Health Research Authority

# ICR Ethics and GCP Forum

## 14th 2021

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Change Manager

# Combined Review

# What is changing?

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The way applications for CTIMPs are submitted, reviewed and approved.

From Jan 2022 combined review will be the only route for CTIMP to be reviewed in UK

Applications are through a new IRAS platform

# Why is it changing?

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To improve users' experience of IRAS to apply for, and maintain, approvals

To streamline and integrate the research journey

To ensure IRAS is fit for purpose in the future "future proof"

# How is the process changing?

**One** application

**One** coordinated review

**One** decision

# Review process

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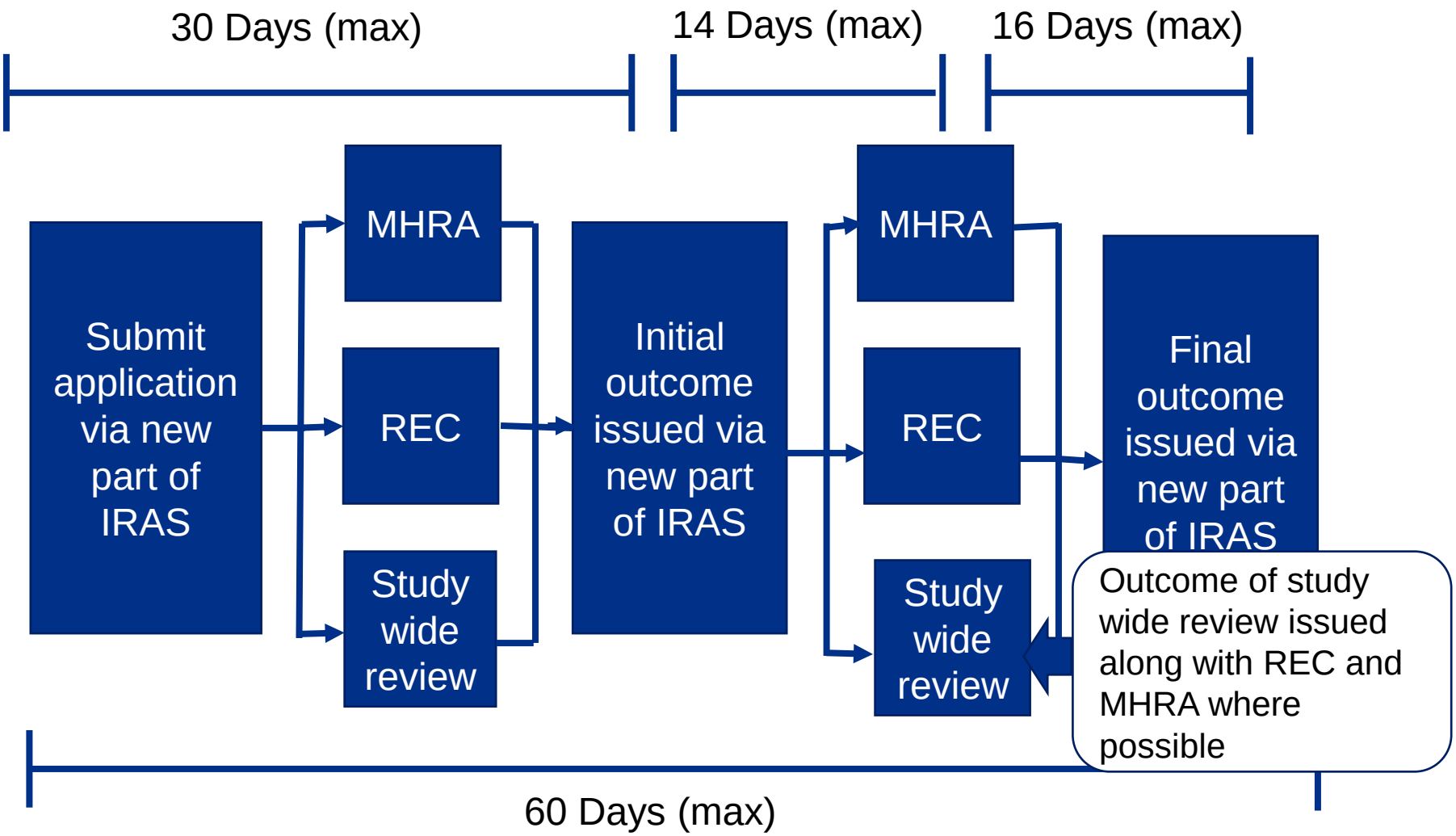

# What is different about the application process?

Built on a new IRAS platform

New roles – project deputy, collaborator

Early sponsor oversight

Task based system – project and organisational level

System generated documentation

It will develop further……

# Agile development

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It is being built in stages to create the best possible system to meet the needs of users.

