UNPACKING INNOVATION RESEARCH: TO IRB OR NOT?

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When you design a new solution that you think has potential to improve work processes or outcomes, you'd normally want to trial the solution to see if it really works, and if it provides significant improvements over the current standard.

Such trials are not uncommon, but you may notice that some trials require Institutional Review Board's (IRB) approval, whereas others may not.

Research studies involving human subjects will require IRB review. The key words to note are "research" and "human subjects".

The IRBs generally draw the definition of research from the Code of Federal Regulations - a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalisable knowledge .

The full regulations further expands on exemptions. Although the definition commonly seen is just a one-liner, interpreting is not easy.

The question you may now ask is – I am merely conducting a quality improvement project or just evaluating a new solution for operational/clinical needs. Why should I need the IRB's review?

And indeed, this is a valid question.

Pure Quality Assurance/Quality Improvement (QA/QI) projects and evaluation studies do not need IRB's review. However, the **design of the trial/study** is the determining factor.

Quite often, you see an **overlap** in design **between QA/QI, evaluation studies and research trials**. To help you better understand, we are providing some observations, made by two *AAHRPP accredited IRBs, in the bottom panel.

DIFFERENCES BETWEEN QA/QI AND RESEARCH

QA/ QI	RESEARCH
Intent - identify, control a problem or improve program/ service	Intent - generalisable knowledge to improve practice
Benefit to participants or participant's community	Benefit extends beyond participants - usually to society
Data collected to assess/ improve the problem, program or service	Data collected exceeds requirements for patient care
Knowledge is not generalised beyond the scope of activity	Produces generalisable knowledge
No experimental activities	Project activities may be experimental

DIFFERENCES BETWEEN EVALUATION AND RESEARCH

EVALUATION	RESEARCH
Determines merit, worth, or value	Strives to be value-free
Assessment of how well a process, product, or program is working	Aims to produce new knowledge within a field (designed to develop or contribute to generalisable knowledge)
Focus on process, product, or program	Focus on population (human subjects)
Designed to improve a process, product, or program and may include: • Needs assessment • Process, outcome, or impact evaluation • Cost-benefit or cost-effectiveness analysis	May be descriptive, relational, or casual
Designed to assess effectiveness or a process, product, or program	Designed to be generalised to a population beyond those participating in the study or contribute broadly to knowledge or theory in a field of study
Assessment of program or product as it would exist regardless of the evaluation	May include an experimental or non-standard intervention
Rarely subject to peer review	Frequently submitted for peer review
Activity will rarely alter the timing or frequency of standard procedures	Standard procedures or normal activities may be altered by an experimental intervention
Frequently, the entity in which the activity is taking place will also be the funding source	May have external funding
Conducted within a setting of changing actors, priorities, resources, and timelines	Controlled setting (interaction or intervention) or natural setting (observation which may or may not include interaction or intervention)

Notwithstanding the above, the U.S. Food and Drug Administration (FDA) defines clinical nvestigation as – “Experiments using a test article (e.g. investigational drug or biologic, or device) on one or more human subjects, that are regulated by the FDA or support applications for research or marketing permits for products regulated by the FDA.”

Such clinical investigations will require IRB's review and approval. In our local context, the Health Sciences Authority (HSA) do not regulate clinical investigations involving devices.

However, it is stated on their website that Clinical Research Materials (CRM) may only be used in IRB approved clinical research.

CRM refers to – “Any registered or unregistered therapeutic product, medicinal product, medical device, applicable cell, tissue and gene therapy product or placebo, that is manufactured, imported or supplied for the purpose of being used in clinical research, by way of administration to a trial participant in accordance with the research protocol or for a clinical purpose” .

With all the information above, you can now understand why there is no published resource that would confidently state when an IRB's review is required, instead they come with a disclaimer to confirm with a local IRB.

One last thing to note is that although a project may fall out of the IRB’s purview, there may still be ethical issues associated with the conduct of the project.

They come in the form of risks to participants and privacy and confidentiality concerns that should be considered and addressed.

References:

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