Joint Clinical Research Office

Conducting research in the NHS: The Clinical Project Regulatory Framework

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Joint Clinical Research Office

26th June 2025

University of Sussex
brighton and sussex medical school
NHS University Hospitals Sussex NHS Foundation Trust
NHS Sussex Partnership NHS Foundation Trust
University of Brighton

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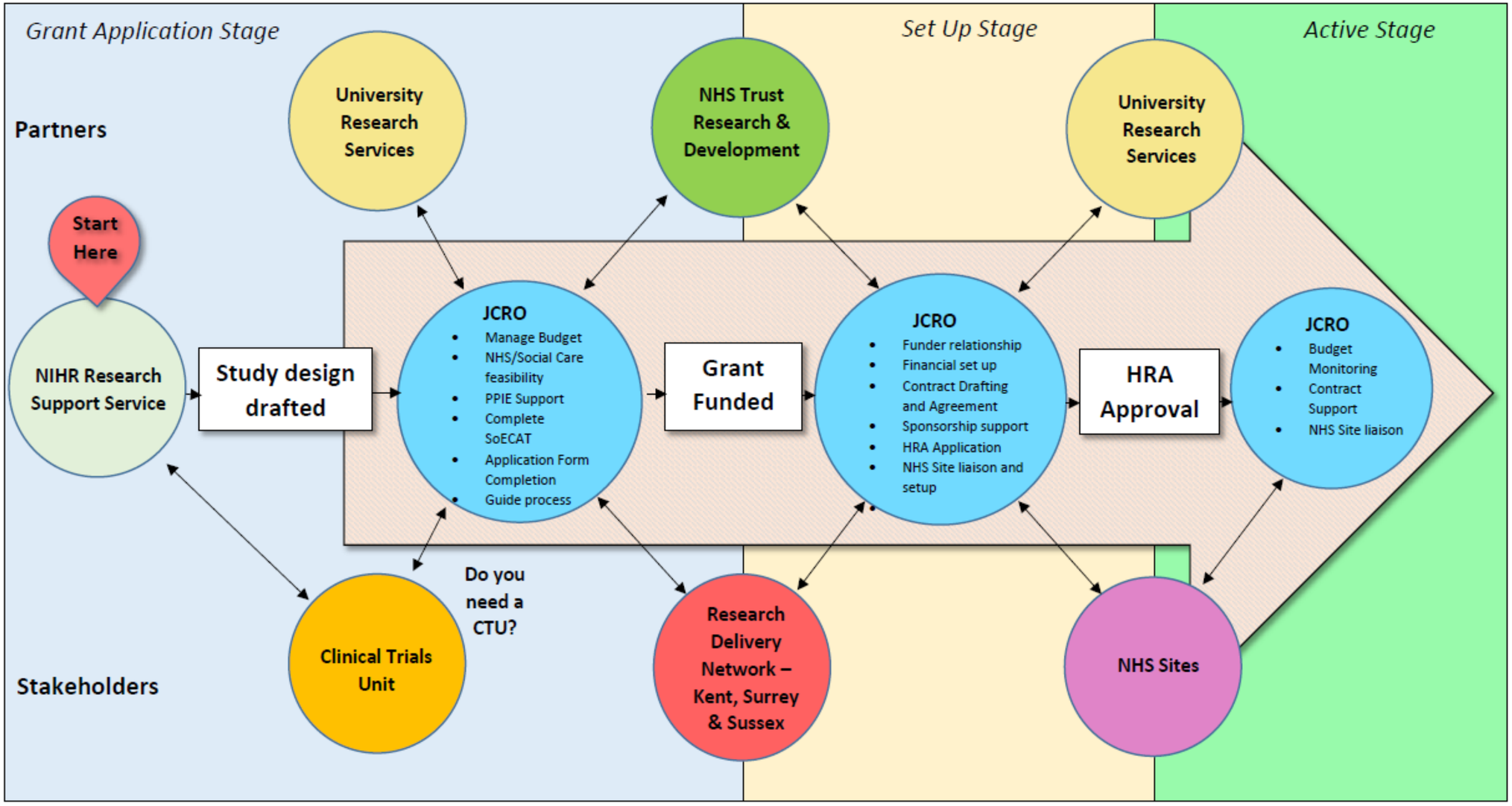
Joint Clinical Research Office – The Research Support Pathway

