



# Rapid Translational Incubator Networking and Webinar

## Ethics

Thursday 20 June 2019, 12 – 12:30



# *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>

[HOME](#) | [LOGIN](#) | [CREATE ACCOUNT](#) | [E-LEARNING](#) | [HELP](#) | [CONTACT US](#)



**4 June 2019: IRAS updated to v5.12.** This version update supports the implementation of changes related to UK-wide requirements for information related to participating NHS/HSC and non-NHS/non-HSC organisations. These changes mean that site specific information (SSI) forms will no longer be used and so this IRAS update removes the functionality to create SSIs. Applicants should refer to the [Updates](#) page for more information about this version release.

**19 February 2019: IRAS updated to v5.11.** This version update enables electronic submission of the application to MHRA Devices for clinical investigations of medical devices. Applicants should refer to the [Updates](#) page for more information about this version release.

**13 December 2018: IRAS updated to v5.10.** This update is a maintenance release that includes some updates to reference data and minor edits of embedded text. Please refer to the [Updates](#) page for more information.

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IRAS captures the information needed for the relevant approvals from the following review bodies:

- Administration of Radioactive Substances Advisory Committee (ARSAC)
- Confidential Advisory Group (CAG)

Please Login

First time and new users please [click here](#).

Login:

(Your full e-mail address)

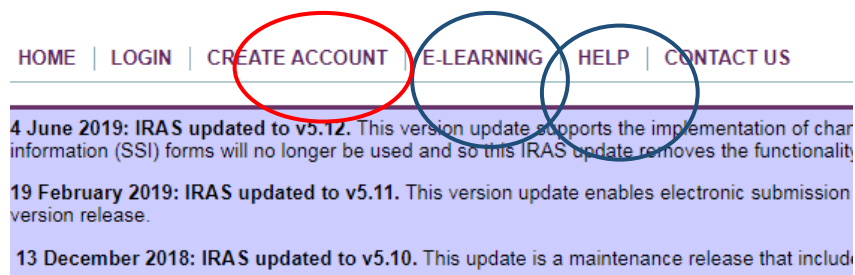
Password:

Forgotten Password? [Click here](#)

\* Passwords are case sensitive.

# 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?

'My Projects' page.

numbers below:

HOME MY PROJECTS MY CONTACTS MY DOCUMENTS MY ACCOUNT E-LEARNING HELP CONTACT US LOGOUT

IRAS

My Projects

New Project Import

Project Categories

Project Search Requests for Authorisation (0) Authorisation history

Project Title	IRAS Project ID	Created On	Status	Last Opened
Basic science study involving procedures with human participants	202242	12/02/2016	Active	19/02/2016
CTIMP Research Study	202159	11/02/2016	Active	04/03/2016

IRAS PROJECT ID: 203209

Navigate Print Notes Save Now Undo

Welcome to the Integrated Research Application System

IRAS Project Filter

The integrated dataset required for your project will be created from the answers you give to the following questions. The system will generate only those questions and sections which (a) apply to your study type and (b) are required by the bodies reviewing your study. Please ensure you answer all the questions before proceeding with your applications.

Please complete the questions in order. If you change the response to a question, please select 'Save' and review all the questions as your change may have affected subsequent questions.

On-line guidance is available wherever you see a hyperlinked word or this symbol displayed . Please read this guidance carefully.

For Help with your application, click [here](#).

Please enter a short title for this project (maximum 70 characters)

1. Is your project research?

Yes  No

2. Select one category from the list below:

- Clinical trial of an investigational medicinal product
- Clinical investigation or other study of a medical device
- Combined trial of an investigational medicinal product and an investigational medical device
- Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice
- Basic science study involving procedures with human participants
- Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology
- Study involving qualitative methods only
- Study limited to working with human tissue samples (or other human biological samples) and data (specific project only)
- Study limited to working with data (specific project only)



