



NHS/HSC Site set-up - Sharing UK Local Information Pack

This bite size presentation provides a high level overview on sharing the UK Local Information Pack with NHS/HSC organisations.

It should be read in conjunction with the full guidance available in [IRAS](#)

Purpose of the UK Local Information Pack?

The purpose of the UK Local Information Pack is to provide a clear and consistent set of documents to support NHS/HSC organisations set up research studies

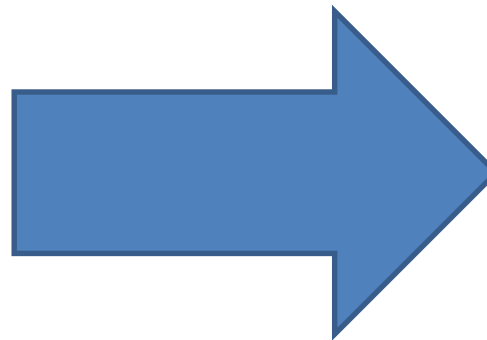
This;

- Maintains **compatible** systems across the UK
- Supports **cross border** research
- Makes it **easier** to do research across the UK

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



How to share the Local Information Pack

- Use standard template email
 - All are available in IRAS
 - Nation specific templates
 - Non commercial and commercial templates
- Ensure you complete table in nation specific template email with version and dates of documents to be attached
- Attach required documents as per nation specific email (ensuring these match the versions listed in the email)

What makes up a non-Commercial UK Local Information Pack?

Non Commercial Studies

[Covering email in standard template format](#)

Model Agreement if applicable

IRAS Form

IRAS Schedule of Events or SOECAT

Protocol

Delegation Log (Required for all interventional studies with a principal investigator. Indicate if this is being provided at a later date)

Patient information sheet and consent form

Localised Organisation Information Document (non-commercial)

For England and Wales –Initial Assessment Letter /or Approval letter

What makes up a Commercial UK Local Information Pack?

Commercial Studies	
<u>Covering email in standard template format</u>	Model Clinical Trial Agreement
IRAS Form	Industry Costing Template or Tool
Protocol	Delegation Log (Required for all interventional studies with a principal investigator.)
Patient information sheet and consent form	
Localised Organisation Information Document (commercial)	For England and Wales –Initial Assessment Letter/or Approval letter

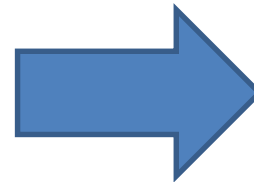
When to share the Local Information Pack



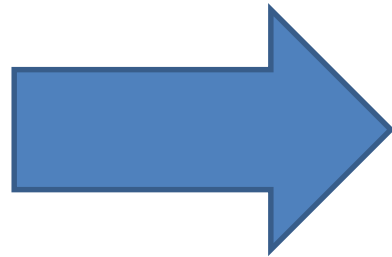
After initial discussion with sites – expression of interest, feasibility



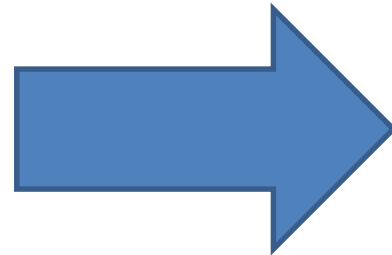
After IRAS submission and validation by lead nation or Initial Assessment for England and Wales



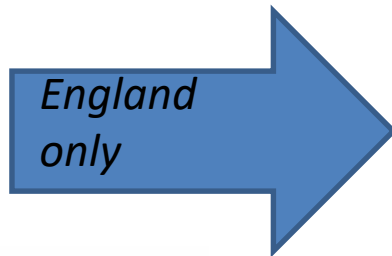
Who to share pack with (England, Wales and Northern Ireland)



**Delivery
team**

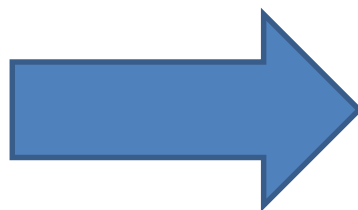


R&D



LCRN

Who to share pack with (Scotland)



nhsg.nrspcc@nhs.net

Localised Organisation
Information Document

Delegation Log

NRSPCC make documents
available to NHS sites in
Scotland

What happens next?



- Agree costings and contracts
- Sponsor and site complete Organisation Information Document
- Site confirms capacity and capability through exchange of agreement (England Wales and Northern Ireland)
- NHS permission (Scotland)

FURTHER GUIDANCE:

IRAS

4 Nation Programme