Health
Hunter New England
Local Health District

Navigating Research Ethics in HNE Health: An overview of pathways & tips for a smooth approval process

Sarah Moberley, BN, MPH, PhD
Manager Research Ethics

Key contacts

Dr Sarah Moberley Manager Research Ethics (teams best contact)

Ms Lisa Woseen Research Support Coordinator Ph: 4921 4943

Ms Debbie Madden Ethics Administrative Officer Ph: 4985 5929

Website:

https://www.hnehealth.nsw.gov.au/research-office/research_ethics

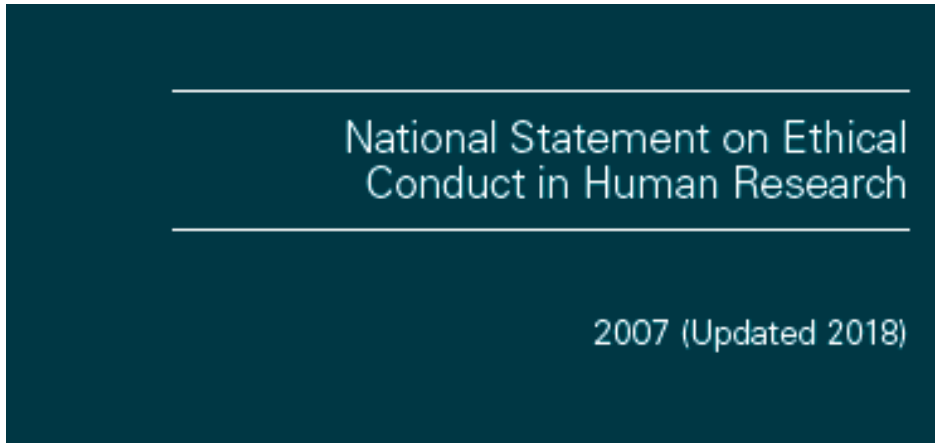
Key messages

- Contact early
- Pre-submission review available
- Use National Statement & other relevant legislation
- Write for the reviewers

Topics for today

- National Guidelines
- When ethical clearance is/not required
- Ethical review pathways
- Ethical review processes
- Post approval activities
- Tips
- Accountability
- KPIs / how well are we doing

Ensure research is conducted according to the relevant guidelines



- Research Merit & Integrity
- Justice
- Beneficence
- Respect

A judgement that a human research proposal meets the requirements of this National Statement and is ethically acceptable must be made before research can begin and before full funding for the proposal is released.