User groups will see and experience changes over time

We are listening to different views

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**Dec 2021**

- No new CTIMPs can be created in standard IRAS from 14 Dec

**Jan 2022**

- Submit CTIMPs in standard IRAS by End of Dec 2021
- 03 Jan – all CTIMPs through combined review

**Q1 2022**

- Radiation Technical Assurance
- IRAS Part B Section 3 & ARSAC PRA form in new IRAS

# How can I prepare?

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Attend a combined review webinar:

- Live or on demand via our LMS
- Sponsor, applicant and site available

Read guidance, further information on HRA website

Assess internal processes for impact of changes

Don’t delay, submit via combined review today

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# Technical Assurances

# Ionising Radiation

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- ✓ Stream lines study set up
- ✓ Open to all studies involving ionising radiation
- ✓ Available to studies going through combined review
- ✓ Being built into new IRAS for combined review
- ✓ Sponsors can go through self managed

Start using without delay

# Pharmacy

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- ✓ Call from sites for sponsor to use to help streamline study set up
- ✓ Open to Phase I-III Oncology, and all non-oncology CTIMPs
- ✓ Available to studies going through combined review
- ✓ Presents technical information in a consistent and standardised manner

Start using today

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# Improving *your* experience with HRA

# What are we seeing?

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- Missing contracts and costings
- Copy/paste answers in IRAS not reflecting the study
- Contradiction between documents
- No IRAS ID on PIS
- Unclear on information governance
- Unclear on tissue handling
- Unclear on contracts and modifications
- Costing template not validated by CRN

# Queries raised in REC meetings

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- Detail on recruitment strategy – including approach
- Which tests are standard and which additional
- Justification on inclusion of adults lacking consent
- Is access to medical records necessary
- What support for participants in distress or anxious

# Requests raised in REC letter

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- Clarity on study procedures – expectations
- Will (and how) findings be fed back to participants
- How is the research different from standard care
- General risks and burdens to the participant should be made explicit
- Travel/expense reimbursement provided
- Complaints procedure
- Written in lay language

# Issues with Industry PIS

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- Handling of clinically significant findings
- No distress policy
- Not clear how the substance has previously been used
- Side-effects frequency is not clear
- Summary information sheets not produced
- No information on alternatives
- No information about *relative* risk and benefit. How does the risk profile of the research option compare with that of the alternative available treatment (or no treatment) options?

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#MakeItPublic

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High quality health and social care research must be transparent if it is to improve people's lives

The HRA has a legal duty to promote research transparency (Care Act)

# Registering research

Clinical trials must be added to a publicly accessible register before the first participant is recruited, or no later than six weeks afterwards.

In 2022, new registration service for CTMPs to go live, where HRA will register clinical trials with ISRCTN.

# Reporting results

Strengthened and improved our guidance to make it clearer for researchers to know what is required

Published online final reporting form.

- Standard set of information
- Making transparency the norm

# Informing participants

Plain language summary of the study findings to be submitted as part of the final report

Developing new guidance to support researchers

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# New releases and things to look out for…

# Setting up interventional research at NHS sites

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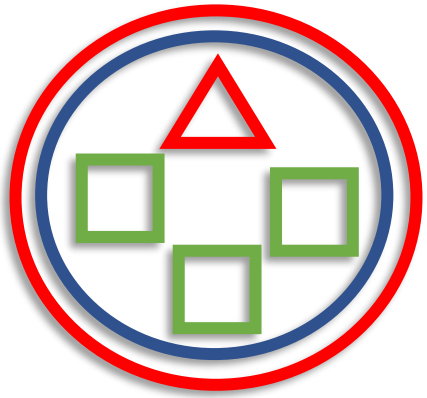
Principles and guidance for:

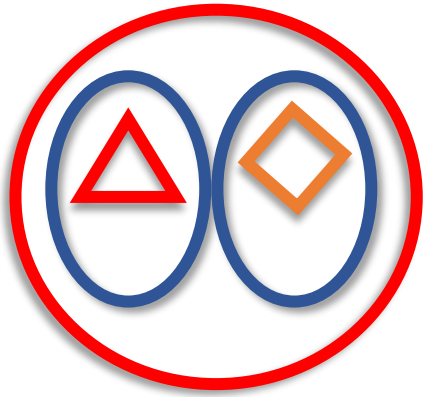
- Determining whether an activity should be overseen by a Principal Investigator (PI)
- Determining if for effective oversight PI must be employed by organisation
- Advice on undertaking a risk assessment to support research sponsors in making these determinations

Investigator site and trial site are identical

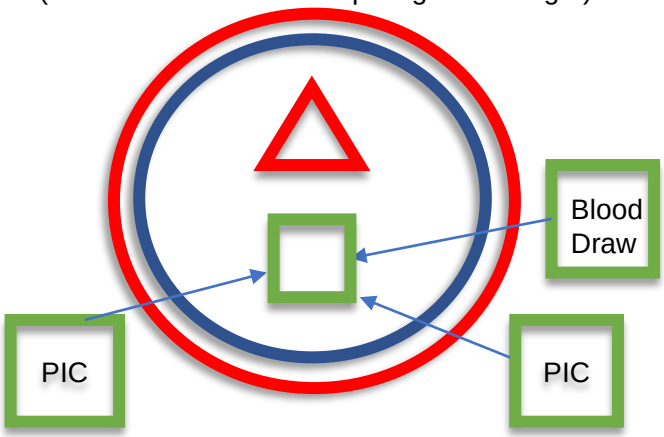


Two investigators sites within one legal entity

Two legal entities within one investigator site



Investigator site and trial site are identical
(external activities not requiring PI oversight)




**Key**

Trial Site (legal entity)

Investigator site (activities overseen by one PI)

Location (e.g. Hospital)

Principal Investigator

Sub-Investigator

# Creating a UK Ideal Path

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The right information at the right time to the right place

Integrating with other systems

Signposting to advice and support

# UK Approval

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# HRA Now

Operational bulletin for those working in research

Sign up for HRA Now/ update subscriber options if you receive HRA Latest

# Thank you for listening

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