Symposium

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What is a Research Site?
(and other questions for conducting research in the new structures)

Presented by: Alastair Nicholson
Head of Coordination and Standardisation,
Health Research Authority

NHS
Research and Development Forum

ICS and Research

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What is a Research Site?

- Why does this matter?
- Why does this matter (specifically, now)?
- Do I have all the answers…….?

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What is a Research Site?

- Why does this matter?

There should be clear designation of responsibility and accountability with clear lines of communication between all those involved in research. *(RGF, 9.1)*

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What is a Research Site?

- Why does this matter?
- Why does this matter (specifically, now)?

Integrated care pathways will present new, or more frequent questions as to who is responsible for what, when, etc.

Threat? Opportunity?

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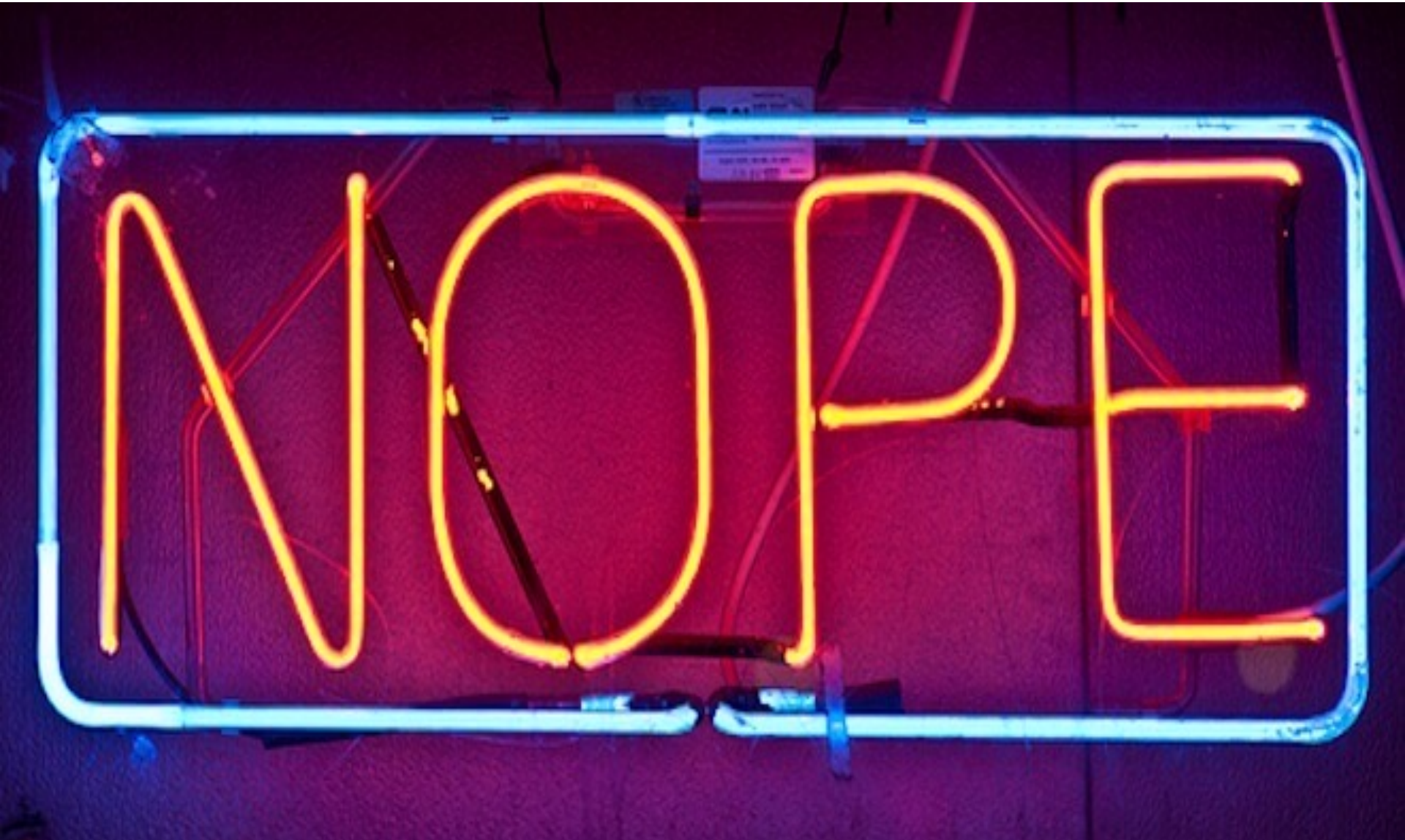

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What **IS** a Research Site?

Who **SHOULD** be a Research Site?
What **SHOULD** a Research Site be?

How can we help – by updating legislation, policy and/or guidance to be fit for the new structures?

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The Medicines for Human Use (Clinical Trials) Regulations 2004

'trial site' means a hospital, health centre, surgery or other establishment or facility at or from which a clinical trial, or any part of such a trial, is conducted;'

Whilst…….. ICH-GCP (E6(R2))

Trial site: The location(s) where trial-related activities are actually conducted.'

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And……..UK policy framework for health and social care research

the organisation with day-to-day responsibility for the location where a research project is carried out.

