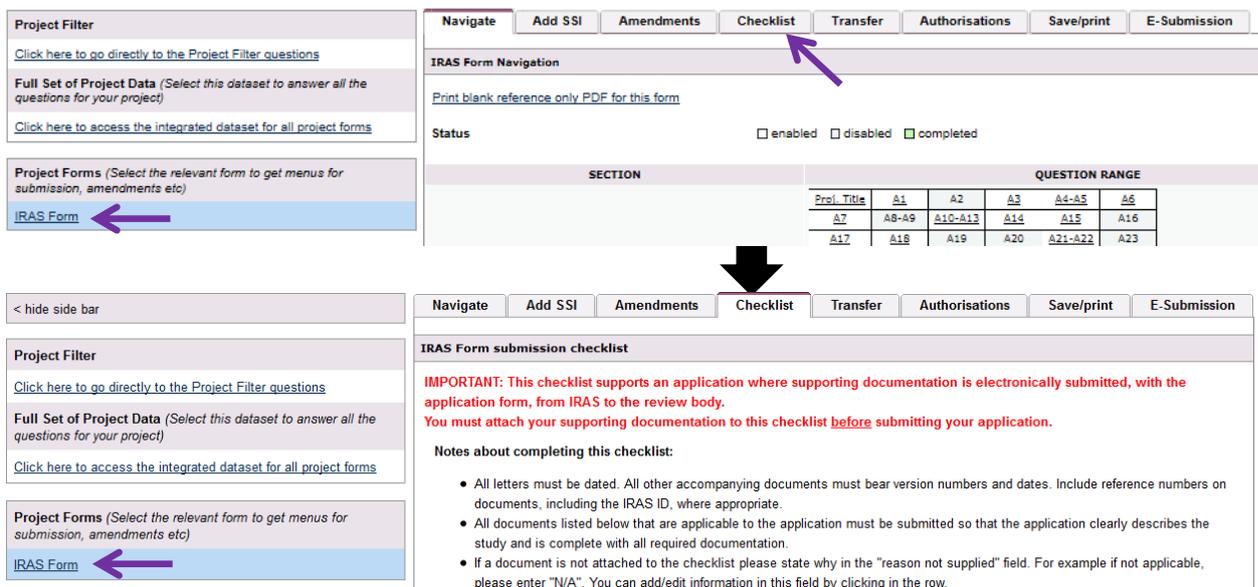
The IRAS Form dataset is accessed by selecting the IRAS Form and then the Navigate tab associated with the form. Selecting a question number opens that part of the dataset.



4. Upload the supporting documentation for your application to the Checklist tab for the IRAS Form.

! Upload all relevant supporting documentation and enter information for these supporting documents in checklist rows (document subtitle, date and version number, as applicable).

! If a listed document type is not applicable to your project you should indicate this in the ‘reason not supplied’ box.



Tip >> The Checklist tab for the IRAS Form sets out supporting documentation for this application.

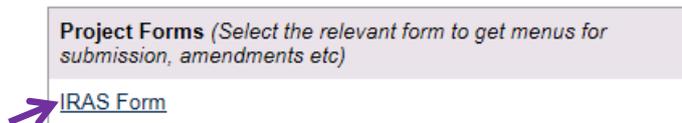
Tip >> You can upload documents using the multiple file upload feature or through single document upload; refer to the instructions on the Checklist tab.

Tip >> Some document types have further guidance and links to templates – click on  icons.

Prepare to electronically submit your application:

! Your application must be electronically submitted from IRAS.

1. Start by selecting the IRAS Form while in the Navigation page for the project



2. Check that your application (i.e. the IRAS Form) is complete.

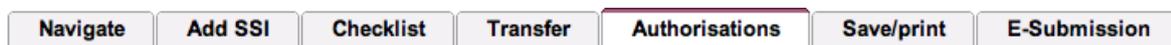
- a. Review the form page by page and/or Print draft version from 'Save/print' tab

- b. Use **Check Your Form**

! This function only works if you used the completion tracking tool icons next to questions



3. Ensure that all necessary supporting documents have been uploaded to the Checklist for the IRAS Form (see point 4 of 'Prepare your application' above).
4. Gather electronic authorisations for all declarations in the IRAS Form.



! Electronic authorisation of declarations is mandatory for application form

Tip >> Refer to the [IRAS step by step guidance on electronic authorisation](#)

Tip >> Electronic authorisations will invalidate if you change the data after it has been authorised, so:

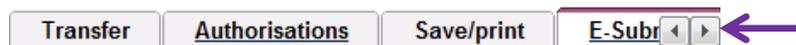
- Only seek electronic authorisations once the form is complete and ready for submission.
- Do not make any changes to dataset after gaining authorisations.
- Remember some questions are shared across multiple forms. If you change data in another form or in the integrated dataset your form may be updated and invalidate authorisations.

Verify your application is ready for electronic submission:

Go to the E-submission tab for the IRAS Form.