# 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)

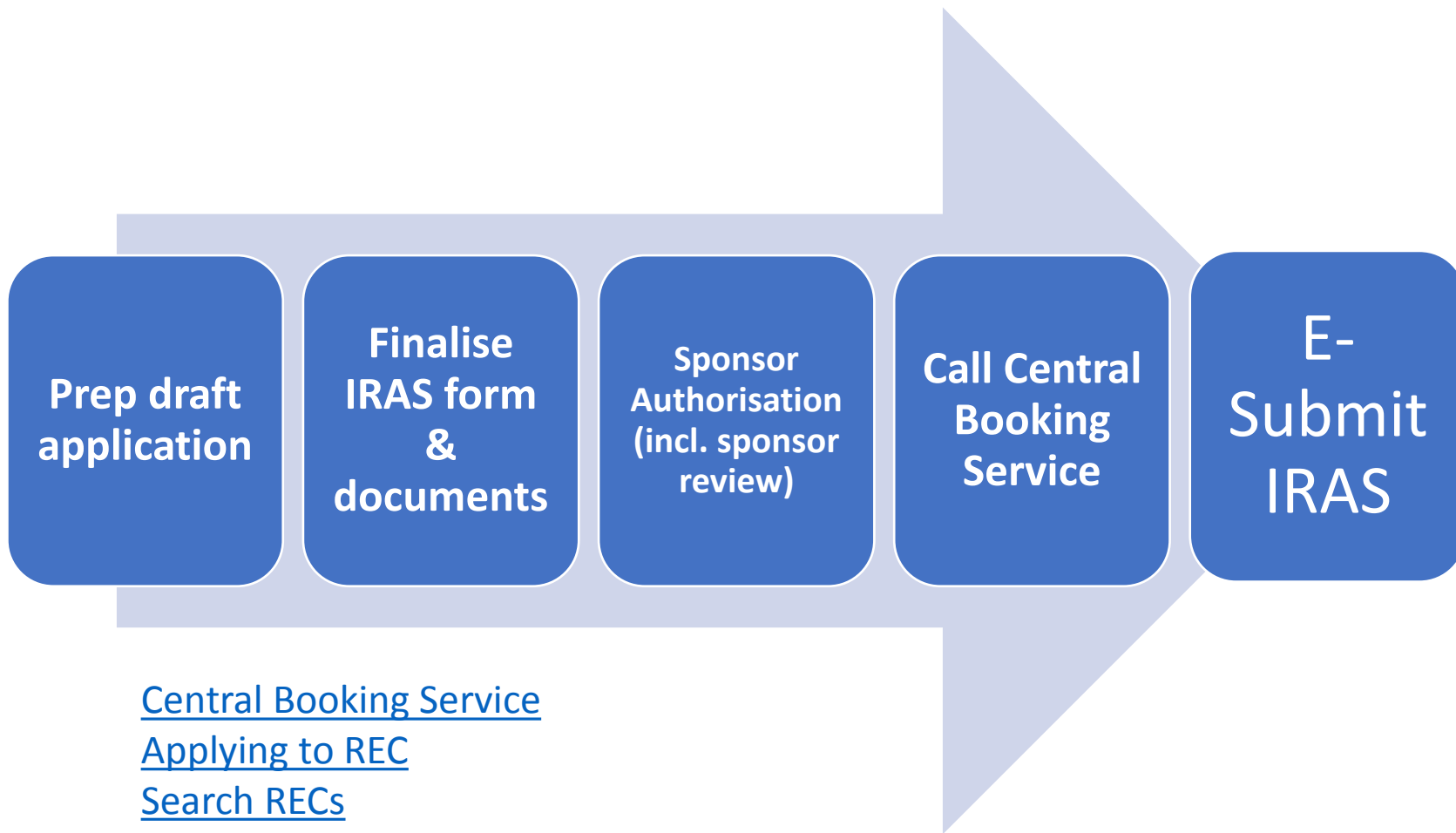
SECTION	QUESTION RANGE
<b>Part A: Core study information</b>	
Administrative details	Proj. Title-A1   A2   A3   A4-A5
Overview of the research	A6
Purpose and design of the research	A7   A8-A9   A10-A13   A14   14
Risks and ethical issues	A15   A16   A17
Research procedures, risks and benefits	A18   A19   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
<b>Part B: Additional information</b>	
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