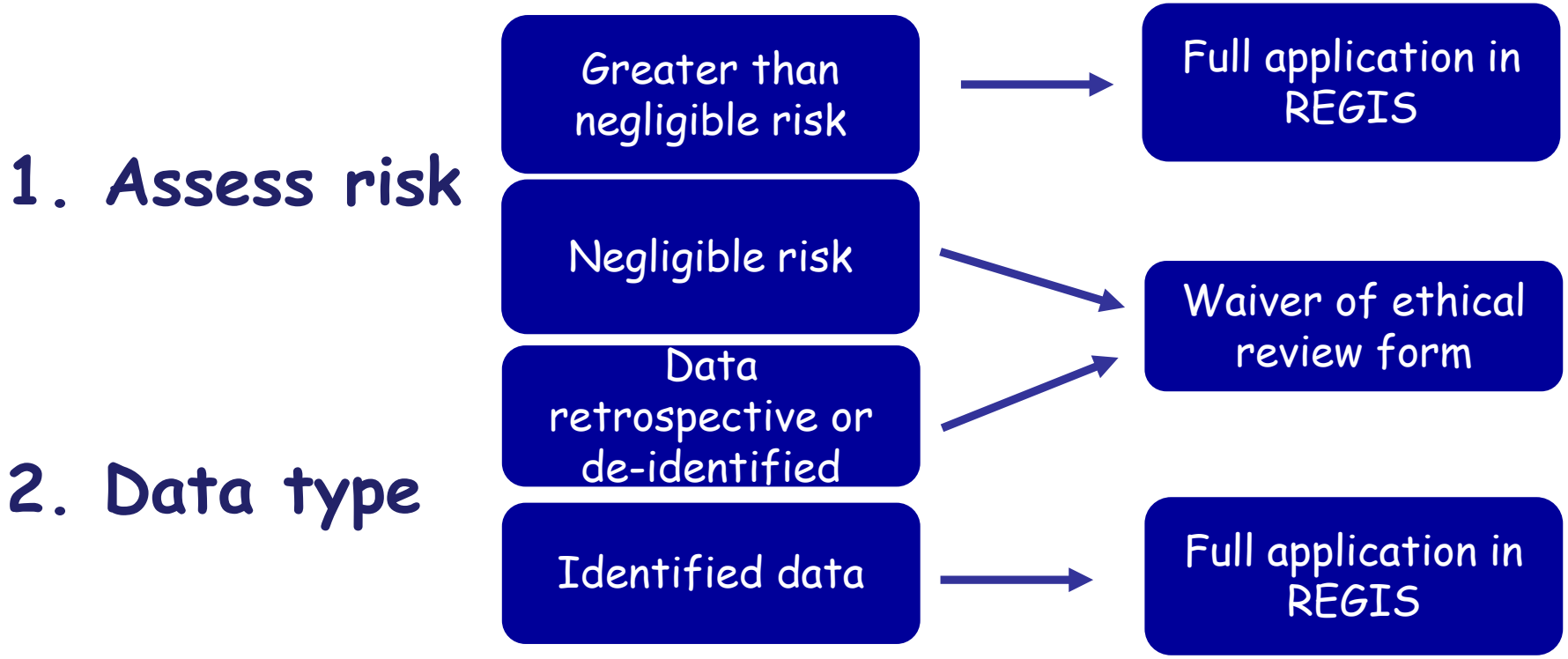
Deciding on review pathway

- Improvement activity - not generating new knowledge & no plan to publish or present
  - No need for ethical clearance

- Trigger for review
  - **Gathering information about the participant beyond that which is collected routinely.**
  - **Testing of innovative / experimental protocols or equipment.**
  - Where the activity potentially infringes the privacy or professional reputation of participants, providers or organisations.
  - Secondary use of data - using data or analysis from QA or evaluation activities for another purpose.
  - Information may include biospecimens or additional investigations.
  - Comparison of cohorts.

