NIHR | Manchester Biomedical Research Centre

Rapid Translational Incubator Networking and Webinar

Ethics

Thursday 20 June 2019, 12 – 12:30

TranslationManchester

Today's webinar

- Ethics
- Q&A

Speaker:

Nailah Brown, Project Manager, Hearing Health and Respiratory themes, NIHR Manchester Biomedical Research Centre

Host:

Matthew Krebs, Senior Lecturer and Honorary Consultant in Medical Oncology, The Christie NHS FT. NIHR Manchester BRC Precision Medicine theme.

What is HRA: what do they do and why?

- Health Research Authority (HRA): Protects and promotes the interests of patients and the public in health and social care research, by:
  I. make sure research is ethically reviewed and approved
  II. promote transparency in research
  III. oversee a range of committees and services
  IV. provide independent recommendations on the processing of identifiable patient information where it is not always practical to obtain consent, for research and non-research projects.

- HRA Approval was fully implemented in April 2016, provides an approval for research involving patients or staff in NHS organisations in the UK.
- HRA approval brings together the assessment of legal compliance and ethical approval
- Ethical approval is applied for through IRAS

Is my project research? And if it is what approvals are needed?

- The responsibility for determining whether a project is classed as research lies with the managing organisation
- The HRA provide a Decision Tool to assist in determining this

- ***If it's not research***: No need to apply for HRA Approval or to an NHS REC. However, you should contact the clinical governance or R&D office of the organisation at which the project will be conducted to discuss what other local review arrangements or sources of advice may apply

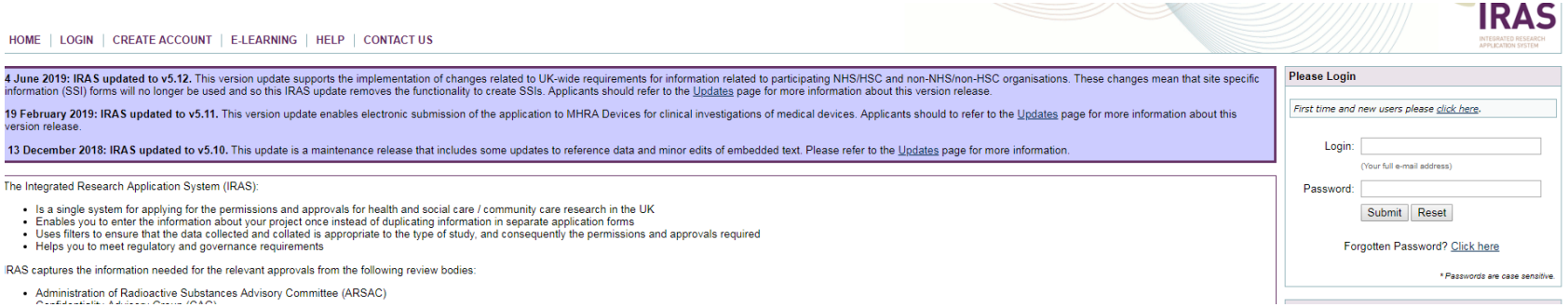
- ***If it's Research:*** You then need to know what approvals you need
- *HRA approval needed if:*
  - *I. The lead NHS R&D Office is in England or Wales*
  - *II. It is a project-based study type.*
  - *III. NHS premises and/or NHS patients and/or NHS staff in England and/or Wales are participating in the project*

- Other types of approval include Confidentiality Advisory Group (CAG), Radiation assurance and Research Ethics Committee Only

The Integrated Research Application System (IRAS)

I. Is a single system for applying for the permissions and approvals for health and social care / community care research in the UK
II. Enables you to enter the information about your project once instead of duplicating information in separate application forms
III. Uses filters to ensure that the data collected and collated is appropriate to the type of study, and consequently the permissions and approvals required
IV. Helps you to meet regulatory and governance requirements

https://www.myresearchproject.org.uk/Signin.aspx



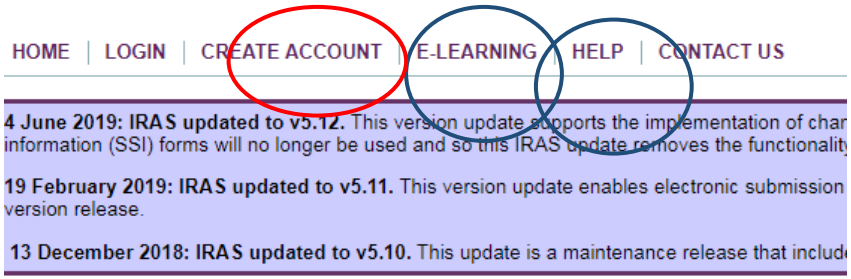
IRAS cont.

