Innovative System Introduced for Research Applications

A streamlined system being launched today is expected to bring some welcome relief to a large number of UK health researchers. IRAS (Integrated Research Application System) is an online system which is designed to make the process of applying for approval to conduct research in the health sector easier and less bureaucratic.

A long-held criticism from researchers has been that applying for approvals to conduct a piece of research in the UK health service involves grappling with a bewildering array of forms, many of which require the same details. It has been up to the researcher to duplicate this information on each separate review body’s application form, which has been a time-consuming and frustrating process.

IRAS combines seven review bodies’ applications, so researchers only need to enter their study information once. Once the information is entered into IRAS, it will populate the applications relevant to the type of research being undertaken.

IRAS builds on a system originally set up in 2004 to manage research ethics approvals which currently has 65,000 registered users. Lessons learnt from the implementation of this system have been applied to developing IRAS. While some successful integration of the governance and ethical applications systems has occurred, IRAS is a major step forward in integrating and simplifying processes for researchers.

Led by the National Research Ethics Service (NRES), a division of the National Patient Safety Agency, this project has been run under the umbrella of the UK Clinical Research Collaboration (UKCRC). This UK-wide initiative is also supported by the NHS R&D Forum, the major regulatory and governance bodies, the UK Health Departments, the UK Clinical Research Network, the Forum of NHS Wales for R&D Management in Health & Social Care and funders of research. This collaboration is a crucial part of the Government’s strategy to have an integrated programme of improvement in health research.

Dr Liam O’Toole, CEO of the UKCRC, said; “IRAS is an excellent example of how the UKCRC and partnership working can make a tangible impact by bringing together a range of organisations in order to solve a common problem. It is a simple idea that a researcher should only have to provide the details of their study once. In reality the task was very complex and has required a lot of people working together to come up with this elegant solution.”
Sir John Lilleyman, Chair of the UKCRC Working Group set up to look at streamlining research applications, said; “Researchers have rightly been critical of the regulatory steeplechase required when applying for approvals for health research. There was ready agreement within the health sector that the duplication of effort in providing information for different bodies was time-consuming and potentially avoidable. IRAS is a major step forward in our drive to improve these processes.”

Dr Janet Wisely, Director of NRES, says consulting widely with researcher users will be vital in the next few months before IRAS becomes compulsory. “It is important to us that researchers have the opportunity to use this system widely and give us feedback on all aspects, especially whether it is helpful to them and how it could potentially be more useful.

“Researchers will find the IT platform familiar but IRAS is now more than that. It is the combination of data sets and application forms that can be shared and used for a number of different governance approvals. It is envisaged that even more improvements will be made both to content and the operating platform. The planned functionality to exchange information with Eudract will be a major benefit for those needing approval from MHRA. There is also potential to extend the system further to include additional partners such as funding bodies.”

IRAS will continue to be improved as feedback is received. The traditional systems will still be available for those researchers who want to use them but they will be phased out later in the year.

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Background Notes

1. IRAS can be accessed directly at www.myresearchproject.org.uk. Guidance and information will be found on that website. Information can also be found at www.nres.npsa.nhs.uk, www.ukcrc.org/iras.aspx and www.rddfournhs.uk. Feedback on the system can be sent to iras@nres.npsa.nhs.uk.

2. IRAS will capture information needed to submit for the relevant approvals for the following review bodies:
   - Administration of Radioactive Substances Advisory Committee (ARSAC)
   - Gene Therapy Advisory Committee (GTAC)
   - Medicines and Healthcare products Regulatory Agency (MHRA) – Medicines and Devices
   - Ministry of Justice (National Offender Management Service)
   - NHS / HSC research offices
   - NRES / NHS / HSC Research Ethics Committees
   - Patient Information Advisory Group (PIAG)

3. The National Research Ethics Service, a division of the National Patient Safety Agency, works with colleagues in the UK to maintain a UK-wide system of ethical review that protects the safety, dignity and well being of research participants, whilst facilitating and promoting ethical research within the NHS. NRES is leading collaborative work with other organisations involved in research regulation to integrate and harmonise the information required from applicants; IRAS is one initiative that has resulted from this work.

4. This initiative is part of a broad area of work by the UK Clinical Research Collaboration (UKCRC) to promote a streamlined regulatory and governance environment in the UK that facilitates high quality clinical research whilst protecting the rights, dignity and safety of patients. The UKCRC, established in 2004, is a partnership of organisations working together to establish the UK as a world leader in clinical research by harnessing the research potential of the National Health Service. The Partners include the key stakeholders that shape the health research environment, including research funders, the NHS, government, industry, academia, regulators, charities and patients. The UKCRC Partners are working together to address a broad agenda of issues affecting clinical research through several interconnected areas of activity. These are: developing the infrastructure to underpin clinical research in the NHS, building up an expert workforce to support clinical research, streamlining the regulatory and governance environment, developing incentives for research in the NHS and coordinating research funding. The Partners have already implemented many of the changes needed to transform the clinical research environment in the UK. Detailed information on UKCRC activities can be found on the UKCRC website: www.ukcrc.org.

5. IRAS is a collaborative initiative supported by:
   - Academy of Medical Sciences (AMS)
   - Administration of Radioactive Substances Advisory Committee (ARSAC)
   - Cancer Research UK (CRUK)
   - Medical Schools Council, formerly Council of Heads of Medical Schools (CHMS)
   - Department of Health for England
• Gene Therapy Advisory Committee (GTAC)
• Human Fertilisation and Embryology Authority (HFEA)
• Ministry of Justice
• Medical Research Council (MRC)
• Medicines and Healthcare products Regulatory Agency (MHRA)
• National Institute for Health Research (NIHR)
• National Research Ethics Service (NRES)
• NHS R&D Forum
• Patient Information Advisory Group (PIAG)
• R&D Office Northern Ireland
• Scottish Government Health Directorates
• The Forum of NHS Wales for R & D Management in Health & Social Care (FORWARD)
• UK Clinical Research Collaboration (UKCRC)
• UK Clinical Research Network (UKCRN)
• Welsh Assembly Government
• Wellcome Trust

6. The bureaucratic burden for research and the need for effective collaboration between all stakeholders including industry, regulatory agencies and Government, has been described in a number of reports, including:
  • Pharmaceutical Industry Competitiveness Task Force (PICTF) reports. See http://www.advisorybodies.doh.gov.uk/pictf/publications.htm

7. The UK Health Departments are implementing a series of measures to unify and streamline research administration and management. These are stated in their respective R&D Strategy Documents:
   d. Wales – The strategy document is under review. For further information contact Helen Jones, Project Manager, Wales Office of Research and Development for Health and Social Care (WORD) on Email: Helen.jones2@wales.gsi.gov.uk; Tel: 029 2082 3662.

8. The system originally set up to manage research ethics approvals only, which was established in 2004, cost £220,000 and currently has 65,000 registered users. IRAS builds on the existing online research ethics system. The cost of developing IRAS on top of the current system has been achieved for £150,000 and takes the system beyond current use for research ethics and NHS governance approval.