**IRAS Approval Process**

**Process chart and guidance notes**

**Guidance Notes**

**Integrated Research Approval system (IRAS)** [**https://www.myresearchproject.org.uk/**](https://www.myresearchproject.org.uk/)

Integrated Research Approval System (IRAS) is a single system for applying for Health Research Authority (HRA) permissions and approvals for health and social care / community care research in the UK. **IRAS** enables you to enter the information about your project once instead of duplicating information in separate application forms and uses filters to ensure that the data collected and collated is appropriate to the type of study, and consequently the permissions and approvals required.

If you are unsure whether you should complete an IRAS form, please check with your supervisor in the first instance and then your Departmental Ethics Lead.

**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**

**IRAS Review Process**

**Northumbria University approval processes for IRAS submission**

**STEP ONE**

1. Complete University Ethical Approval
2. Ensure all funding, if any, is in place

As the Principal Investigator (whether student or staff), you will be required to get ethical approval from the University before you submit your application to IRAS.

You should ensure that all funding, if any, is in place before completing your IRAS application form.

**STEP TWO**

1. Complete IRAS application online <https://www.myresearchproject.org.uk/>
2. Complete NU IRAS pro-forma including Agresso number (if any)
3. Send PDF copy of IRAS application to [ethicssupport@northumbria.ac.uk](mailto:ethicssupport@northumbria.ac.uk)

You should complete your IRAS application as soon as possible to ensure you do not delay the start of your active research. IRAS has an extensive Help section to enable you to complete it. You can also print a blank form to enable you to gather information together.

Once the form is complete you are ready to get it authorised. To do this first download a PDF copy of the full data set. To do this:

1. Click the ‘Print’ button (at the top or bottom of the Full Set of Project Data or your form); or
2. Go to the Navigation page, select the Full Set of Project Data or form (from the menu on the left) and use the ‘Save/print’ tab.
3. Follow the instructions to produce a pdf file of your Full Set of Project Data or your form, which you can save electronically.

Send the PDF to [ethicssupport@northumbria.ac.uk](mailto:ethicssupport@northumbria.ac.uk) for consideration by the IRAS Review Group.

**STEP THREE**

1. IRAS Review Group considers applications
2. Following review sponsor template sent to CI/PI for sign off and any amendments
3. IRAS Review Group advises Executive Dean signs off Sponsor template - CI/PI alerted

IRAS now contains a number of different authorisations (e.g. resources, insurance) that require high level authorisation within the University. The IRAS Review Group meets monthly to advise and support the IRAS submission and authorisation process.

Once the Group has considered the IRAS submission it advises the PI of approval, and or amendments, and requests completion of the Sponsor template. The Sponsor template is then signed off by the Executive Dean.

Once the internal sign off has been completed the electronic IRAS authorisation and submission can proceed.

**STEP FOUR**

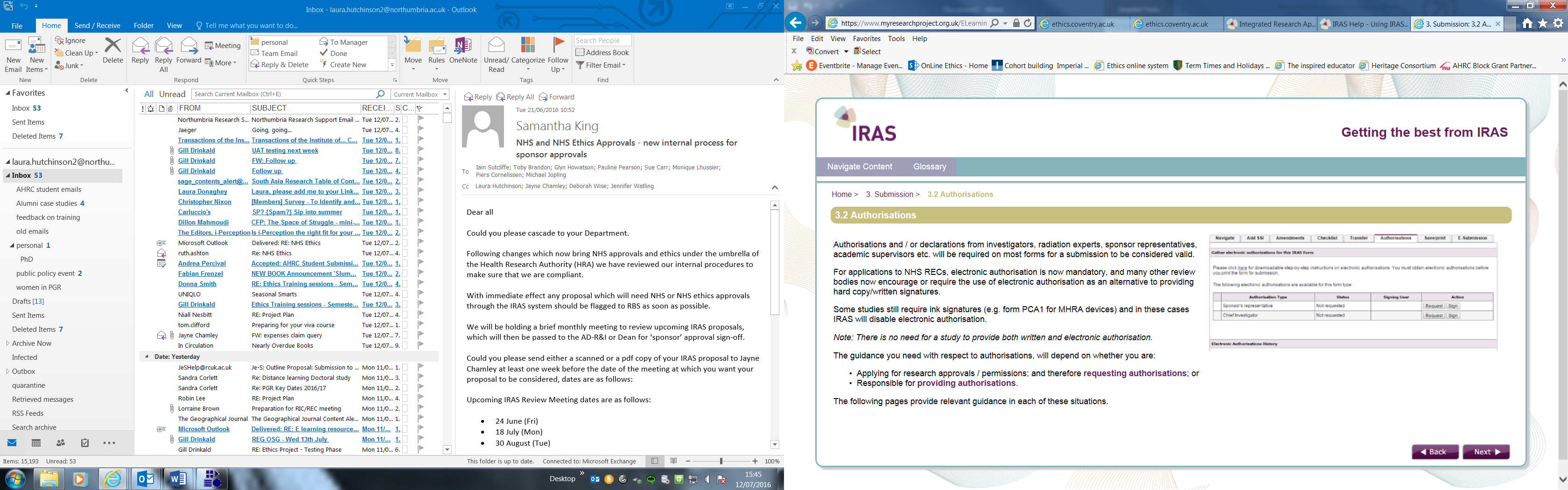
1. PI submits IRAS electronic form for e-authorisation
2. Once e-authorisation is completed submits e-Form to HRA
3. If going to NHS REC submits form on the same day as booking REC appointment