(Where the location of the research is wholly independent of any of the individuals and organisations with responsibilities under this policy 21 framework (e.g. a public or private space that is not under contract for the research, such as a public library or a café), these responsibilities fall instead to the principal investigator's employer[…])

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Also…….EU Clinical Trial Regulation

No definition……. But:

(15) 'Investigator' means an individual responsible for the conduct of a clinical trial at a clinical trial site;

(16) 'Principal investigator' means an investigator who is the responsible leader of a team of investigators who conduct a clinical trial at a clinical trial site;

Plus…….. Set up of research activity at NHS organisations (interventional research)

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Each 'Trial Site' (which, in this guidance we take to mean a legal entity responsible for some element of an interventional research study for which PI oversight is required) is not necessarily an 'Investigator Site' in its own right.

This guidance therefore adopts the term 'Investigator Site' to mean the activities (regardless of their location) with effective oversight by one Principal Investigator.

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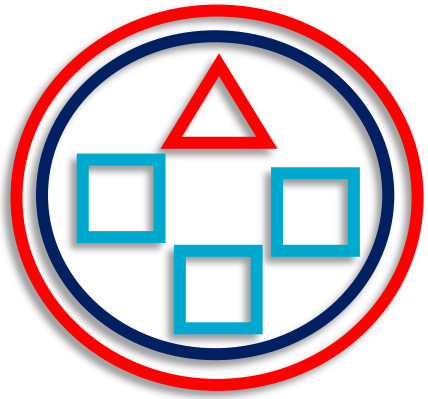
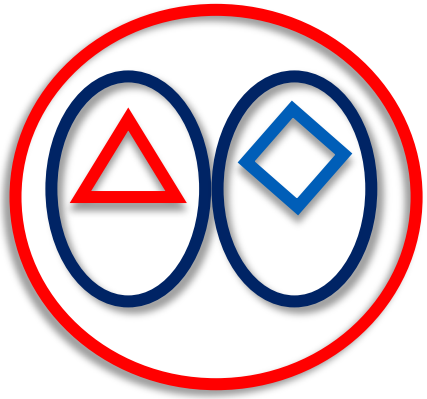
Investigator site and trial site are identical

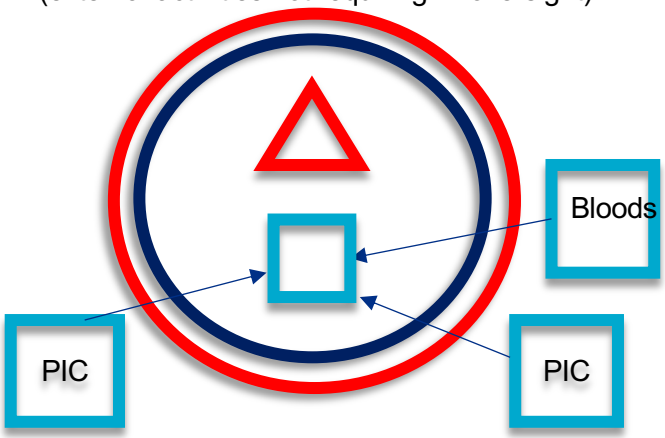


Two investigators sites within one legal entity

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

[IRAS Help - Preparing & submitting applications - Interventional Research (myresearchproject.org.uk)]

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UK Policy Framework: Responsibilities

9.2 Chief Investigators

9.6 Research teams

9.9 Funders

9.10 Sponsors

9.10 Contract Research Organisations

9.14 Research Sites

9.17 Regulators of Professions

9.18 Other Regulators

9.20 Employers

9.23 Health and Social Care Providers

Research Sites

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- Demonstrate that location is suitable
- Be aware of all research
- Agree/document roles/responsibilities of staff/collaborators
- Ensure approvals are in place
- Stay aware of and make info available about capacity and capability
- Take account of sponsor timelines if additional arrangements need to be made
- Take appropriate assurances
- Avoid disproportionate inflexible processes
- Facilitate patient transfer
- Quick co-operation (urgent need/small window)
- Designate/share staff to fulfil these responsibilities

Employers of researchers

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- Encourage high quality research culture
  - Support and hold to account
  - Manage safety, well-being, environment and facilities
  - Financial probity
  - Agreements with partners
- Ensure researcher know responsibilities
- HR GP Pack
- Act on breaches, etc.
- Ensure learning and competence (SOPs, etc)
- Open and honest reporting

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A ‘normal’ care pathway

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- A patient visits GP *a*
- GP *a* refers to diagnostic centre led by Trust *x*
- Diagnostic centre staff from Trust *y* and *z*, and GP *b* provide care to patient and take consent to clinical trial
- Patient received IMP at home
- Visits Trust *z* for scans
- 3rd party nursing team conduct home visits – at nursing home
- Inpatient appointment at Trust *y*
- Local Authority Adult Mental Health Team undertake novel intervention
- GP a and Trust y provide follow up data

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- This is (sort of…) a description of one trial as it might occur in one ICS
- The trial is to take place in all ICSs and in each of the devolved administrations

So…. What is a research site?

Or, to put it another way

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- How do we all work together to facilitate research across organisational boundaries?
- What can HRA do to provide guidance, update legislation, policy, etc. to help make this easier?
- When might it be possible for an ICS to be one-single-site?

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Now over to you

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Thank you for listening

Contact information:

- **Alastair Nicholson**
- alastair.nicholson@hra.nhs.uk

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