- You will need to create an account to use IRAS

- I advise you to review IRAS Help section and the IRAS E-Learning prior to starting your application.
- It is very helpful

- There is also a section on https://www.myresearchproject.org.uk/help/hlphraapproval.aspx#Tips-for-HRA-Approval

(NB: copy and paste link into search engine)



What do you need to know before starting an IRAS application

Who's involved

- Sponsor Representative
- Chief Investigator / Principle Investigator
- Research Team
- R & D office
- Research Support
- Hospital Research & Innovation Manager / Research Support Manager
- *Pharmacy (CTIMP)*
- Statistician

Documents

- Protocol (HRA Protocol template)
- Participant Information Sheet (PIS)
- Consent forms (HRA PIS & Consent Templates)
- Organisation Information Document & schedule of events
- Funding letter
- Curriculum Vitae (CI, PI & academic supervisors)
- Research passports or honorary contracts
- *Costing template*
- *Model agreements*
- Manual

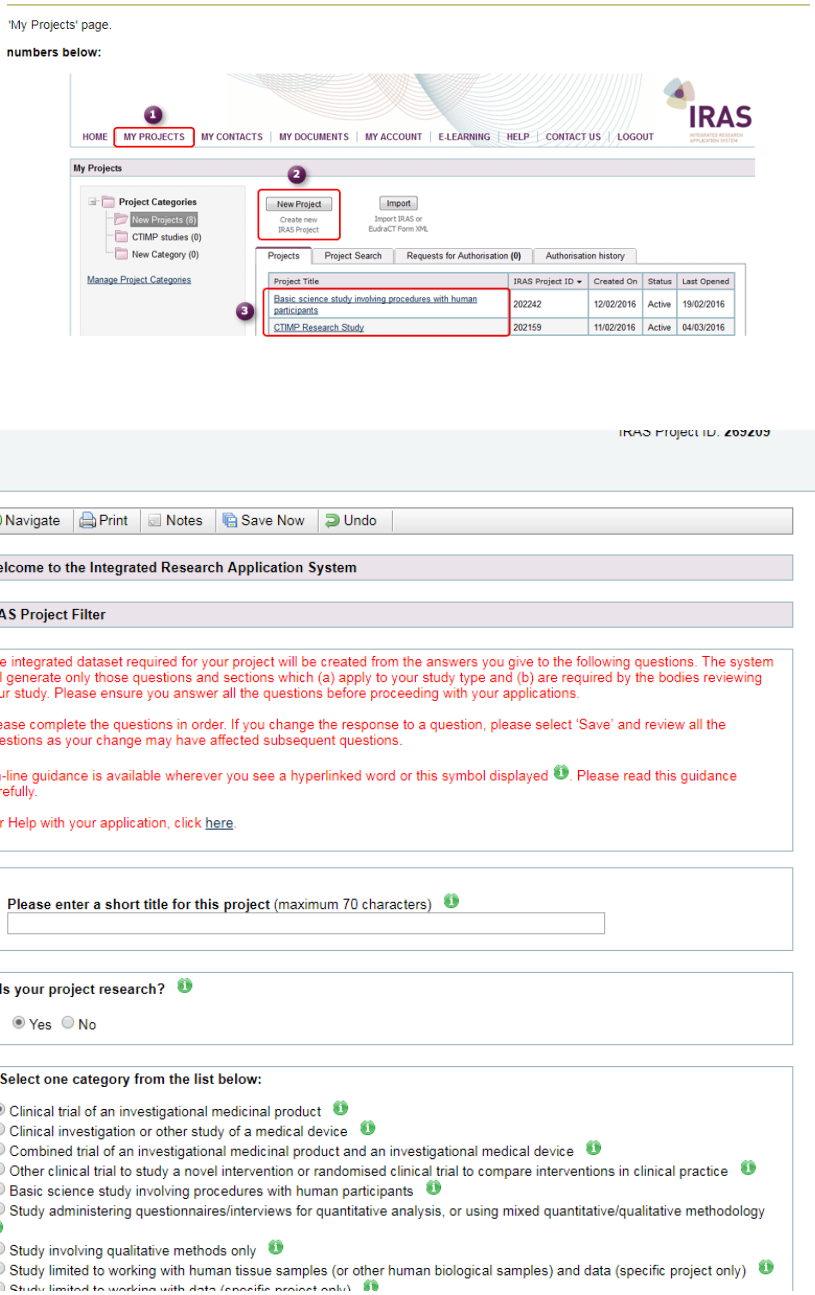
Planning & improving Research

HRA: Preparing study documentation

HRA GDPR Guidance

IRAS application

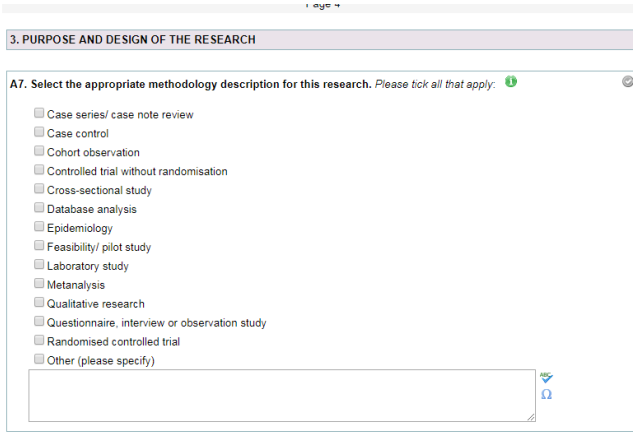
- To create a project, click New Project
- IRAS Project Filter: The answers you give may cause subsequent filter questions to appear or disappear.
- Questions include:
  - Type of study (tissue bank, CTIMP, basic science, medical device)