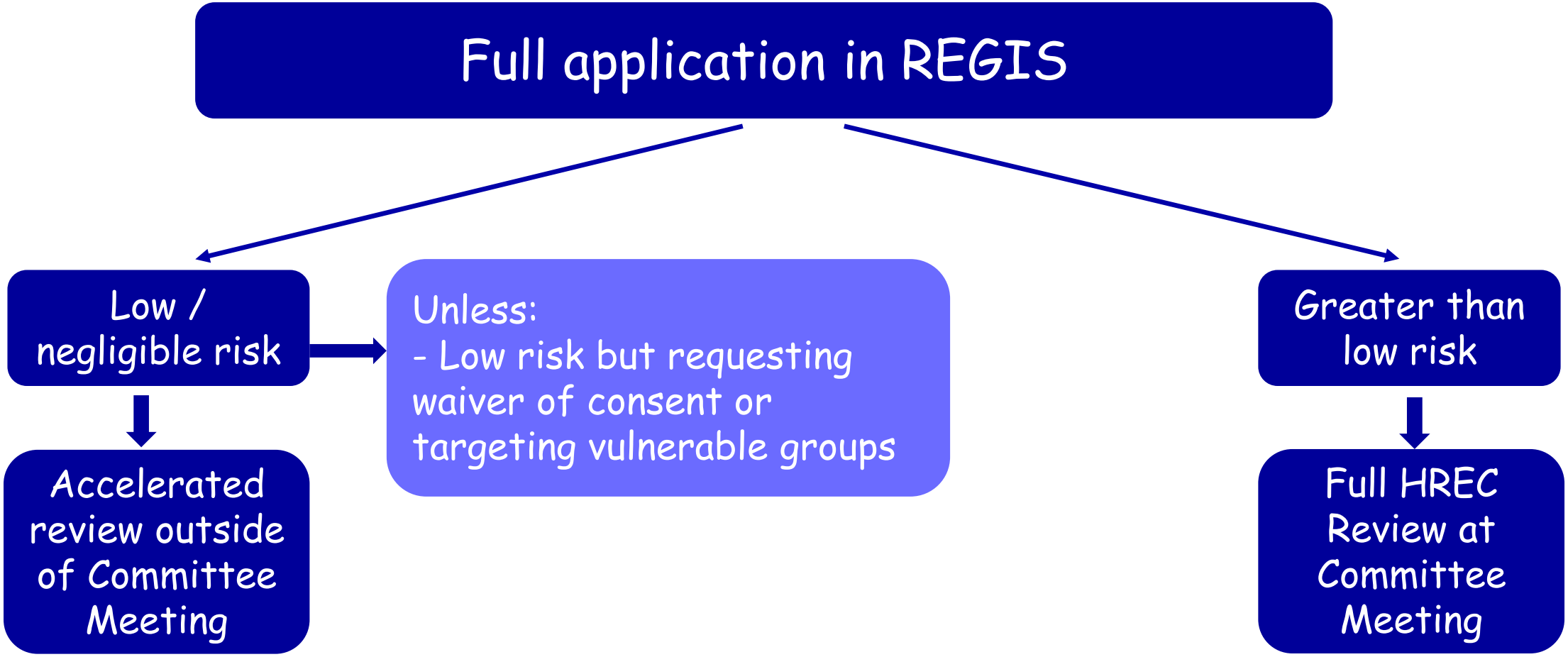
Be sure, there is no retrospective approval

Some level of ethical clearance required?



The expression 'negligible risk research' describes research in which there is no foreseeable risk of harm or discomfort; and any foreseeable risk is no more than inconvenience.

