



Manchester University
NHS Foundation Trust

Research and innovation

Alison Robinson, Senior R&I Manager
Manchester University NHS Foundation Trust



Our Hospitals

One of the largest comprehensive healthcare campuses in Europe

Through our pioneering research and innovation, we are improving lives by giving patients the opportunity to shape and take part in clinical studies and evaluations.

North Manchester
General Hospital

Manchester Royal
Infirmary

Wythenshawe Hospital

Royal Manchester
Children's Hospital

Manchester Royal Eye
Hospital

Saint Mary's Hospital

University Dental
Hospital of Manchester

Withington
Community Hospital

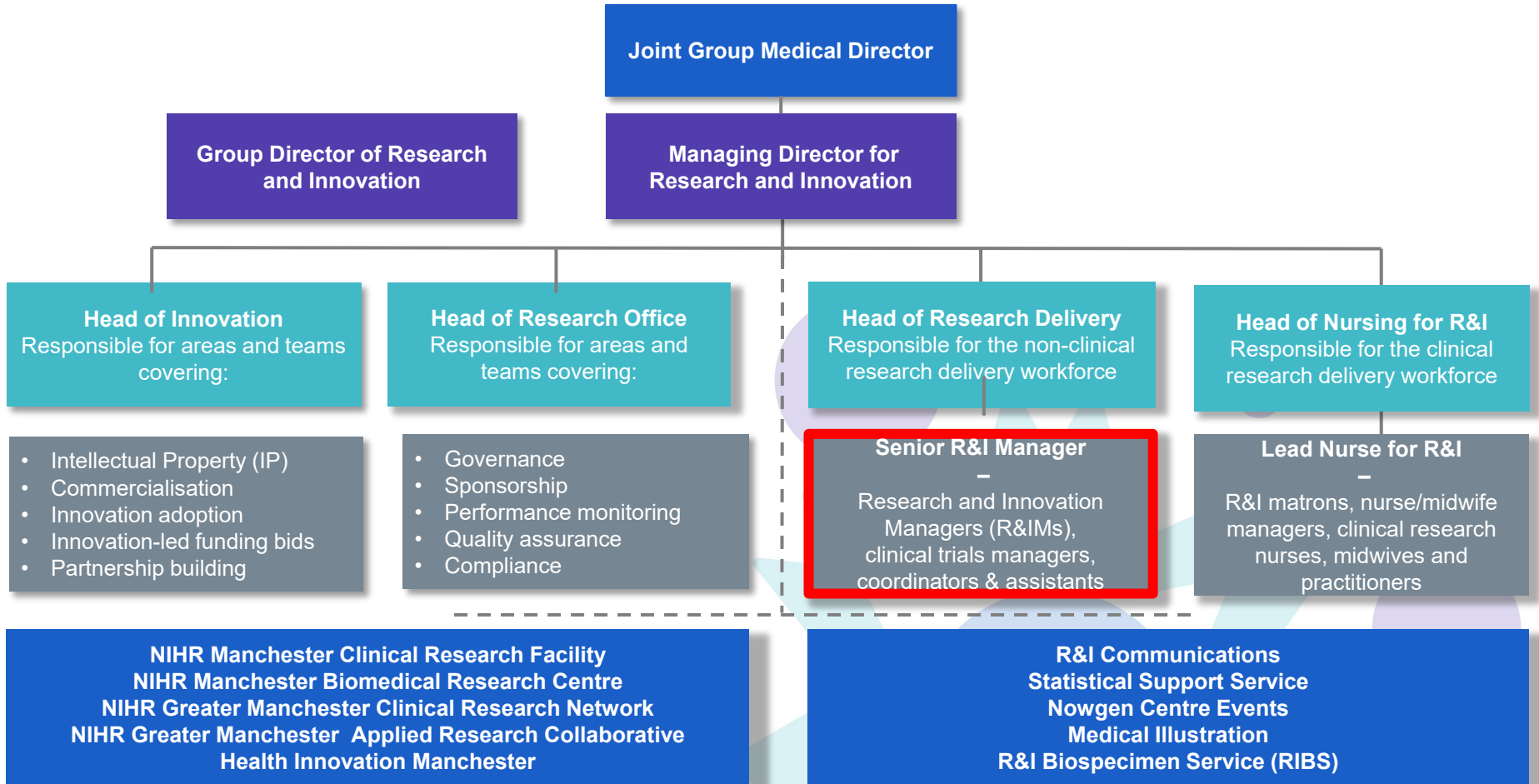
Trafford General
Hospital

Altrincham Hospital

Transforming the
Future at North
Manchester General
Hospital

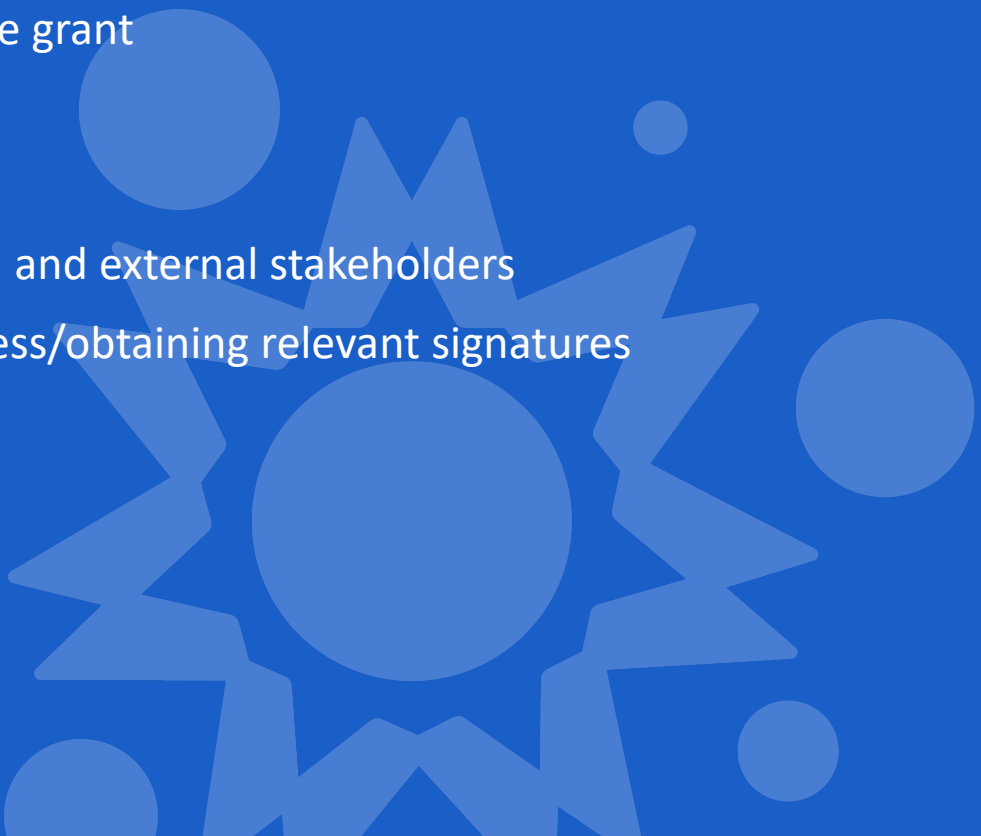
Transforming the
Future of
Wythenshawe Hospital

Our structure



Overview

The importance of engaging with Research Management EARLY so they can help you with:

- The Sponsorship decision
 - Which organisation should host the grant
 - Research Management support
 - Identifying appropriate costings
 - Engagement with relevant internal and external stakeholders
 - Support with the submission process/obtaining relevant signatures
 - Declaration of Interests
 - Post Submission Support
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Who Sponsors Your Study?

Default

The substantive employer of the main applicant/chief investigator will act as Sponsor of the study proposed by the grant application

(e.g., MFT = MFT)

Clinical Academic

University employed clinicians can request Sponsorship from either the University of Manchester or the Trust in which they are clinically based

(e.g., if the grant is to be hosted at MFT and our patients are being recruited, then Trust sponsorship is likely, especially for a CTIMP)

But you must still get agreement from the organisation to act as Sponsor, not least to be able to consider appropriate costings for the work required

Trust Sponsorship Decision

Q.