To complete the IRAS submission the PI requests e-authorisations. Northumbria’s sponsor representatives are:

* Samantha King (Research Funding and Policy manager)
* Laura Hutchinson (Research Development Manager)

You will be informed at the internal sign-off stage who you should request to sign off your

e-authorisation.



**Electronic Submission**

**Are you ready to submit?**

* Have you read the instructions on how to submit to the relevant review body (under the ‘Submission’ or ‘E-submission’ tab)?
* Have you [checked that your form is complete](https://www.myresearchproject.org.uk/ELearning/submission.html)?
* Have you completed the relevant [Checklist](https://www.myresearchproject.org.uk/ELearning/checklist.html)?
* Are all of the appropriate [authorisations](https://www.myresearchproject.org.uk/ELearning/authorisations.html) in place?

If you can answer yes to all of the above, then you may proceed with your submission or e-submission.

Before submitting your application, you should ensure that you have read the submission instructions available on IRAS for each form. To find this information, click on either the ‘Submission’ or ‘E-submission’ tab of the relevant form.

It is important that you establish whether your form will be a submission, or an e-submission as the process is different for each. You can tell which one by the tabs on your form (i.e. you will either have a 'Submission' or 'E-submission' tab).

If you can't see a ‘Submission’ or ‘E-submission’ tab on your navigation page, scroll right as these tabs may be on the page but just not visible in the current window. You will never submit the Full Set of Project Data to a review body.

**Submission to NHS Research Ethics Committee**

All applications for NHS and Social Care REC review are prepared using IRAS. NHS RECs usually review applications in full REC meetings. However, projects that meet certain criteria deemed not to raise material ethical issues may not need to go to a full committee. This [proportionate review service](http://www.hra.nhs.uk/resources/nhs-rec-proportionate-review-service/) is for studies that present minimal risk or burden for the participant, uses a proportionate review sub-committee to review applications within shorter timeframes on receipt of a valid application.

NHS RECs are geographically located across the UK. You do not have to choose your nearest REC, although that option may be available, depending on the type of research you plan to undertake. Some studies must be reviewed by a REC that is ‘flagged’ for the type of research which is to take place. For other types of research it may be recommended  to use a [REC flagged for that type of research](http://www.hra.nhs.uk/resources/applying-to-recs/nhs-rec-where-to-book/).

**Preparing to book**

You must ensure that your IRAS application is ready to submit when you telephone to book it in for ethical review. You must electronically submit your application on the same day as you book your application for review. So before booking you must ensure:

* Your application form is complete
* You have all necessary supporting documents to the checklist in IRAS
* The declarations in your application forms have been electronically authorised.

**Booking your application**

Once you are ready to submit, you must book your application for review.

For NHS RECs, bookings are made through the [Central Booking Service (CBS).](http://www.hra.nhs.uk/research-community/applying-for-approvals/research-ethics-committee/www.hra.nhs.uk/resources/applying-to-recs/nhs-rec-central-booking-service-cbs/) Phase 1 studies in healthy volunteers may be booked direct with your [preferred REC,](http://www.hra.nhs.uk/resources/applying-to-recs/nhs-rec-where-to-book/) which is recognised to review this type of research. Social Care REC applications should be booked directly with the [Social Care REC](mailto:barbaracuddon@nhs.net). Please refer to HRA for more information <http://www.hra.nhs.uk/resources/applying-to-recs/>

When you book your application for REC review you will be offered the first available slot for a REC which is suitable for the type of study.  You should have your application in front of you as you will be asked some questions to determine which RECs are available to you, dependent on the study type.

Once the REC meeting is booked, you will need to enter the details of the name of the REC and the REC reference number at the start of the NHS REC application form in IRAS. Data entry in these fields will not invalidate your electronic authorisations, however please note that if you alter any other part of your application electronic authorisations will be invalidated.

You must electronically submit your application and supporting documents to the REC on the same day as making the booking.