

## Research Study Set-up

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## Aim

- To provide an understanding of research study set-up and approval processes UK wide as they apply in NHS Wales.
- To inform you of forthcoming changes in UK processes and consider how they may impact on different stakeholders.
- In considering the processes, we will be specifically considering:
  - Non-commercial sponsorship of studies
  - Study-wide review by UK Nations
  - Study set-up at sites in participating NHS/ HSC organisations
- The outcomes of the workshop will be used to:
  - further develop the process flow for NHS Wales,
  - Identify the steps of the flow that may require revision, and
  - Inform the content of associated guidance documents.



## Shared Local Information Pack (1)

- Builds on and extends the current **collaboration** between the NHS and Sponsors
- Concept of site specific **submissions** is removed
- Site set-up is a two way conversation
- Not submitted. “**Shared**” with NHS/ HSC organisation and “**jointly agreed**” within IRAS
- Shared with Principal Investigator (PI) and local research team **AND** R&D at the same time, **so all know what is happening**
- Sponsor chooses the time to **share**
- NHS organisations **confirm** agreement to take part in study



## Shared Local Information Pack (2)

- Will replace the NHS SSI submission in Northern Ireland, Scotland and Wales
- Will replace the Statement of Activities in England
- Used for commercial and non-commercial studies
- Will be the mechanism by which Sponsor (or delegate) **shares and agrees** project information with site
- **Sharing** will be in IRAS



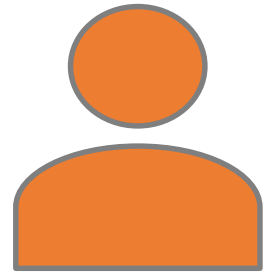
# Study wide reviewer perspective

## Behaviour change

- IRAS Form submission will include site type master templates
- Sense check

## Potential benefits

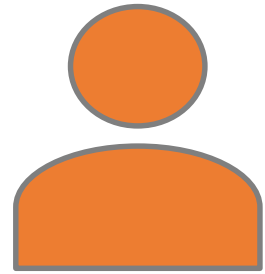
- Aids clarity about what is happening in the study



# Sponsor or delegate perspective (1)

## Behaviour change

- Support study coordination staff to understand changes
- Early conversations with potential NHS/ HSC organisations to establish probable sites
- Be very clear what is happening at NHS/ HSC organisations, as well as funding and contract arrangements
- After the IRAS Form has been submitted, and as per study delivery plan, share complete Local Information Pack with R&D and local research team via IRAS
- Be available to have open conversations to agree arrangements for study delivery
- Expect NHS/ HSC organisations to confirm capacity and capability – note for some studies this will be by provision of signed agreement



## Sponsor or delegate perspective (2)

### Behaviour change

- Set start date once NHS/ HSC organisation confirms capacity and capability (most site types)
- Update Sponsor SOPs to reflect new way of working – especially around agreements

### Potential benefits

- Consistent approach from all UK NHS/ HSC organisation R&D offices
- Sponsor controls when documents are shared (expectation that site selection conversations have previously occurred)
- Able to prepare documents for all sites at same time
- Manage site confirmation of capacity and capability within IRAS
- Able to see which sites have confirmed



# NHS/ HSC organisation R&D office perspective (1)

## Behaviour change

- Prepare to align processes to be nationally consistent
- Plan SOP update to include changes to local processes for managing Sponsor to Site agreements
- Prepare for dialogue rather than receiving a submission
- Collaboratively work with Sponsors to agree arrangements
- Receive shared Local Information Pack via IRAS
- Actively facilitate site set-up rather than check documents
- Ensure Principal Investigators/ study teams have an IRAS account
- Ensure R&D office has an official IRAS account to receive Local Information Packs and confirm capacity and capability
- “Confirm capacity and capability” to deliver the study instead of grant “NHS/ HSC Permission”





## NHS/ HSC organisation R&D office perspective (2)

### Potential benefits

- Consistent process across UK sites means less confusion across borders
- Sponsor and NHS/ HSC organisation conversation ensures collaborative set up and delivery
- Aids clarity about what is happening in a study
- Transparency between Sponsor, R&D office and Principal Investigator
- Clear time point when Local Information Pack is shared



# Principal Investigator/ local study team perspective

## Behaviour change

- Prepare to work to new processes to be nationally consistent
- Note and be trained in updates to organisation SOPs
- Prepare for early dialogue in collaboration with R&D office
- Have an IRAS account

## Potential Benefits

- Consistent process for UK sites means less confusion across borders
- Principal Investigator is clear what is going on at all times
- R&D office receives information at same time so can provide set up support

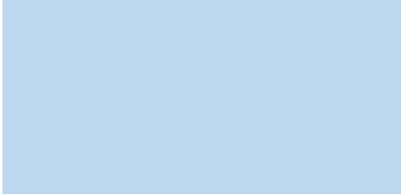

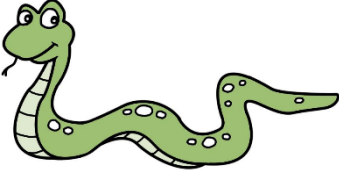


## Workshop activities

- You now have 30 minutes to build (and discuss) the flow of research study set-up from sponsorship to delivery.
- Each table has a swim lane sheet representing part of the flow:
  - Non-commercial sponsorship of studies
  - Study-wide review by UK Nations
  - Study set-up at sites in participating NHS/ HSC organisations
- Using the cards provided, construct the process flow representing the section of the research study set-up that your table has been assigned.
- Connect the cards using a snake (down), a ladder (up) and a bridge (across).
- Post-its will be provided for you to note any areas of the processes that require clarification or additional guidance.

## Outcomes

- The outcomes of the workshop will be used to:
  - Further develop the process flow for NHS Wales,
  - Identify the steps of the flow that may require revision, and
  - Inform the content of associated guidance documents.
- Additionally the workshop outcomes will be used to inform ongoing developments that are part of the UK Four Nations NHS/ HSC Compatibility Programme.

# Key

	SWIM LANE		UP
<div data-bbox="175 714 370 953" style="border: 1px solid black; padding: 5px; width: fit-content; margin: auto;">Confirm capacity and capability</div>	PROCESS STEP		DOWN
	ACROSS		UP & DOWN