Strengthening the UK environment for clinical research - progress
Radiation Assurance

Currently open to all phase oncology, rheumatology, neurology & cardiology studies in NHS/HSC secondary care

Continuing to recruit reviewers ahead of Phase 3 (final phase) of rollout

Current HRA-managed timeline: 31 days
Current self-managed timeline: 34 days
97 HRA-managed studies/4 self-managed studies
Feedback from Applicants

“The reviews have been well accepted by all UK sites participating in our studies.”

“Streamlining the process though a central contact and inbox, has also taken a lot of the burden away from the research teams. Reviewers are quickly identified, and we are always kept up date on progress. Overall it has been a very positive experience for our centre.”
Take home messages and actions

• Identify and submit all eligible studies to Radiation Assurance studies
• Liaise with sponsor – you can check if they have reviewers on HRA website
• Test the process – don’t wait for it to become part of HRA Approval
Pharmacy Assurance

Currently open to all phases of oncology and phase III non-oncology studies in NHS/HSC secondary care in England and Wales

Early submission encouraged – day of e-submission at latest

IRAS form no longer required as part of Pharmacy Assurance document set

Current HRA-managed timeline: 27 days
Current self-managed consistency review timeline: 4 days
15 HRA-managed studies/2 self-managed studies
Feedback from Applicants

“impressed with the timelines in which the study was reviewed”

“allows the information to be efficiently shared with the sites … making the setup process quicker”
Take home messages and actions

- Identify and submit all eligible studies to Pharmacy Assurance
- Liaise with sponsor – check for reviewers on HRA website
- Test the process – don’t wait for it to become part of HRA Approval
Amendment Tool Pilot
Easy fixes to improving your Approval application experience
Some simple resolutions based on common findings...
Frequent themes for further clarification from REC

• Detail on recruitment strategy – including approach
• How is the research different from standard care
• Inclusion of GDPR wording
• Changes to the PIS / ICF
Top three reasons for delay in HRA & HCRW Approval

1. Missing Organisation Information Document/Costing Template or Contract
2. No response to favourable opinion with conditions
3. Lack of clarity about site activity/site types
UK Local Information Pack and working with sites
UK Local Information Pack

5 June 2019

- Organisation Information Document
- Standard template emails for sharing packs with sites
- Short learning modules are available
 http://www.nhsresearchscotland.org.uk/services/uk-wide-working
How to share the Local Information Pack

1. Use nation specific template email from IRAS
2. Complete version control table
   Attach **all** documents as per email
3. Send to recipients as indicated in nation specific template email
### What makes up a UK Local Information Pack?

<table>
<thead>
<tr>
<th>What</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Covering email in standard template format – see IRAS Help</td>
<td>Model Agreement if applicable</td>
</tr>
<tr>
<td>IRAS Form</td>
<td>IRAS Schedule of Events or SOECAT/Industry Costing Template or Tool</td>
</tr>
<tr>
<td>Protocol</td>
<td>Template Delegation Log (Required for all interventional studies with a principal investigator.)</td>
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<tr>
<td>Patient information sheet and consent form</td>
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<tr>
<td>Localised Organisation Information Document (non-commercial/commercial)</td>
<td>For England and Wales – Initial Assessment Letter /or Approval Letter</td>
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Site specific information

request Organisation Information Documents). The decision to work on this way rests with the NHS organisations. If unsure of local arrangements please discuss with your HEI/NHS Sponsor team.

Participating NHS organisations in England and Wales

The Sponsor localises the Organisation Information Document(s) and emails it together with the other documents that make up the UK Local Information Pack to the R&D office and study delivery team (Principal Investigator or Local Collaborator, as applicable) at participating NHS organisation(s).

If the study is an NIHR portfolio study, the Sponsor should copy the Local Information Pack to the LCRN of participating organisations in England.

This should take place after the Sponsor receives the Initial Assessment Letter or the Approval Letter from HRA/HCRW.

IMPORTANT: The Sponsor is expected to use the correct email template when sharing the UK Local Information Pack with participating NHS organisations in England and/or Wales:

- Non-commercial study email template and guidance
- Commercial study email template and guidance

We are keen to hear feedback

- Sites requesting further documents
- Strange practices
- Rejecting packs
- Amendments
- Also let us know really good practice

Feedback to:
Jennifer.harrison2@nhs.net
The consultation

The consultation ran from 17 June to 6 September.

In total, 717 people took part in the consultation.

• Online survey
• Open workshops
• Focus groups
• Webinars for REC members
• HRA staff workshop
Any questions or feedback?
Thank you for listening

Contact information:
- Jen Harrison
- Jennifer.Harrison2@nhs.net

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