Tip >> This tab is located to the right, so depending on your screen, you may need to use scroll to it using arrows:



If you have completed all of the steps to prepare to submit your application as set out above, click on the **Verify your form** button.

If the application passes verification you will see a pop-up message confirming a successful verification. If something is missing from your application the pop-up box will indicate which section(s) are missing information.

! Electronic submission is not enabled until the application passes the verification step.

Tip >> Refer to the [IRAS verification tool guidance](#)

Booking and electronically submitting your application:

- ! All IRAS Form applications must be booked for review prior to electronic submission. Submissions will be automatically rejected if the application has not been booked.
- ! Booking and electronic submission must be completed on the same day; late submissions will usually be rejected.

1. Prepare for booking your application by gathering information ready to make booking. You'll need:

- Your IRAS Project ID
- To be ready to answer questions about your application



Tip >> You may find it helpful to have your project in IRAS open in front of you when you telephone to book.

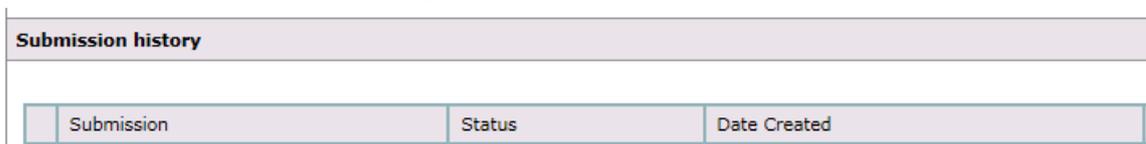
2. Book your application for review. You will need to telephone the [Central Booking Service \(CBS\)](#).
3. After completing the booking, you will receive an email confirming the details of your booking; enter these details into page 1 of the IRAS Form.

! Do not amend or add to any other fields in your IRAS Form as this will invalidate your electronic authorisations.

4. In IRAS, return to the E-submission tab



- Click on **E-Submit application** button to electronically submit application. This will send the application form and the files that you uploaded to the Checklist.
- Check submission history, at bottom of E-submission tab, to make sure your application has:
 - Successfully submitted; and
 - Been accepted for processing

A screenshot of the "Submission history" table in the IRAS system. The table has a header row with the following columns: "Submission", "Status", and "Date Created". The table is currently empty of data rows.

Submission	Status	Date Created
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Tip >> It may take a few minutes for the status to update and you may need to refresh your browser.

- Once you have electronically submitted your application, the "E-submit application" button will be disabled. This ensures that only one copy of your form and supporting documentation is submitted. You will need to contact the lead coordinating function for your research if you:
 - Have made a mistake and/or need to withdraw your application
 - Need to supply additional supporting documents
 - Need to submit a response to a request from the reviewers

Projects created prior to 28 June 2018

If you created your project in IRAS prior to 28 June 2018 and selected the IRAS Form:

Please refer to the section below that describes your project.

- All projects led from England – should follow the instructions provided in the previous section for submitting the IRAS Form.
- Projects led from Northern Ireland, Scotland or Wales *requiring ethical review*:
 - If you have not yet completed your application and submitted it then you should follow the instructions in the previous section for submission of the IRAS Form.
 - If you have already electronically submitted your application for ethical review but not submitted the application for NHS/HSC study-wide review then you should email the completed IRAS Form (pdf and XML), supporting documents and completed checklist to the coordinating function for the lead nation:
 - Northern Ireland: research.gateway@hscni.net
 - Scotland: nhsq.NRSPCC@nhs.net
 - Wales: research-permissions@wales.nhs.uk
- Projects led from Northern Ireland, Scotland or Wales *not requiring ethical review*:
If you have not already submitted your application by email then you will now be able to submit it electronically by following the instructions in the previous section.

If you created your project in IRAS prior to 28 June 2017 and used separate NHS REC and/or NHS R&D Form(s) then when you open the project you will see the pop-up message as shown below:

The project filter has been updated since you created this project.

You have indicated that your project involves the NHS/HSC. In June 2017 the 'IRAS Form' replaced the separate NHS/HSC R&D Form and NHS REC Forms for research projects involving the NHS/HSC.

If you have already submitted your separate NHS/HSC R&D Form and/or NHS REC Form (if applicable) then you should continue to use the original, separate application form(s). There is no need to change your selection to the IRAS Form.

You can dismiss this pop-up and you will see the Navigation Page for your project as usual.

In this situation the next step depends on where you are in the application process.

- If you have already submitted the NHS/HSC R&D Form or the NHS REC Form or both, or if you are about to submit the separate forms (e.g. you have uploaded documents and/or sought electronic authorisations) then you should continue to use the separate form(s).
- If you have not yet started or only partially started to complete the dataset and not yet submitted the NHS/HSC R&D Form or the NHS REC Form then you can choose to change to the IRAS Form at this point. To do this select the Project Filter link while on the Navigation Page for the project. Once in the Project Filter you can amend your form selections at filter question 4 and review/update the remainder of the project filter as appropriate. Any data you had entered in the dataset will be retained.