  - Where research sites and lead R&D office are (England, Wales, Scotland etc.)
  - Which applications you require (IRAS, MHRA, Gene therapy etc.)
  - Any samples or radiation involved?
  - Who does it involve?
-



IRAS application Cont.

- Work through each question and section of the full set of project data
- You can use the Completion Tracking Tool to manually mark questions as complete, as you fill in your project dataset.
- Each question also has helpful information attached to it (green “I” symbol)

SECTION	QUESTION RANGE
Part A: Core study information	
Administrative details	Proj. Title-A1 | A2 | A3 | A4-A5
Overview of the research	A6
Purpose and design of the research	A7 | A8-A9 | A10-A13 | A14 | 14
Risks and ethical issues	A15 | A16 | A17
Research procedures, risks and benefits	A18 | A19 | A20 | A21-A22 | A23 | A24 / A25-A26
Recruitment and informed consent	A27 | A28-A30 | A31-A33 | A34 | A35
Confidentiality	A36-A38 | A39 | A40-A42 | A43-A45 | A46-A49
Publication and dissemination	A50-A53
Scientific and Statistical Review	A54 | A55 | A56-A57 | A58-A62
Management of the research	A63-A64 | A65-A69 | A70-A72 | A73 | A74-A75 | A76 / A77 | A78-A79 | A80
Part B: Additional information	
B.1: Medicinal products	1-8 | 9 | 10-12 | IMPs | 20 | 21-1-21-2 / 22-1-22-3 | 23-1-25-1 | 26-1-26-7 | 27-29 | 30-31 | 32-33 / 34-35 | 36-37-3 | 38