Deciding on review pathway in REGIS

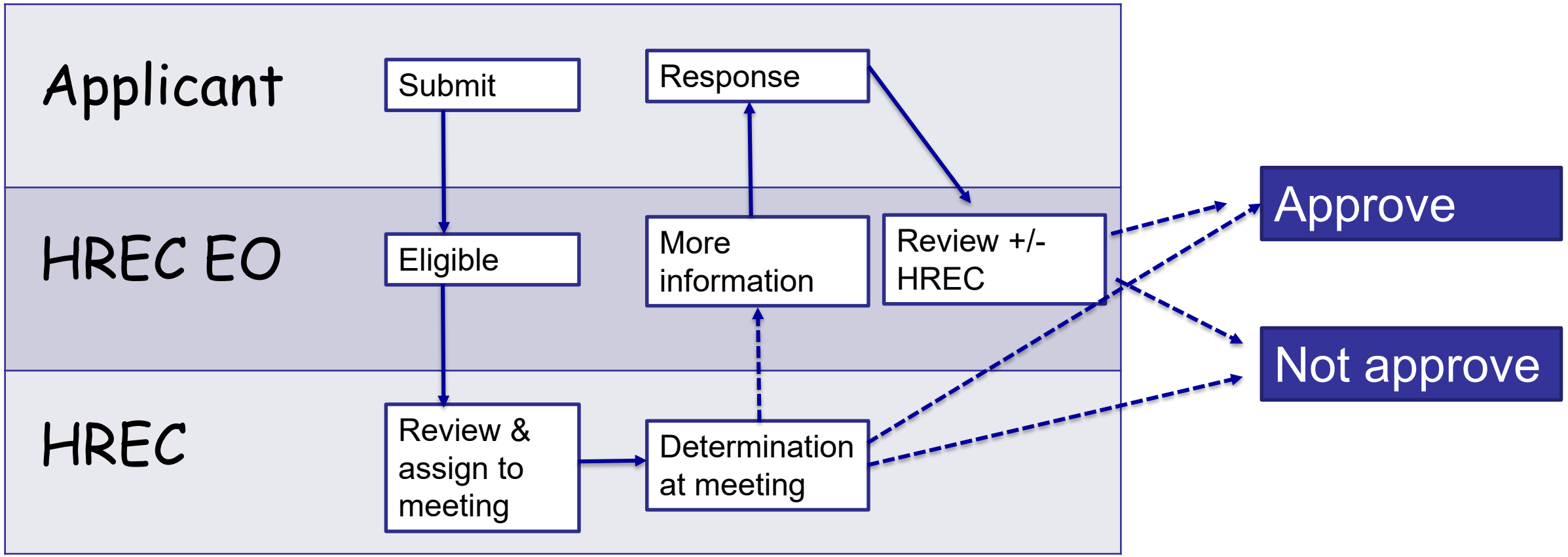


Low risk research is defined as nothing greater than discomfort such as a nose swab.
Any risk of distress or there is a potential harm, then the research is greater than low risk.

Remember the three steps

- Registration
- Ethics
- Governance

What happens after submission



Most common avoidable request for more info

- Contradictions between documents
- Participant information does not meet the requirements of the Australian Commission on Safety and Quality in Health Care National Standard on Health Literacy grade 8 or below (Hemingway or health literacy editor)
- Documents needing footer (title, version #, date)
- Lack of justification of sample size
- Lack of details of data management or retention of data
- Approach to recruitment not taking into account potential of coercion
- Incorrect complaints statement (or no ETH reference number)

What makes a good application?

- We are relying on the written word, write for the reviewer
- Refer to the National Statement & justify accordingly – Merit & Integrity, Justice, Beneficence, Respect throughout the research process
- Consider options for equal access for all relevant community members
- Careful language in participant facing documents & project titles
- Consider how to protect participant wellbeing and management if distressed
- Provide adequate details (recruitment, inclusion)
- Be thoughtful & consistent
- Refer to templates
- Plain language information – check readability with health literacy tool
- Pre submission review
- Give yourself options & pilot tools/ consent to avoid amendments

Data management

Must comply with approved protocol for data management – not able to take research data home on usb for eg.

The minimum period for retention of research data is 5 years from the date of publication

https://www.nhmrc.gov.au/sites/default/files/documents/attachments/Management-of-Data-and-Information-in-Research.pdf

What next?

- General amendment
  - Affecting the conduct, design or methodology of a project and includes changes to: Info given in the HREA, the Protocol, any other supporting documentation (consent, participant information)
- New Site
- Change CPI/ site PI
  - Not project staff
- Extension of approval
- Progress reporting

For each change only:

- What is new?
- Rationale
- Ethical implications

Note on accountability

The Coordinating Principal Investigator will:

- provide the HREC with an annual report and the final report when the project is completed at all sites.
- immediately report anything that might warrant review of ethical approval of the project.
- submit proposed amendments to the research protocol, including; the general conduct of the research, changes to CPI or site PI, an extension to HREC approval, or the addition of sites to the HREC before those changes can take effect.
- will notify the HREC if the project is discontinued at a participating site before the expected completion date, with reasons provided.

Note on accountability

- In breach if conducting research outside of approvals and conditions including milestone reports
- Principles of responsible research conduct
  1. Honesty
  - All listed Investigators must have been involved in the submission and consent to be listed.