Is the project you are proposing a clinical trial or complex study?

Any study which is listed in one of the top 4 study types on IRAS will require submission to our Sponsorship and Governance Oversight Committee (SAGO) for agreement 'in principle'.

There is an application form and a process at MFT.

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Research Management Support



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At MFT, six Research & Innovation Managers (R&IMs) plus support from a NIHR Grants Research Assistant

- support for **grant applications** and other high-quality outputs of research
- R&IM has **Budgetary** responsibility for all research projects AND infrastructure including space and staff time devoted to research
- Line management of non-clinical research delivery staff
- Risk assessments and **performance management** of studies
- Overall **strategic direction** and general troubleshooting
- **Liaison** with external partners: identifying opportunities to develop, use and **exploit innovation** to improve the delivery of care to patients

Working Out the Budget

It is essential that the NHS and its partner organisations identify and quantify the full cost of research and reach a shared understanding of how these costs are recovered through appropriate funding contracts and agreements.

Staff pay - Increments and pay awards need to be considered so Research Accountant must cost all appropriate MFT staff time

Non-staff pay - All equipment, travel, consumables, tests and so on need to be considered

Research, Service Support or Treatment Costs?

Only Research Costs will be paid by the grant - we help identify these and advise on how the other costs will be met

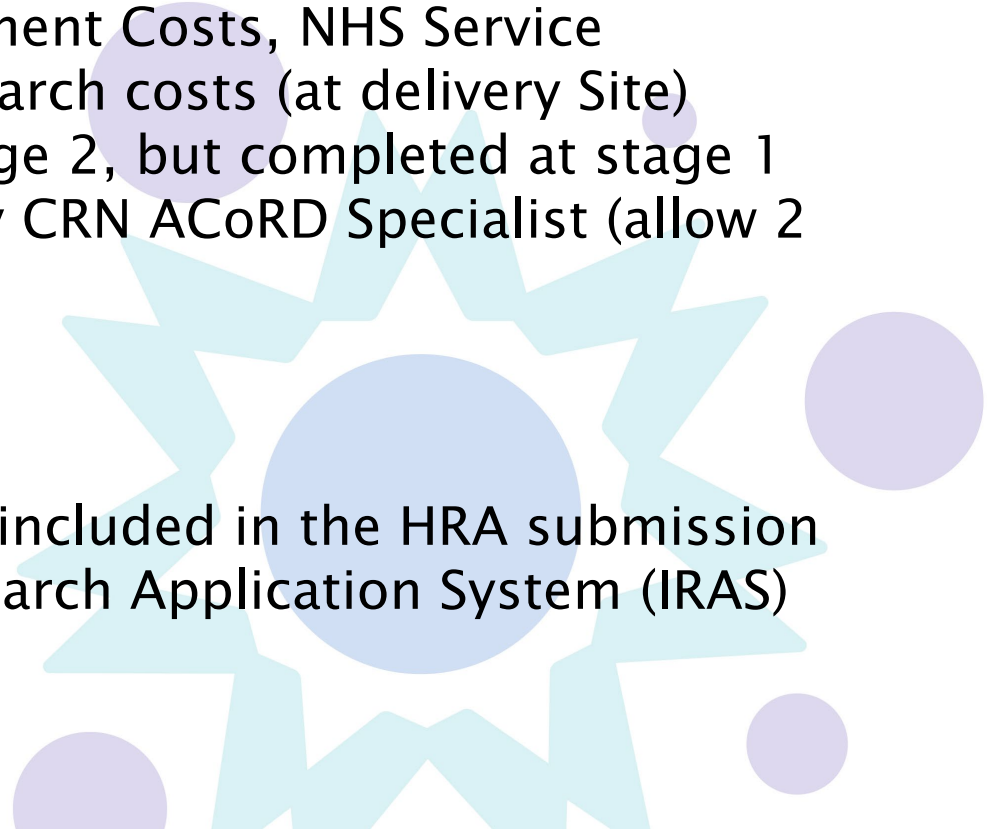
SoECAT

Schedule of Events Cost Attribution Template

- Required for all NIHR grants
- Required for AMRC and Research Council grants
- Used to ensure **site-level NHS costs** are appropriately identified and attributed
- Calculates Excess Treatment Costs, NHS Service Support Costs, and Research costs (at delivery Site)
- Usually submitted at stage 2, but completed at stage 1
- Approval requirement by CRN ACoRD Specialist (allow 2 weeks)

