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Differentiate research from other projects

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Differentiating Research from non-Research

Not all projects submitted to the CIRB are Research

1. Intent >>>

For **Research**, the **intent** is primarily to develop generalisable new knowledge systematically.

All projects usually have an intent to develop generalisable new knowledge. But this is usually a secondary purpose for the following projects (non-research):

Service Evaluation

To assess and/ or improve healthcare service delivery. Designed and conducted solely to define or judge current care.

Clinical Audit

To improve patient care and outcomes. Designed and conducted to produce information to improve delivery of best patient care.

Surveillance

To monitor the epidemiological trends of diseases and behavioural risk factors. Designed to guide public health policies, programmes and actions to prevent and control the diseases.

Outbreak Investigation

To investigate outbreaks or public health incidents. Designed to determine the source of an outbreak and actions needed to prevent and control transmission of the disease. Findings may also guide public health policies.

2. Focus of study >>>**Research:**

Focus on human subjects or information derived from human subjects (in the form of data or human biological materials)

Under some circumstances, research involving only unidentifiable/ de-identified or coded* private information or biological specimens is not human subjects research because investigators cannot readily ascertain the identities of the individuals to whom the data or samples belong.*

For such cases, submission to CIRB is not required, unless the research is a restricted research as defined under HBRA.

**Principal investigators or study team does not have the linkage key.*

Non-Research:**Service Evaluation**

Looking at capacity and capability of staff, as well as processes to improve efficiency, save costs, reduce error rates or undesired outcomes.

Clinical Audit

Looking at processes and capability of staff.

Surveillance

Human subjects or information derived from human subjects (in the form of data or human biological materials).

Outbreak Investigation

Human subjects or information derived from human subjects (in the form of data or human biological materials).

3. Study design >>>

Research:

Quantitative research – designed to test a hypothesis

Qualitative research – identifies/ explores themes following established methodology

Non-Research:

Does not demand changing treatment/ patient care from accepted standards for any of the patients

Service evaluation

Designed to answer:
“What standard does this service achieve?” OR
“Can we provide a more efficient, cost-effective and safer delivery of services?”

Clinical audit

Designed to answer:
“Does this service reach a predetermined standard?”

Surveillance

Designed to answer:
“What is the trend of the disease, the likely cause of this trend and the associated risk factors?”
and intervene where possible.

Outbreak investigation

Designed to answer:
“What is the cause of this outbreak?” and intervene where possible.

4. Evidence >>>

Research:

May not have existing evidence.

Service evaluation & Clinical audit:

Usually based on existing practices, systems and processes.

Surveillance & Outbreak investigation:

Based on existing understanding of disease epidemiology

5. Responsibility of researcher >>>

Research:

- Must assure research design is scientifically sound.
- Must not expose participants to unnecessary risk
- Risks must be weighed against relative benefits, if any, and the importance of the knowledge to be gained
- No coercion - Appropriate consent to be obtained
- Participant’s privacy and other rights are protected

Service evaluation & Clinical audit:

- Data to be reasonably collected, results are aggregated and trends observed over time
- Protect participant’s confidentiality

6. Sharing of generalisable knowledge >>>

Research:

Method of sharing research knowledge is commonly via publications in peer-reviewed journals

Service evaluation:

May share at conferences or forums

Clinical audit:

Usually not shared

Surveillance:

Method of sharing is commonly via epidemiology bulletins and survey reports or publications in peer-reviewed journals

Outbreak investigations:

Method of sharing is commonly via investigations reports, epidemiology bulletins and publications in peer-reviewed journals

7. Study approach >>>

Research:

- States research problem
- Conceptualise: hypothesise, design, planning
- Method/ analyse
- Results
- Conclusion

Service evaluation & Clinical audit:

Involves:

- Quality improvement process
- Systematic review of care against explicit criteria
- Implementation of change

Surveillance:

- Usually involve seroprevalence studies and biological monitoring

Outbreak Investigations:

- Establish the existence of an outbreak
- Perform descriptive epidemiology
- Develop hypothesis
- Perform expdemiological studies and collect samples for laboratory analysis
- Implement control and preventive measures

8. Additional risk to the participant as a result of the study >>>

Research:

May involve activities that impose additional risk to the subject as a result of the research

Non-Research:

Generally does not involve activities that impose additional risk to the participant as a result of the study

Takeaway message...

Not all submissions to the CIRB are Research. Some may fall under the non-Research category which do not need to be reviewed by the CIRB. However, if they have research intent, they should be submitted for review.

If you have any questions, please contact CIRB at irb@singhealth.com.sg

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