Sussex Health&Care Research Partnership



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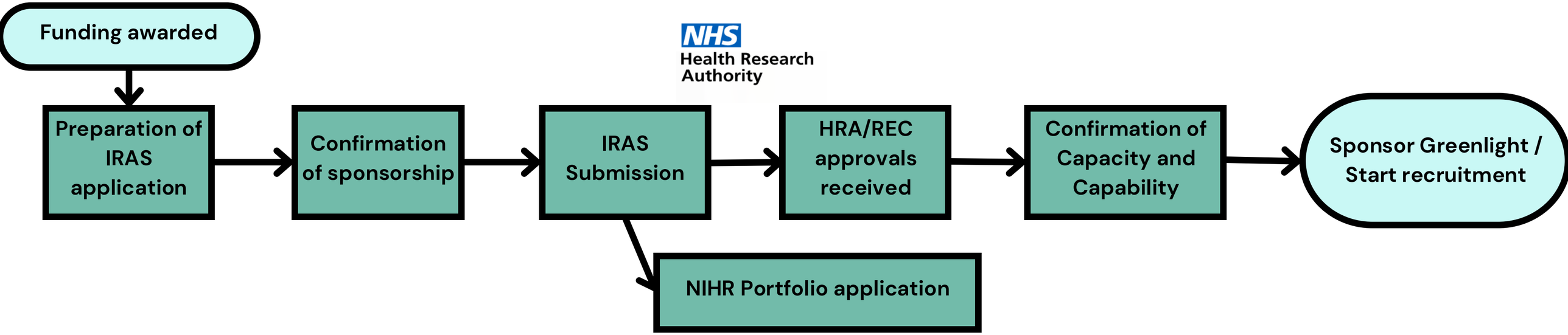
Session Plan 26th June 2025

1. What sort of research might take place in the NHS?
2. What approvals do I need for my research?
3. How do I obtain these approvals?
4. What happens once my research project is open?



NHS Health Research Authority

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1. What sort of Research might take place in the NHS?

NHS involvement in research may include:

- Identification and recruitment of patients, carers or staff on the basis of their association with NHS services
- Investigation of a new treatment, intervention or medical device
- Questionnaires, interviews or focus groups
- Extraction and analysis of patient data

NHS

All research within the NHS must have a **Sponsor:** an organisation which agrees to take on overall responsibility for proportionate, effective arrangements being in place to set up, run and report a research project

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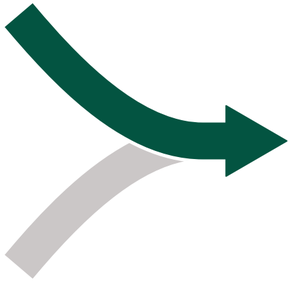
2. What approvals do I need for my Research?

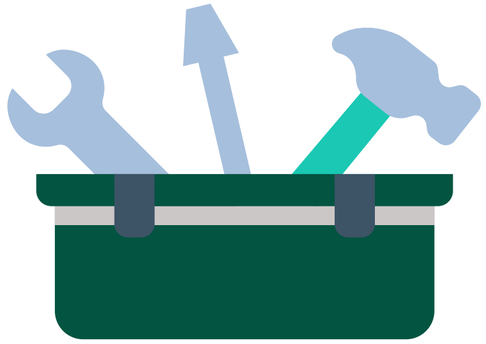
The HRA regulates research in the NHS

NHS Health Research Authority



HRA approval combines an assessment of governance and legal compliance with an NHS REC review

HRA online toolkits can help you determine whether your project requires HRA and REC review



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Defining Research

Research is “designed using documented methodology which will allow results to be extrapolated or applied from the study sample to a larger population” (HRA, 2022)

Service Evaluation

Clinical Audit

Quality Improvement

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There's a toolkit for that

Do I need NHS Research Ethics Committee (REC) review?

https://www.hra-decisiontools.org.uk/ethics/

Is my research taking place in the NHS and will it need NHS approval?

Click for link

Is it research?

https://www.hra-decisiontools.org.uk/research

What type of NHS ethics review do I need?

Click for link

Can I carry out my research as a student?