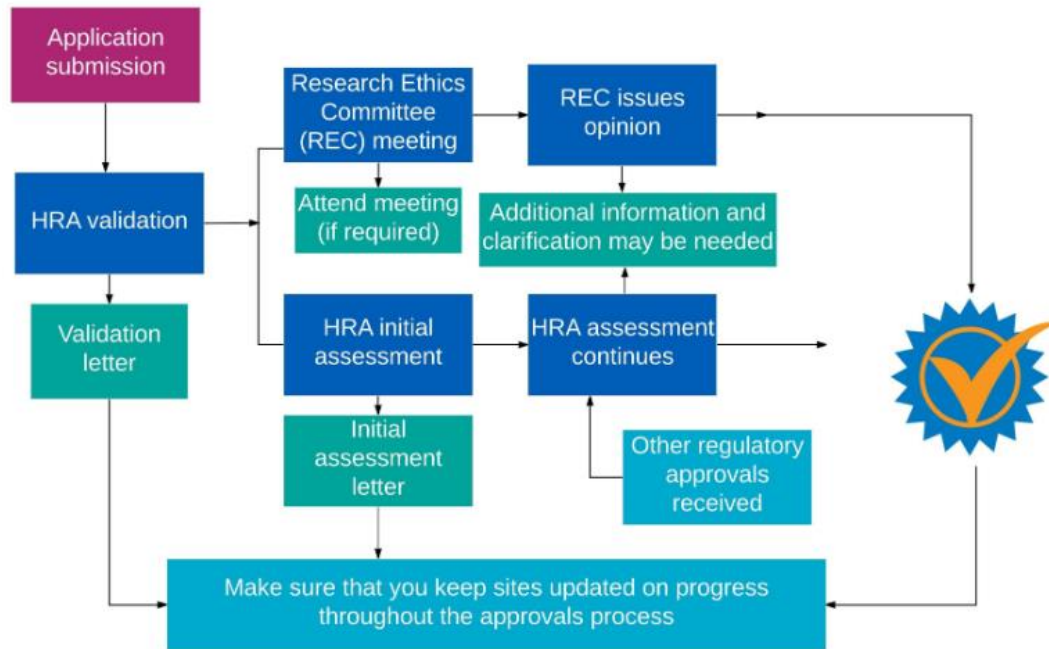
A7. Select the appropriate methodology description for this research. Please tick all that apply. ⓘ

- 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?



# After Submission: HRA Process



# *What next after HRA & Ethical approval*

## The UK Local Information Pack (From 5<sup>th</sup> 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 5<sup>th</sup> Jun 19)
- Sign up to the newsletter to keep updated (sign up located at the bottom of the HRA home page)

Stay up to date with latest news, updates to regulations and upcoming learning events

Sign up to our newsletter

First Name	Last Name	Email Address	Sign up
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# Contacts

## The University of Manchester: Research Support Managers

Biological Sciences	<a href="mailto:sbsresearchsupport@manchester.ac.uk">sbsresearchsupport@manchester.ac.uk</a>
Medical Sciences	<a href="mailto:smsresearchsupport@manchester.ac.uk">smsresearchsupport@manchester.ac.uk</a>
Health Sciences	<a href="mailto:shsresearchsupport@manchester.ac.uk">shsresearchsupport@manchester.ac.uk</a>

<https://www.staffnet.manchester.ac.uk/rbe/ethics-integrity/ethics/>

## Manchester University NHS Foundation Trust: Hospital Research and Innovation Managers

St Mary's	<a href="mailto:Kate.Barugh@mft.nhs.uk">Kate.Barugh@mft.nhs.uk</a>
Children's	<a href="mailto:Alison.Robinson@mft.nhs.uk">Alison.Robinson@mft.nhs.uk</a>
Wythenshawe	<a href="mailto:Juliette.Novasio@mft.nhs.uk">Juliette.Novasio@mft.nhs.uk</a>
Manchester Royal Infirmary	<a href="mailto:Lindsay.Murray@mft.nhs.uk">Lindsay.Murray@mft.nhs.uk</a> (& TBC)
Eye & Dental	<a href="mailto:Monika.Cien@mft.nhs.uk">Monika.Cien@mft.nhs.uk</a>
Manchester CRF	<a href="mailto:Caroline.Leech@mft.nhs.uk">Caroline.Leech@mft.nhs.uk</a>
R&D Approvals and governance	<a href="mailto:R&amp;D.Applications@mft.nhs.uk">R&amp;D.Applications@mft.nhs.uk</a>

## Salford Royal NHS Foundation Trust

Commercial studies	<a href="mailto:helen.moffitt@srft.nhs.uk">helen.moffitt@srft.nhs.uk</a>
Non-commercial	<a href="mailto:maureen.daniels@srft.nhs.uk">maureen.daniels@srft.nhs.uk</a> & <a href="mailto:fiona.bray@srft.nhs.uk">fiona.bray@srft.nhs.uk</a>

## The Christie NHS Foundation Trust

[Christie.RandD@christie.nhs.uk](mailto:Christie.RandD@christie.nhs.uk)

[Christiesponsoredresearch@christie.nhs.uk](mailto:Christiesponsoredresearch@christie.nhs.uk) for a research study which the Christie is being asked to sponsor

# Rapid Translational Incubator Networking and Webinar



Thursday 11 July, 12 – 12:30 – [Sponsorship](#)

Autumn programme – in planning