If grant is successful

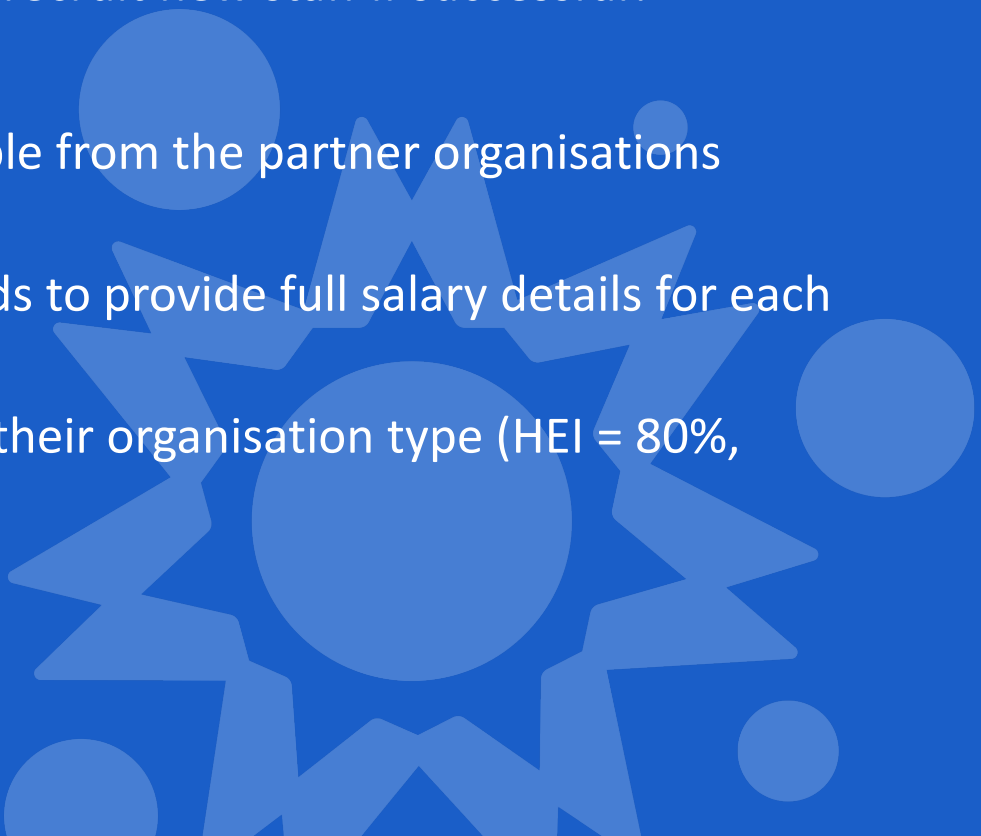
- The approved SoECAT is included in the HRA submission pack via Integrated Research Application System (IRAS)



Talking to all stakeholders

Internal and external discussions

- Are all departments involved, engaged and aware of the application?
 - Do you have agreement to deliver the additional activities?
 - Will these departments need to recruit new staff if successful?