Click for link

Other Regulatory Authorities

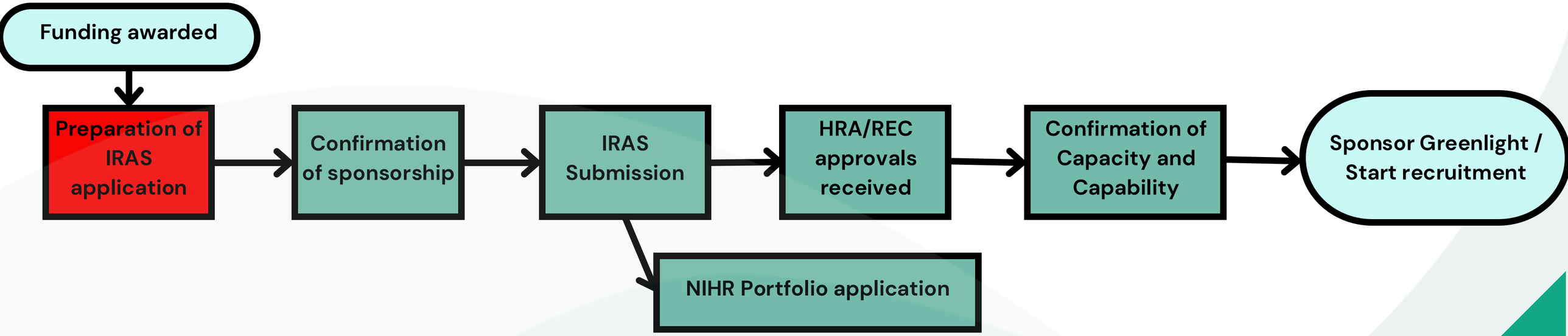
Medicines & Healthcare products Regulatory Agency (MHRA)

HM Prison & Probation Service

HRA Confidentiality Advisory Group (CAG)

Administration of Radioactive Substances Advisory Committee

3. How do I obtain these approvals?



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Preparation of IRAS application

Integrated Research Application System (IRAS)

Applications for regulatory approval are submitted through IRAS

The **project filter questions** on IRAS will determine which additional forms are needed.

Supporting documents such as protocol, participant information sheets and consent forms must be uploaded into IRAS

The HRA has published **Participant Information Quality Standards** and template texts

http://myresearchproject.org.uk/

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Preparation of IRAS application

Participant Information Quality Standards

The HRA has published Quality Standards to improve information given to people who are invited to take part in research.

The Standards set out the basic criteria that all participant information must meet. They include language, accessibility, and content requirements.

- Plain English
- Study summary
- Contact details
- Sponsor template
- Informed by public involvement

[Link to Participant Information Quality Standards]

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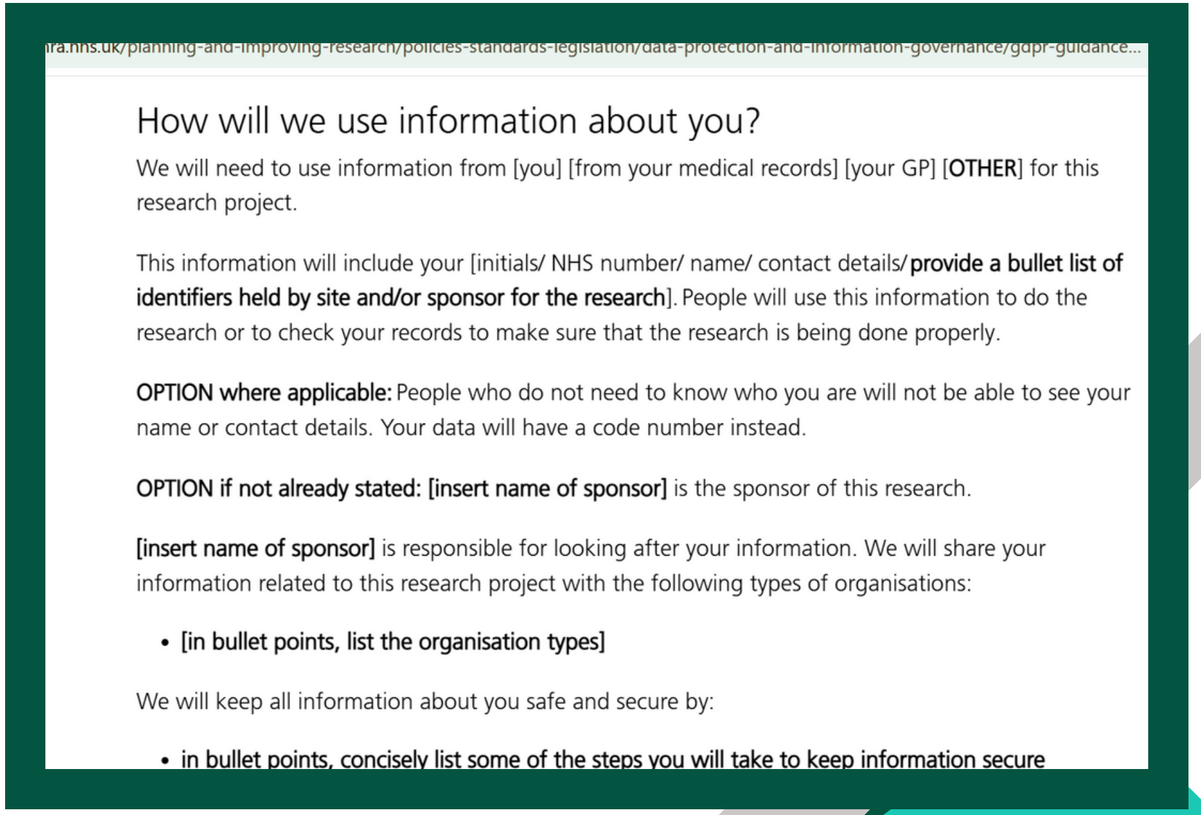
Preparation of IRAS application

