

1 Is my study considered as research using the [HRA decision tool](#) 2 Does my study require REC review using the [HRA REC decision tool](#)

3 For student research [Student Research Toolkit](#)

My study is Research

complete your application and supporting documentation in [Integrated Research Application System \(IRAS\)](#).

The [NHS Research Scotland Permissions Coordinating Centre \(PCC\)](#) shall receive your application, allocate a Study Wide Reviewer and share with the relevant R&D offices in Scotland (they will make sure that all documents submitting with the IRAS will be made available to the R&D offices of the participating NHS organisations.

The Study Wide Reviewer shall undertake the UK and Scotland specific aspects of the governance review (accepted across the UK) and shall provide this to the Permissions Coordinating Centre.

Any regulatory approvals (e.g., REC, MHRA) shall also be provided to the Permissions Coordinating Centre as required.

Local review process will also begin within NHS A&A RDI

My study is not Research

Send your proposal and toolkit result to the RDI generic mailbox RandDProjectTeam@aapct.scot.nhs.uk
You will be sent acknowledgement of your evaluation via email

Please refer to the additional information on the following page for assistance with the submission process.

NB: for student project the Sponsor should be the University, please see [UK Policy Framework for Health and Social Care Research](#)

If external researchers need access to NHS A&A premises, data, staff and / or patients?

Submit NHS-NHS Proforma or Research Passport as early as possible so as not to delay the approval process (if in doubt contact RDI dept)

Following review by the RDI Department, a letter will be issued confirming the decision and conditions of approval.

Research studies cannot commence without a formal letter of approval from the RDI Department

RDI Standard Operating Procedures (SOPs) are available [here](#)

What do applicants completing the IRAS submission require to do?

1. Complete the IRAS Form
2. Upload all supporting documents to the checklist tab for the IRAS form and enter details for the documents in the rows (including subtitles, version numbers and dates, as appropriate)
3. Make sure the application is ready to submit and passes the verification step. The IRAS Form eSubmission tab gives guidance on this
4. Book in the application for review using the Central Booking Service. If the study requires Research Ethics Committee (REC) review, the service will book the REC meeting slot at the same time as enabling e-submission. For non-REC studies the service will enable e-submission. Applicants will receive a confirmation email from the Central Booking Service
5. Add the booking information to the first page of the IRAS Form
6. Click the “E-submit application” button to submit the application.

NB. The Central Booking Service asks questions relating to the application to assign the application to the correct reviewers. Please make sure that the person making the call to the Central Booking Service understands the study.

Please follow the Step-by-Step Guide on IRAS

Supporting documents:

You should enter the details for all the supporting documents that you are submitting in the ‘Checklist’ tab for the application form in IRAS.

Organisation Information Document (OID)

It is the Sponsors responsibility to localise the OID and email it along with the relevant delegation log for the site (if applicable) to NRS Permissions CC (NRSPCC) who will then make the Local Information Pack (LIP) available to NHS sites in Scotland.

For PI involved in a multicenter study:

Once the RDI office has received notification of a study we will send the Localised Organisation Information Document (LOID) to you for checking and the Local Information Appendix (LIA) for you to complete and sign.

Data Protection Act 2018, GDPR, Caldicott Principles and the Common Law of Confidentiality

To ensure your study meets the requirements of the above please refer to the *Guidance on Data Protection, Caldicott and Confidentiality for Researchers*

<http://athena/kmeh/kmeh/igs/Pages/DataProtectionandResearch.aspx>

UK policy framework for health and social care

The above sets out the principles of good practice in the management and conduct of health and social care research in the UK

<https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/>

Frequently Asked Questions

Q. Do you have templates for consent form, information sheet and protocol?

Templates for supporting documents can be found [here](#)

Q. Can we request NHS Ayrshire and Arran sponsorship for our study?

We can Sponsor single site studies where the CI is an NHS Ayrshire and Arran employee (this excludes student projects). A sponsorship review will need to be conducted before formal submission to IRAS so you must contact us as soon as possible so we can start this process.

Q. Can NHS Ayrshire and Arran Sponsor drug studies?

No, we are unable to Sponsor these types of studies.

Q. Who is the R&D contact for IRAS A68-1?

Dr Carolina Borda-Niño-Wildman, NHS Ayrshire and Arran, 56a Lister Street, University Hospital Crosshouse, Kilmarnock KA2 0BB



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