 - Are you talking to the right people from the partner organisations about their costs?
 - **Consider each partner** also needs to provide full salary details for each co-Applicant.
 - Consider the funding model for their organisation type (HEI = 80%, plus indirect/estates costs)
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Other institutional support

Institutional Support (e.g. Stage 1 Fellowship applications)

Letter of Support – work with your R&IM / NIHR Grants Research Assistant to prepare and submit to Professor Rick Body (R&I)
Support from Clinical Director/Line Manager

The Fellowship Academy – we refer to Professor Neil Hanley and Katy Boyle to support fellows linked with the University of Manchester for advice, critique and practice interviews



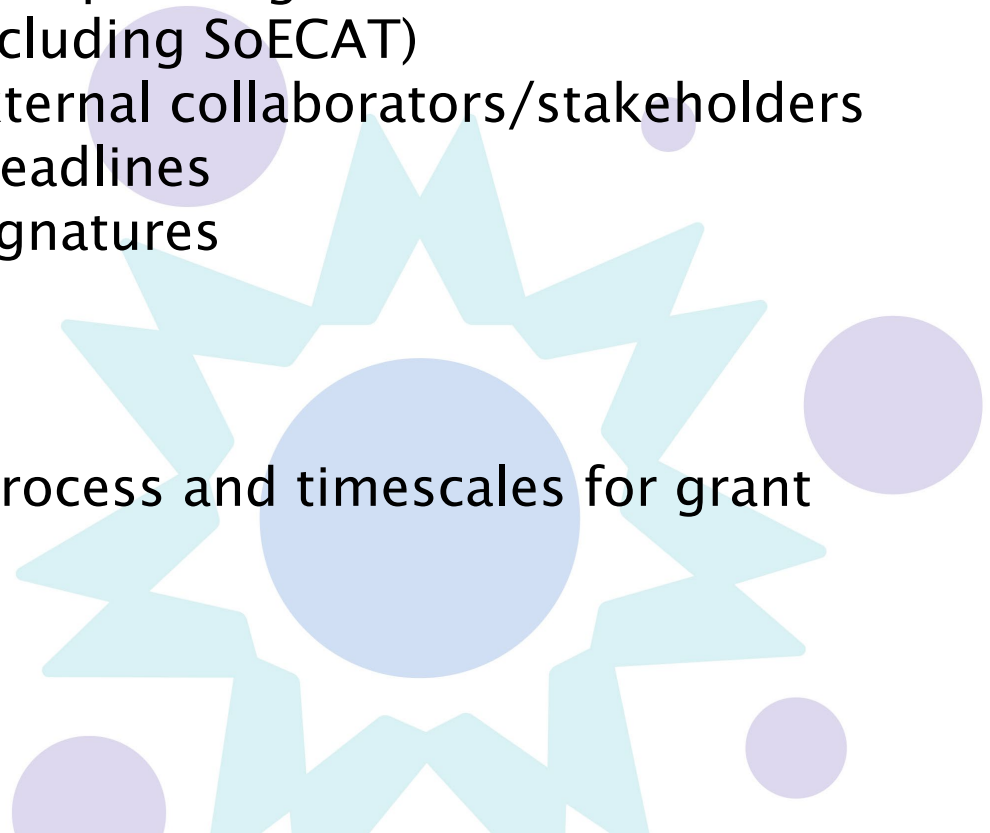
Grants Research Support



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Coordination of grants through our NIHR Grants Research Assistant includes:

- Proposal review
- Checking eligibility and call-specific guidelines
- Co-ordinating costings (including SoECAT)
- Signposting to internal/external collaborators/stakeholders
- Managing/co-ordinating deadlines
- Facilitating institutional signatures
- Deadline updates
- Call matching
- Training and outreach
- Flowcharts outlining the process and timescales for grant submissions