GDPR transparency wording

- Template designed by the HRA to help ensure research participants have all the information they need to make an informed decision about the use of their data
- This is a mandatory requirement for all studies requiring HRA approval
- Insert wording into Participant Information Sheet

Link to Transparency wording



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Mental Capacity Act (2005)

Researcher must show that the research cannot be carried out effectively with participants who have capacity

The research must be connected with an impairing condition affecting the participant

The research must provide direct benefit to the participant OR have potential to improve care for others with a similar condition

Personal or nominated consultee must advise on what the participant's wishes would be about taking part.

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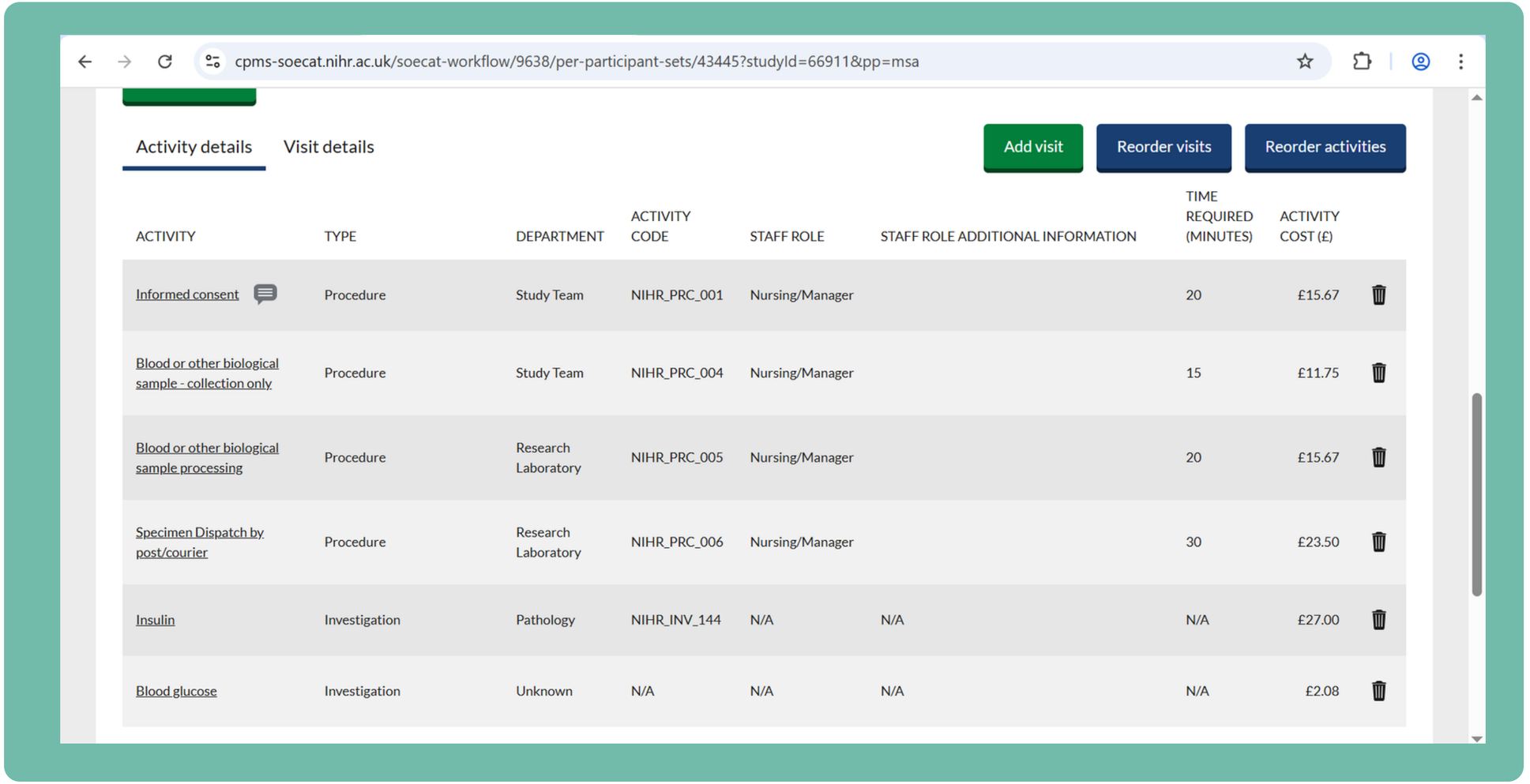
SoECAT: Schedule of Events Cost Attribution Template