Breach of the code – recent examples

- Data management
- Not seeking site approval before recruiting from a public health organisation

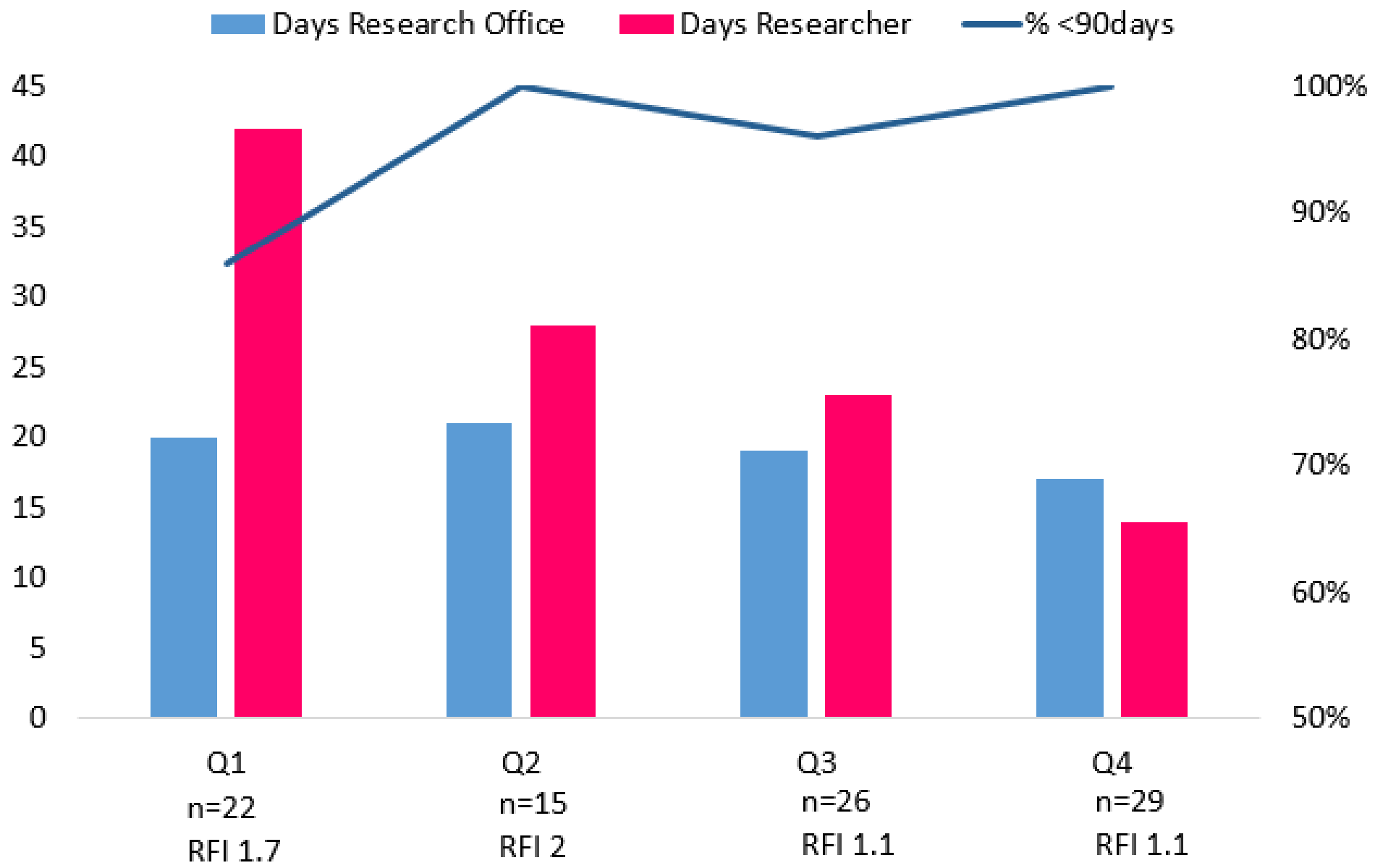
Classifications – WHO definition clinical trial

Any research project that prospectively assigns human participants or groups to one or more health-related interventions to evaluate the effects on health outcomes. Clinical trials may also be referred to as interventional trials. Interventions include but are not restricted to drugs, cells and other biological products, surgical and medical treatments and procedures, radiologic procedures, devices, behavioural treatments, process-of-care changes, preventive care, health-related education etc. This definition includes Phase I to Phase IV trials

Note: Consistent defn across CTMS & national clinical trial framework

How well do we do?

2022 KPIs
GLR
pathway



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