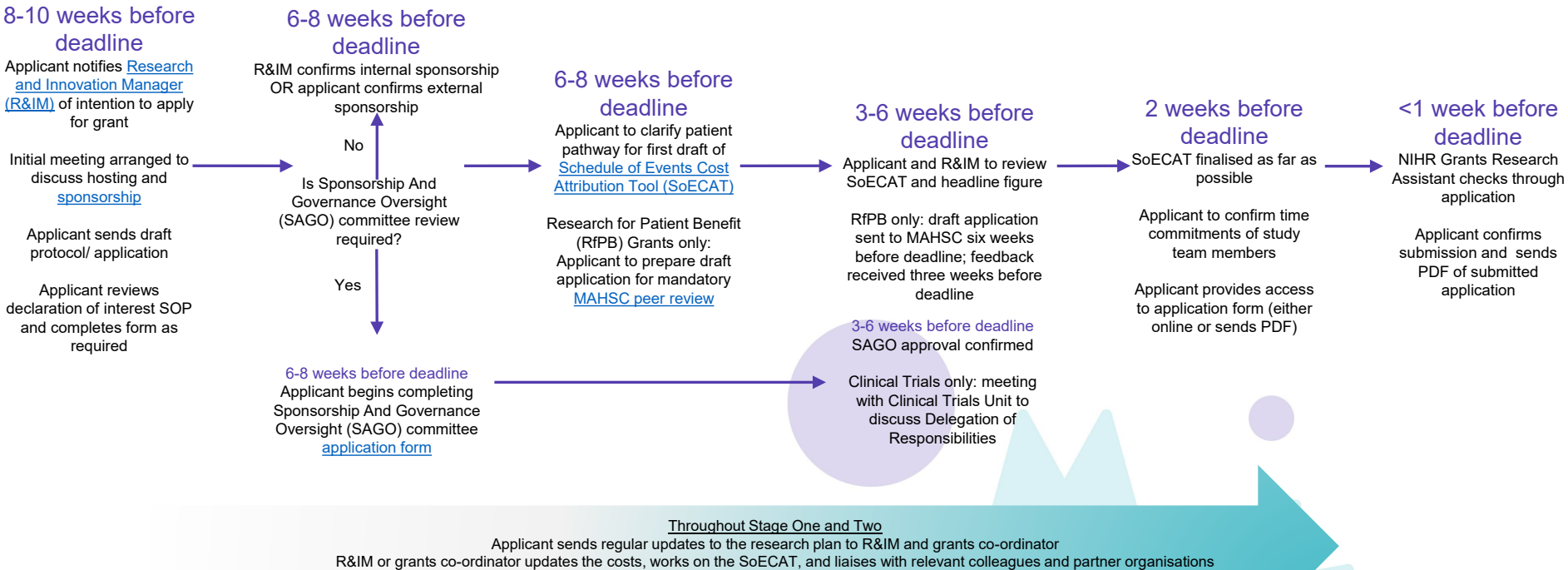


MFT R&I Grant Applications – Milestone Flowchart

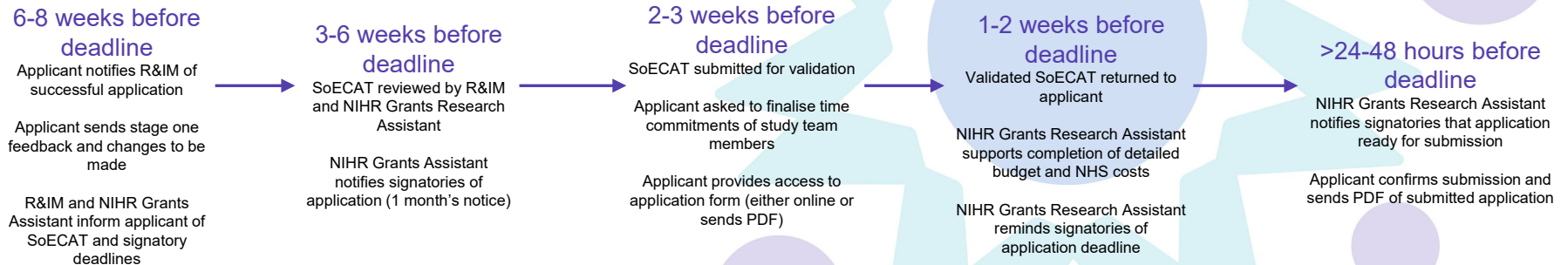


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Stage One

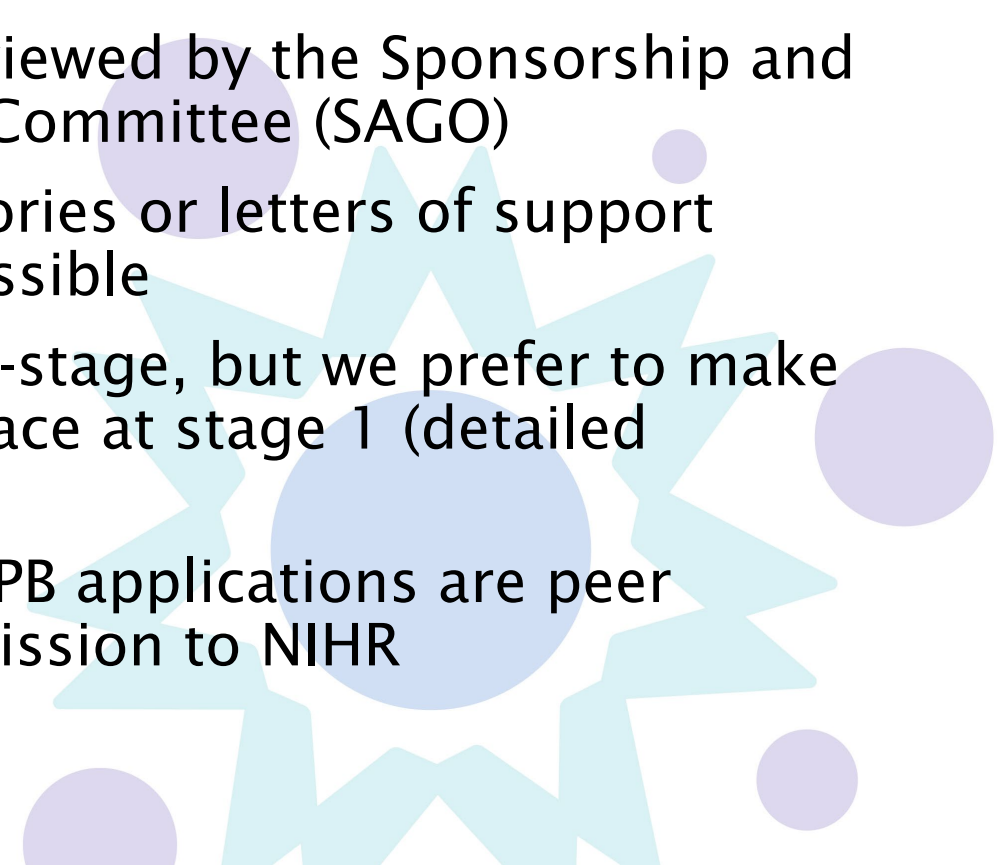


Stage Two



Grant Application Processes

Key points to note:

- Approach early (at least 8-10 weeks)
 - All clinical trials are reviewed by the Sponsorship and Governance Oversight Committee (SAGO)
 - Notify us of any signatories or letters of support required as soon as possible
 - Most NIHR grants are 2-stage, but we prefer to make sure everything is in place at stage 1 (detailed costings, SoECAT, etc.)
 - In Manchester, NIHR RfPB applications are peer reviewed prior to submission to NIHR
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Authorisation Signatures (at Full application stage)

Electronic authorisation

Details of signatories are entered into the application and asked by email to confirm that they accept being a signatory

Once the application is submitted they will be asked to give their electronic approval

Different systems

NIHR have three different online application systems, and each funding scheme differs in the signatures required