The SoECAT includes activities undertaken at **NHS sites** and assigns a cost and cost category to them.



ACTIVITY	TYPE	DEPARTMENT	ACTIVITY CODE	STAFF ROLE	STAFF ROLE ADDITIONAL INFORMATION	TIME REQUIRED (MINUTES)	ACTIVITY COST (£)
Informed consent	Procedure	Study Team	NIHR_PRC_001	Nursing/Manager		20	£15.67
Blood or other biological sample - collection only	Procedure	Study Team	NIHR_PRC_004	Nursing/Manager		15	£11.75
Blood or other biological sample processing	Procedure	Research Laboratory	NIHR_PRC_005	Nursing/Manager		20	£15.67
Specimen Dispatch by post/courier	Procedure	Research Laboratory	NIHR_PRC_006	Nursing/Manager		30	£23.50
Insulin	Investigation	Pathology	NIHR_INV_144	N/A	N/A	N/A	£27.00
Blood glucose	Investigation	Unknown	N/A	N/A	N/A	N/A	£2.08

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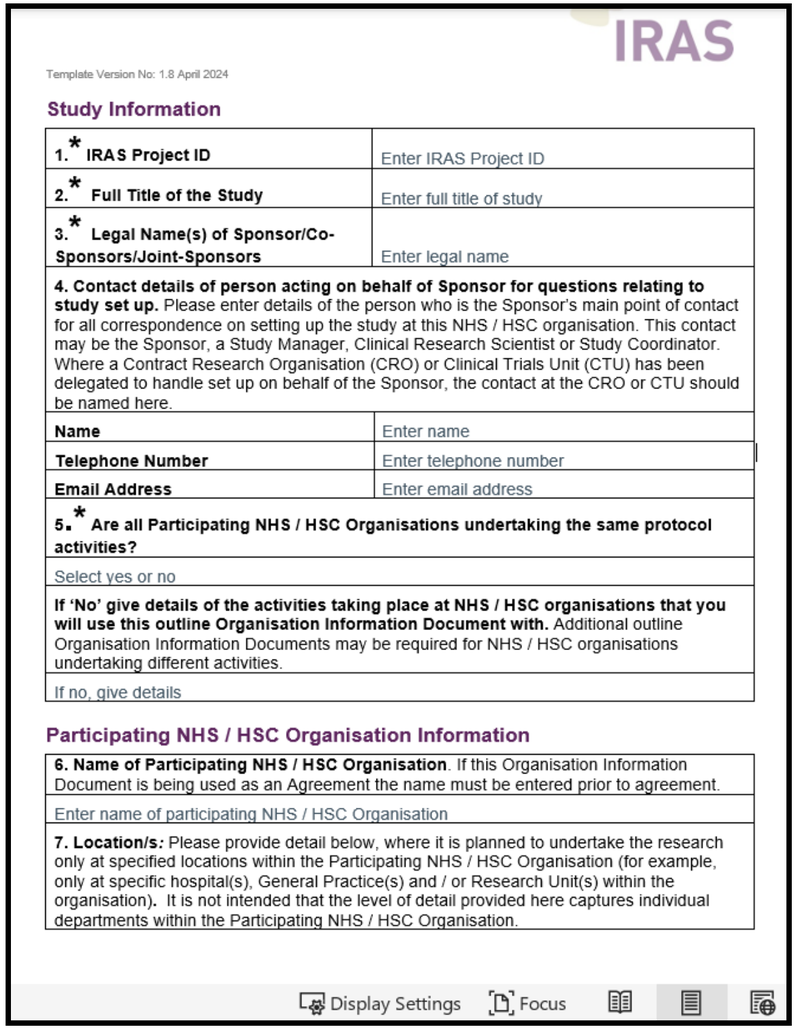
Preparation of IRAS application