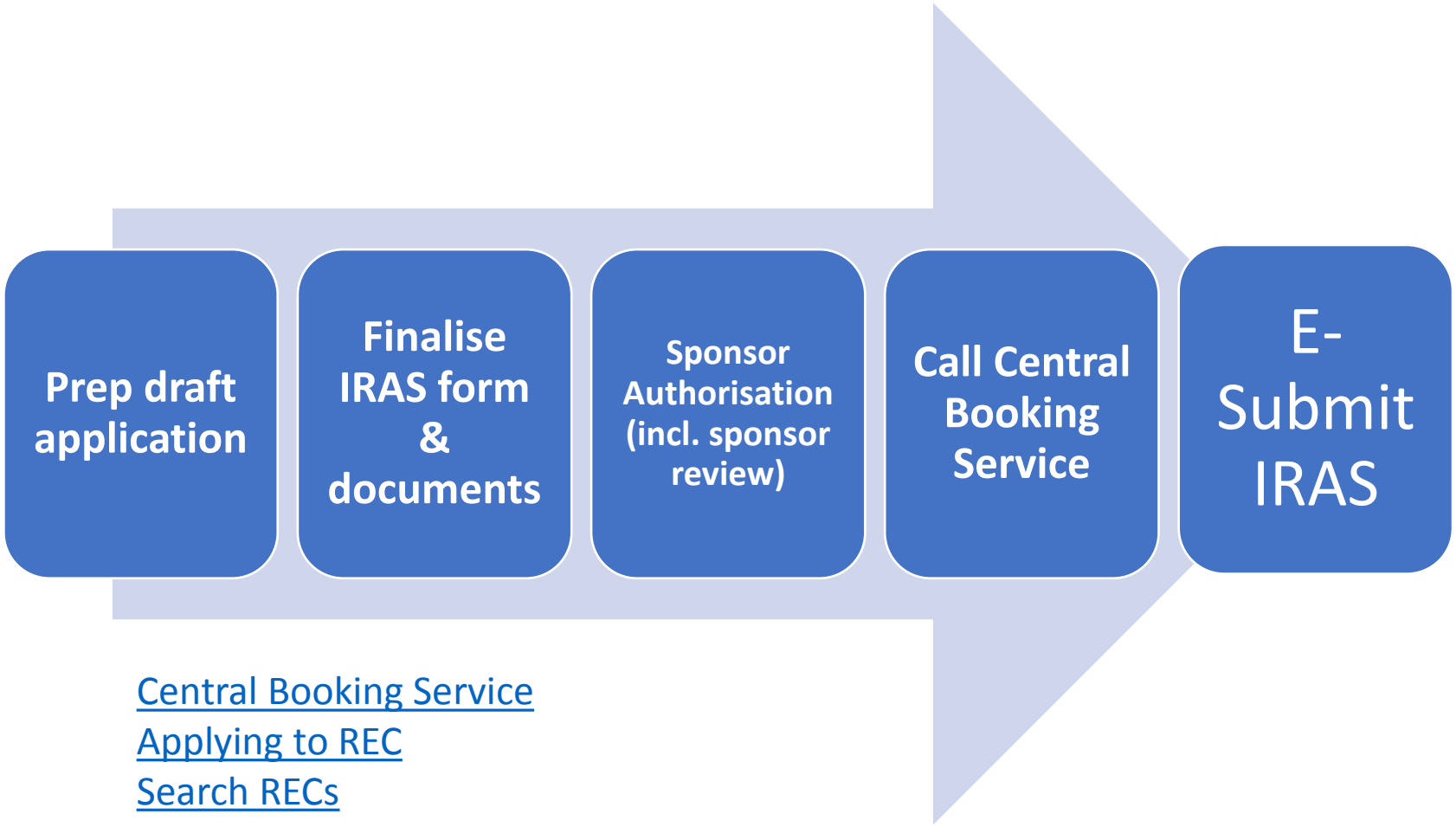


3. PURPOSE AND DESIGN OF THE RESEARCH

A7. Select the appropriate methodology description for this research. *Please tick all that apply:*

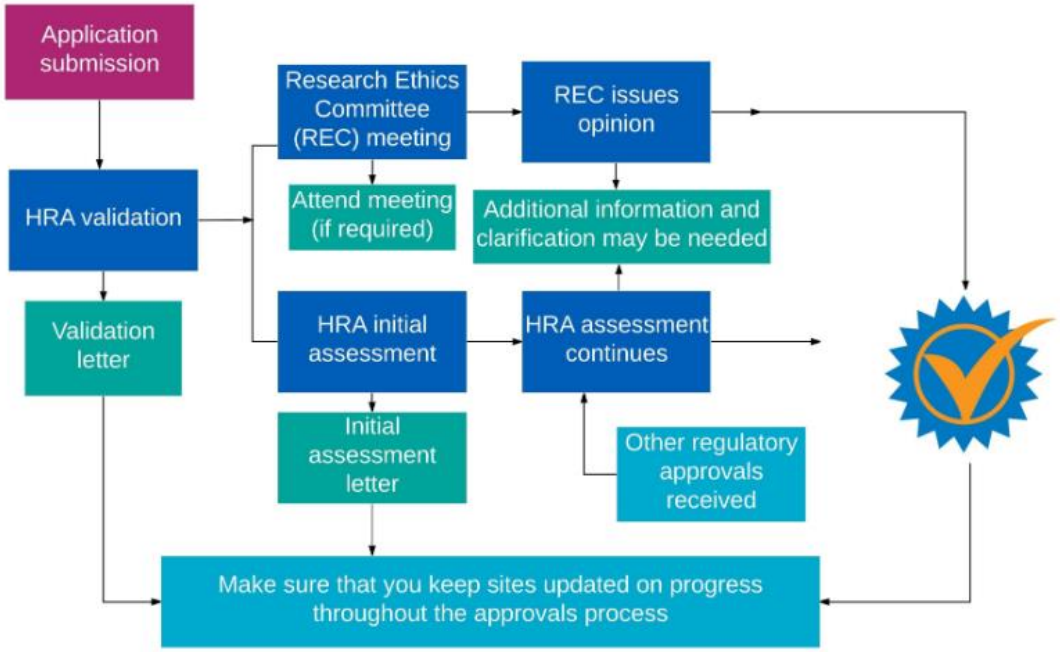
- Case series/ case note review
- Case control
- Cohort observation
- Controlled trial without randomisation
- Cross-sectional study
- Database analysis
- Epidemiology
- Feasibility/ pilot study
- Laboratory study
- Metanalysis
- Qualitative research
- Questionnaire, interview or observation study
- Randomised controlled trial
- Other (please specify)

Ready to Submit?