(Key) Signatories

Head of Department

Director of R&I, Rick Body

Finance up to £350k

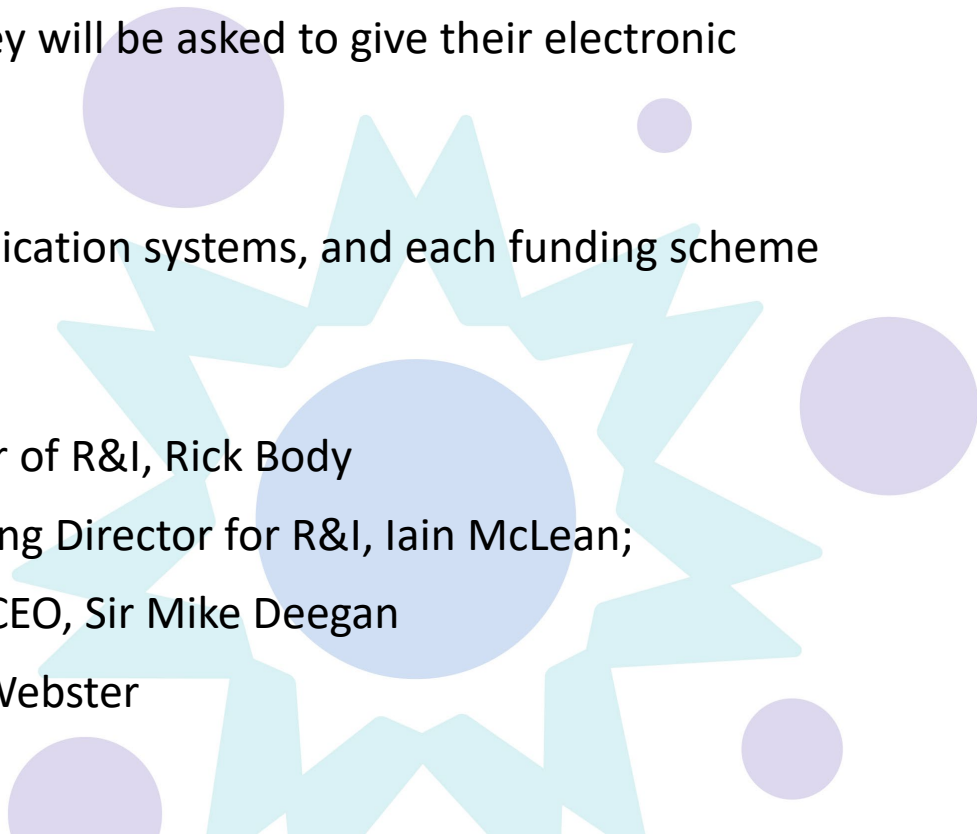
Managing Director for R&I, Iain McLean;

Finance over £350k

Group CEO, Sir Mike Deegan

Sponsor representative

Lynne Webster



Declaration of Interests

Health Research Authority recognises that NHS staff may be subject to “competing interests” in their conduct of research studies and some of those interests, while in tension with the proper conduct of the research,

simply need to be acknowledged and managed appropriately to minimise their impact

Competing interests could be:-

implicit such as

Publication of the research

Career advancement

Simply the need to complete a study, or

explicit such as

A financial interest

Declaration of Interests

Trust's Standards of Business Conduct and Hospitality Policy

Lists situations which require someone to make a declaration

The Management of Potential Conflicts of Interest for Research and Innovations

This policy describes the mechanisms the Trust will use to manage these conflicts on **receipt of a declaration of interest** ; mitigating risks to **research integrity** and **allowing the introduction of innovations into practice without undue bias**

Judgement can then be used to decide if this may unduly influence the conduct of a research study or if there are sufficient measures in place to mitigate this risk.

Post Submission Support

NIHR feedback

- include your R&IM/Grants Research Assistant in any correspondence with the NIHR
- Support for re-costing, liaison with any other stakeholders
- Re-submission at any stage.

Success!

- NIHR pre-contract queries e.g. Intellectual Property (background and foreground)
- Support with financial arrangements, sub-contracts, recruitment of staff

Reporting arrangements with NIHR

ResearchFish – research outputs and publications (HRA Transparency)



Top Tips

- 8-10 weeks in advance
- Pay careful attention to **eligibility** and **funding limits**
- Keep Research Management in the loop about **changes** to the applications or **grant resubmission**, at the earliest possible stage for review

Don't forget:

- Patient and Public Involvement and Engagement (PPIE)
- **Equality, Diversity and Inclusion**
 - ✓ Declaration of Helsinki
 - ✓ NIHR Operating Principle
 - ✓ MFT's aim of Improving Patient Access, Safety, and Experience

If you're not sure about something, ask!

Contact Details

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Thank you for listening