Organisation Information Document (OID)

- This document contains information for the recruiting site about their role and responsibilities
- It must be provided as part of the IRAS submission
- The template is available at: https://www.myresearchproject.org.uk/
- JCRO can support completion



IRAS

Template Version No: 1.8 April 2024

Study Information

1.* **IRAS Project ID**	Enter IRAS Project ID
2.* **Full Title of the Study**	Enter full title of study
3.* **Legal Name(s) of Sponsor/Co-Sponsors/Joint-Sponsors**	Enter legal name

4. Contact details of person acting on behalf of Sponsor for questions relating to study set up. Please enter details of the person who is the Sponsor's main point of contact for all correspondence on setting up the study at this NHS / HSC organisation. This contact may be the Sponsor, a Study Manager, Clinical Research Scientist or Study Coordinator. Where a Contract Research Organisation (CRO) or Clinical Trials Unit (CTU) has been delegated to handle set up on behalf of the Sponsor, the contact at the CRO or CTU should be named here.

Name	Enter name
Telephone Number	Enter telephone number
Email Address	Enter email address

5.* **Are all Participating NHS / HSC Organisations undertaking the same protocol activities?**

Select yes or no

If 'No' give details of the activities taking place at NHS / HSC organisations that you will use this outline Organisation Information Document with. Additional outline Organisation Information Documents may be required for NHS / HSC organisations undertaking different activities.

If no, give details

Participating NHS / HSC Organisation Information

6. Name of Participating NHS / HSC Organisation. If this Organisation Information Document is being used as an Agreement the name must be entered prior to agreement.

Enter name of participating NHS / HSC Organisation

7. Location/s: Please provide detail below, where it is planned to undertake the research only at specified locations within the Participating NHS / HSC Organisation (for example, only at specific hospital(s), General Practice(s) and / or Research Unit(s) within the organisation). It is not intended that the level of detail provided here captures individual departments within the Participating NHS / HSC Organisation.

Display Settings Focus

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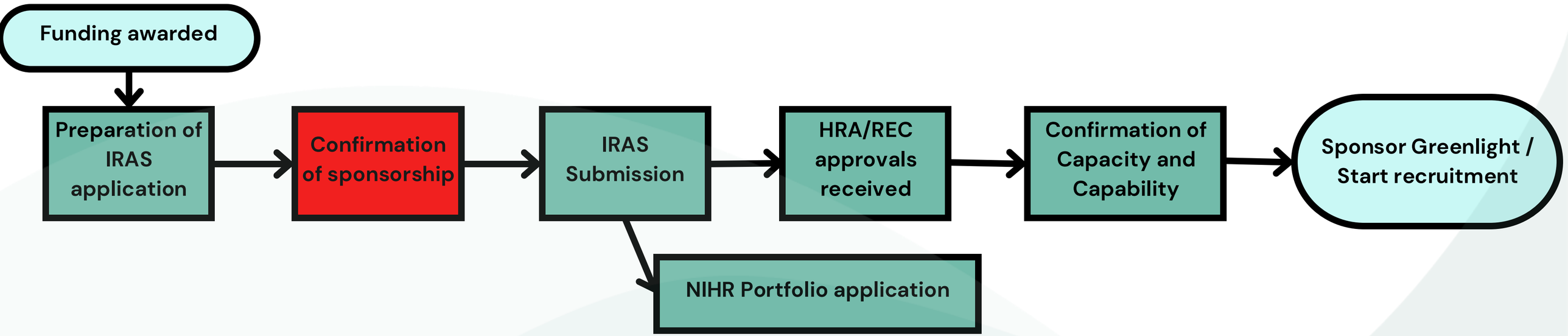
Preparation of IRAS application

