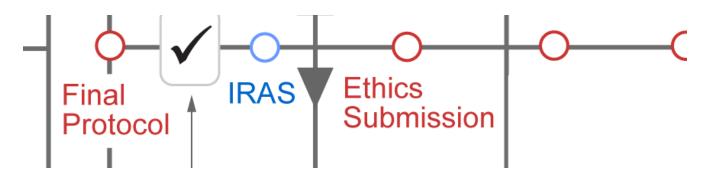
IRAS



Trial Approvals Phase

The IRAS station follows the Final Protocol station and CI Checklist Before Seeking Approval, and precedes the CTA Submission station. Applying to IRAS is good practice and is relevant to all trials. This station is part of the 'trial approvals phase' group of stations.

The Integrated Research Application System (IRAS) is a single system for applying for the permissions and approvals for health and social / community care research in the UK. This includes HRA/HCRW Approval (England and Wales) or NHS/HSC R&D Permission and NHS REC review (where required) for research led from Northern Ireland or Scotland). In addition, IRAS can be used to create other study notifications, for example, 'Notice of Substantial Amendment' forms (see Substantial Amendment station).

For non-commercial studies, there is one consistent package to support study setup and delivery across the UK. <u>The Organisational Information document</u>, in outline format, will be a component of the IRAS form submission and in a localised format will be required as part of the <u>UK Local Information Pack</u> for both commercial and non-commercial research.

IRAS can be used by anyone carrying out health and social / community care research in the UK, including all Chief Investigators and those with delegated responsibility for applying for research approvals and permissions.

Since 1 January 2022, new CTIMPs and combined trials of an investigational medicinal product and an investigational medical device (IMP/Device trials) need to apply using the <u>combined review service</u>, which can be accessed using the new part of IRAS. Users will need to create a new IRAS account. Please see the guidance on the HRA website for a <u>step by step guide on how to apply for combined review</u>. If your combined review application involves ionising radiation and/or an investigational medical device, please refer to IRAS Help guidance.

Further reading:

- R&D Consultation station
- CTA Submission station
- Ethics Submission station
- R&D Submission station.