Central Booking Service
Applying to REC
Search RECs

After Submission: HRA Process



What next after HRA & Ethical approval

The UK Local Information Pack (From 5th Jun 19)

- Provides a consistent package to support study set-up and delivery across the UK (NHS/HSC participating organisations)
- A key component is the 'Organisation Information Document'. This replaces the 'Statements of Activities' that were used in England and Wales for non-commercial studies

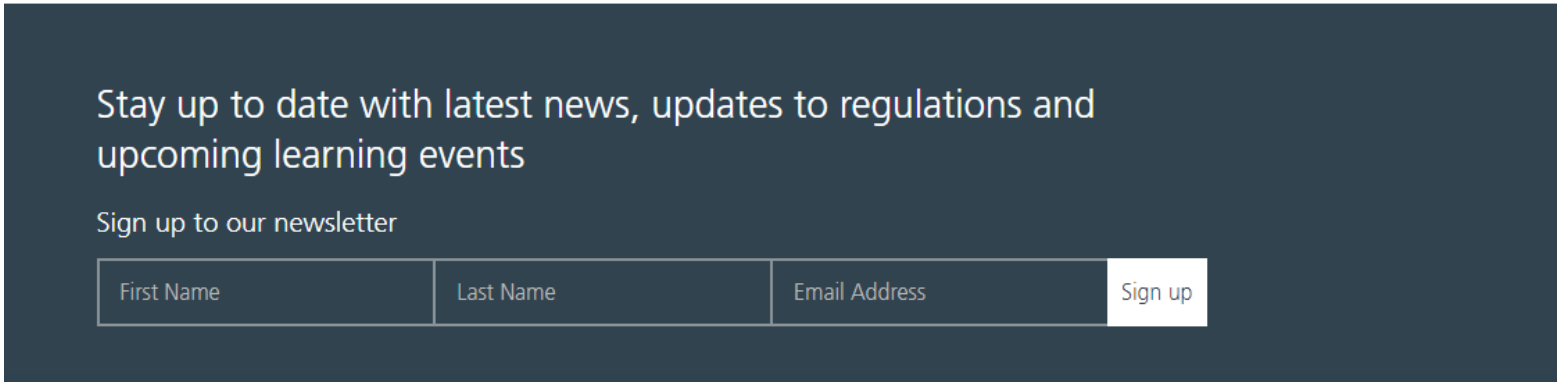
The UK Local Information Pack includes

- Covering email using standard template format.
- Localised Organisation Information Document.
- UK Statement of Events / Schedule of Events Cost Attribution Tool (SoECAT)) (non-commercial studies only)
- Delegation Log
- Relevant supporting documents.

- Guidance and templates: UK Local Information Pack

HRA Updates – Sign Up!

- Updates to procedures occur regularly (last update 5th Jun 19)
- Sign up to the newsletter to keep updated (sign up located at the bottom of the HRA home page)



Contacts

The University of Manchester: Research Support Managers	
Biological Sciences	sbsresearchsupport@manchester.ac.uk
Medical Sciences	smsresearchsupport@manchester.ac.uk
Health Sciences	shsresearchsupport@manchester.ac.uk
https://www.staffnet.manchester.ac.uk/rbe/ethics-integrity/ethics/	

Salford Royal NHS Foundation Trust	
Commercial studies	helen.moffitt@srft.nhs.uk
Non-commercial	maureen.daniels@srft.nhs.uk & fiona.bray@srft.nhs.uk

Manchester University NHS Foundation Trust: Hospital Research and Innovation Managers	
St Mary's	Kate.Barugh@mft.nhs.uk
Children's	Alison.Robinson@mft.nhs.uk
Wythenshawe	Juliette.Novasio@mft.nhs.uk
Manchester Royal Infirmary	Lindsay.Murray@mft.nhs.uk (& TBC)
Eye & Dental	Monika.Cien@mft.nhs.uk
Manchester CRF	Caroline.Leech@mft.nhs.uk
R&D Approvals and governance	R&D.Applications@mft.nhs.uk

The Christie NHS Foundation Trust
Christie.RandD@christie.nhs.uk
Christiesponsoredresearch@christie.nhs.uk for a research study which the Christie is being asked to sponsor

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Rapid Translational Incubator Networking and Webinar

Thursday 11 July, 12 – 12:30 – Sponsorship

Autumn programme – in planning

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