IRAS application tips

- Be consistent about when patients can withdraw their data
- Address Potential for Coercion
- Ensure Proper Document Formatting
- Be Inclusive of Non-English Speakers and those with different communication needs. EDI Webinar
- Avoid Digital Exclusion Digital Inclusion Framework


Funding awarded
Preparation of IRAS application
Confirmation of sponsorship
IRAS Submission
HRA/REC approvals received
Confirmation of Capacity and Capability
Sponsor Greenlight / Start recruitment
NIHR Portfolio application

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Confirmation of sponsorship

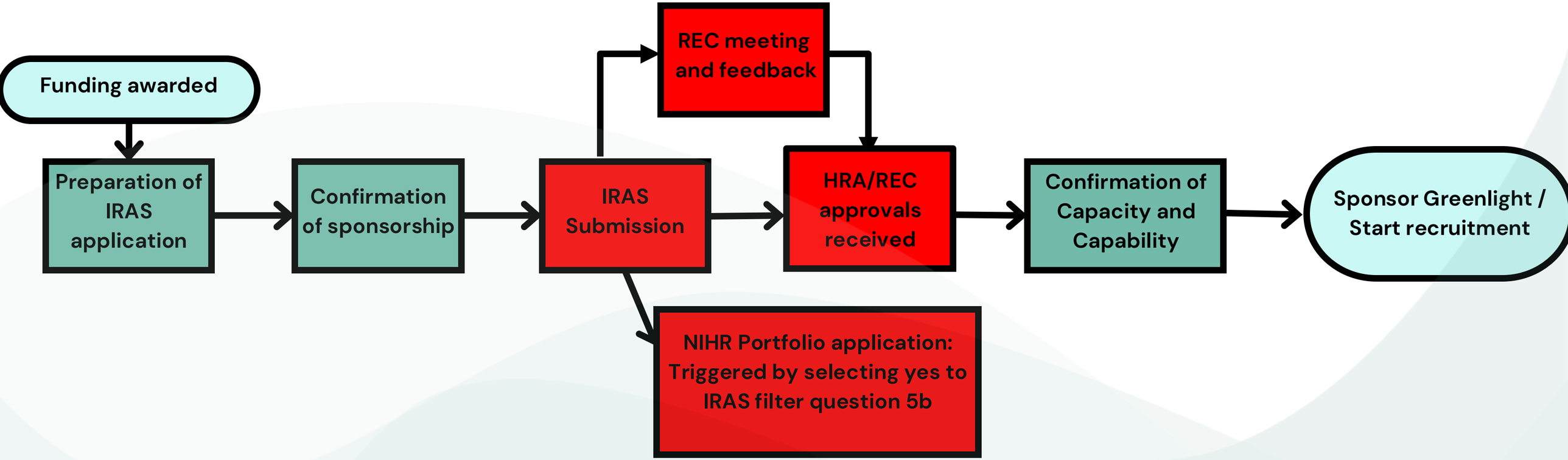
Sponsorship

The sponsor is the organisation that takes on overall responsibility for proportionate, effective arrangements being in place to set up, run and report a research project

The sponsor is typically the employer of the Chief Investigator

If you are employed by a JCRO partner organisation, an application must be made to the PSRP (Pre-sponsorship review panel) in advance of sponsorship being confirmed.

