HRA Update

NHS
Health Research Authority

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Strengthening the UK environment for clinical research - progress

Radiation Assurance

Health Research Authority

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

Health Research Authority

“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

NHS Health Research Authority

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

Health Research Authority

"*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

Health Research Authority

- 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

HSC Health and Social Care

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

NHS SCOTLAND
NHS RESEARCH SCOTLAND

NHS
Health Research Authority

Amendment Tool Pilot

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Easy fixes to improving your Approval application experience

Health Research Authority

Some simple resolutions based on common findings...

Frequent themes for further clarification from REC

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- 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

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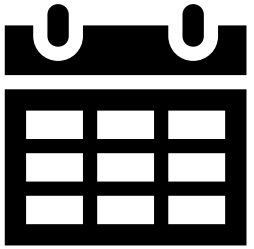
1. Missing Organisation Information Document/ Costing Template or Contract
2. No response to favourable opinion with conditions
3. Lack of clarity about site activity/ site types

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

Use nation specific template email from IRAS

Complete version control table
Attach **all** documents as per email

Send to recipients as indicated in nation specific template email

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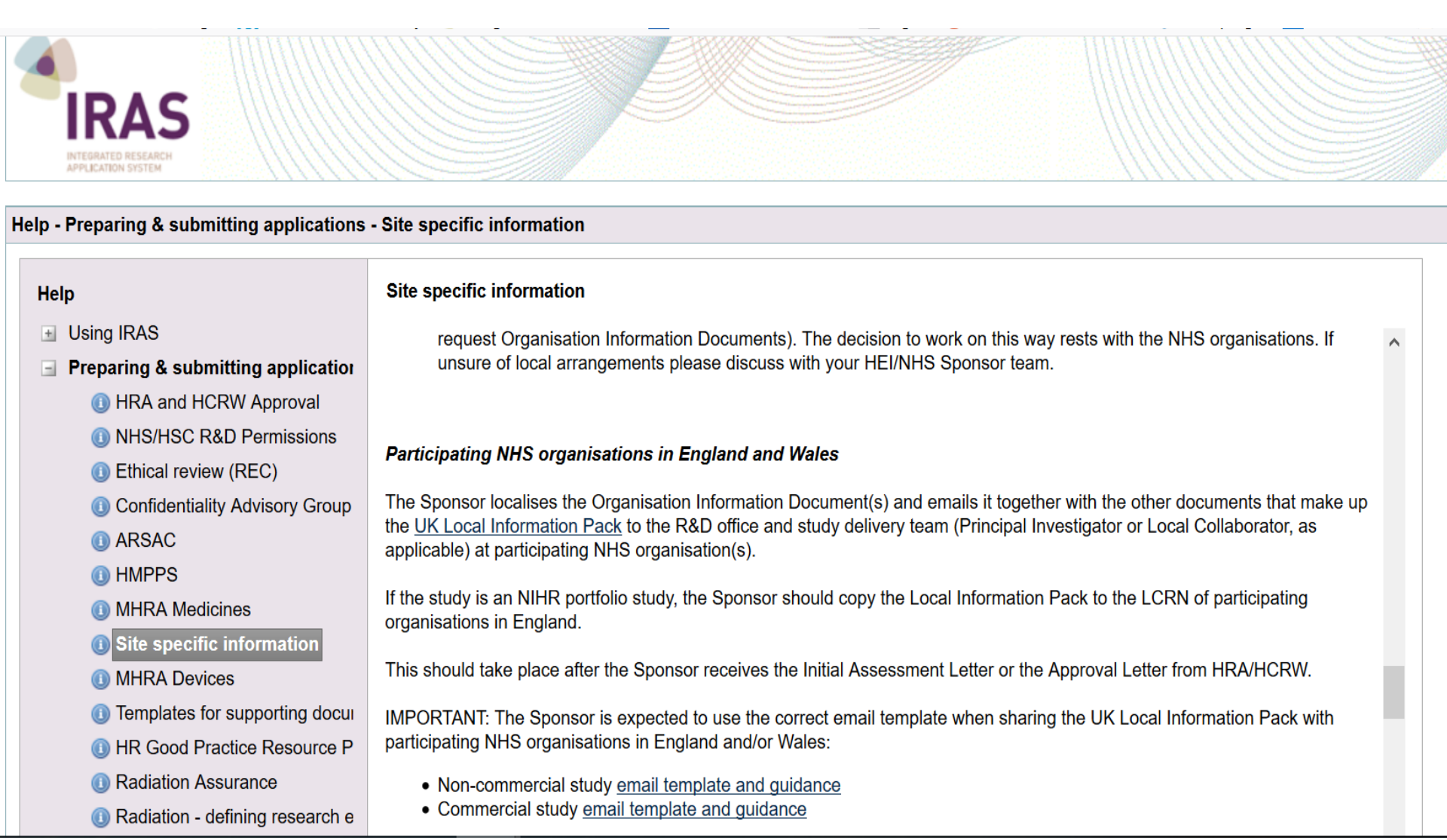
What makes up a UK Local Information Pack?

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



https://www.myresearchproject.org.uk/Help/HelpPage.aspx

We are keen to hear feedback

Health Research Authority

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

Feedback to:

Jennifer.harrison2@nhs.net


#MakeItPublic

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

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Any questions or feedback?

Thank you for listening

Contact information:

- **Jen Harrison**
- Jennifer.Harrison2@nhs.net

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