Pre-Sponsorship Review Panel (PSRP) - BSMS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Preparation of IRAS application
Confirmation of sponsorship
IRAS Submission
REC meeting and feedback
HRA/REC approvals received
Confirmation of Capacity and Capability
Sponsor Greenlight / Start recruitment
NIHR Portfolio application: Triggered by selecting yes to IRAS filter question 5b

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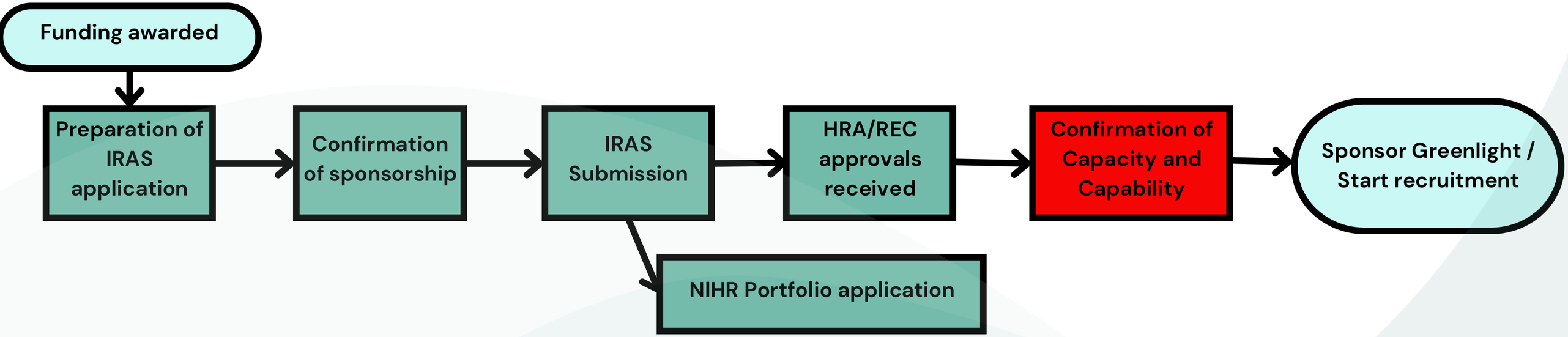
NIHR Portfolio application

NIHR Portfolio adoption

Available to studies with eligible funding

- Support for the planning and delivery of high-quality research by the Local NIHR Research Delivery Network
- Access to research training
- ISRCTN registration is free for portfolio studies
- NHS sites that recruit to a portfolio study are eligible to receive additional support funding (not via grant)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Confirmation of Capacity and Capability

Confirmation of Capacity and Capability

NHS recruiting sites must confirm capacity and capability for a study to commence recruitment.

The Local Information Pack (LIP) should be sent to sites to initiate the C&C process.

IRAS Help - Preparing & submitting applications - Site specific information

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How long will it take?

- We would advise researchers to expect the process from requesting sponsor approval for an application to receiving confirmation of capacity and capability to take 6 months.
- The RECs aim to provide a final opinion within 60 days of receiving a submission
- The time for obtaining sponsorship approval and NHS confirmation of capacity and capability is more variable.
- It's important to start conversations with NHS Research and Development Departments early

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4. What happens once my research project is open?

Substantial Amendments

- Change of Sponsor or Chief Investigator
- Changes to procedures undertaken by participants
- Change to the definition of the end of study
- Significant changes to participant facing documents

Non-substantial Amendments

- Minor changes to the protocol or study documents
- inclusion of new sites (non-drug study)
- Change to study end date
- Changes to Chief Investigators research team

Submit using HRA Amendment Tool

NHS sites must confirm they have no objection to the amendment going ahead

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Ongoing project management

- All adverse events and protocol deviations should be recorded.
- *Serious* Adverse Events that are *unexpected* and *related* to the research procedures must be reported to the NHS REC within 15 days
- Serious breaches to protocol or GCP (Good Clinical Practice) must be reported to NHS REC
- At the end of the study, an end of study declaration should be sent to the REC within 90 days.
- A Final report should be submitted to the REC within 12 months of the study ending

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Upcoming changes for Drug Trials and Clinical Investigations

The new clinical trial regulations will come into force on 28 April 2026

It will become a legal requirement to:

- Register clinical trials in a public registry
- Publish a summary of trial results within 12 months of completion
- Offer to share a summary of results with participants (or their representative) in a format they can easily understand

The HRA are preparing guidance on developing an Inclusion and Diversity plan to be submitted via IRAS – not mandatory

Any questions?

Email: JCRO@Sussex.ac.uk

Website:

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