SingHealth CIRB:

Illuminaté

"To Énlighten... Ethics, above all"

Adapted version for researchers, investigator and study

SingHealth
Defining Tomorrow's Medicine

Issue 11
Jan 2023

In this issue >>>

Incidental Findings in Research

1. What are incidental findings >>>

Incidental finding refers to a finding that has potential health or reproductive importance to the research subject. It is discovered during the conduct of the research but is unrelated to the purposes, objectives or variables of the study.

Type of Findings		Example
Primary Findings	Investigator aims to investigate about A, and result is relevant to A.	A study to investigate if vaccine A is effective against COVID-19 – study compare research participants' immunity status against COVID 19 before and after vaccination.
Secondary Findings	Investigator aims to investigate about A, but also actively investigate about B.	Study objective was to find out the maximum tolerated dose for new drug A. However, study also collects blood to study about the pharmacokinetics of new drug A.
Incidental Findings	Investigator aims to investigate about A, but learn about C (unrelated to the purpose, objective or variables of the study).	A study to compare MRI scans of stroke patients and healthy control. However, unexpected brain tumor was detected in one of the healthy control participants.

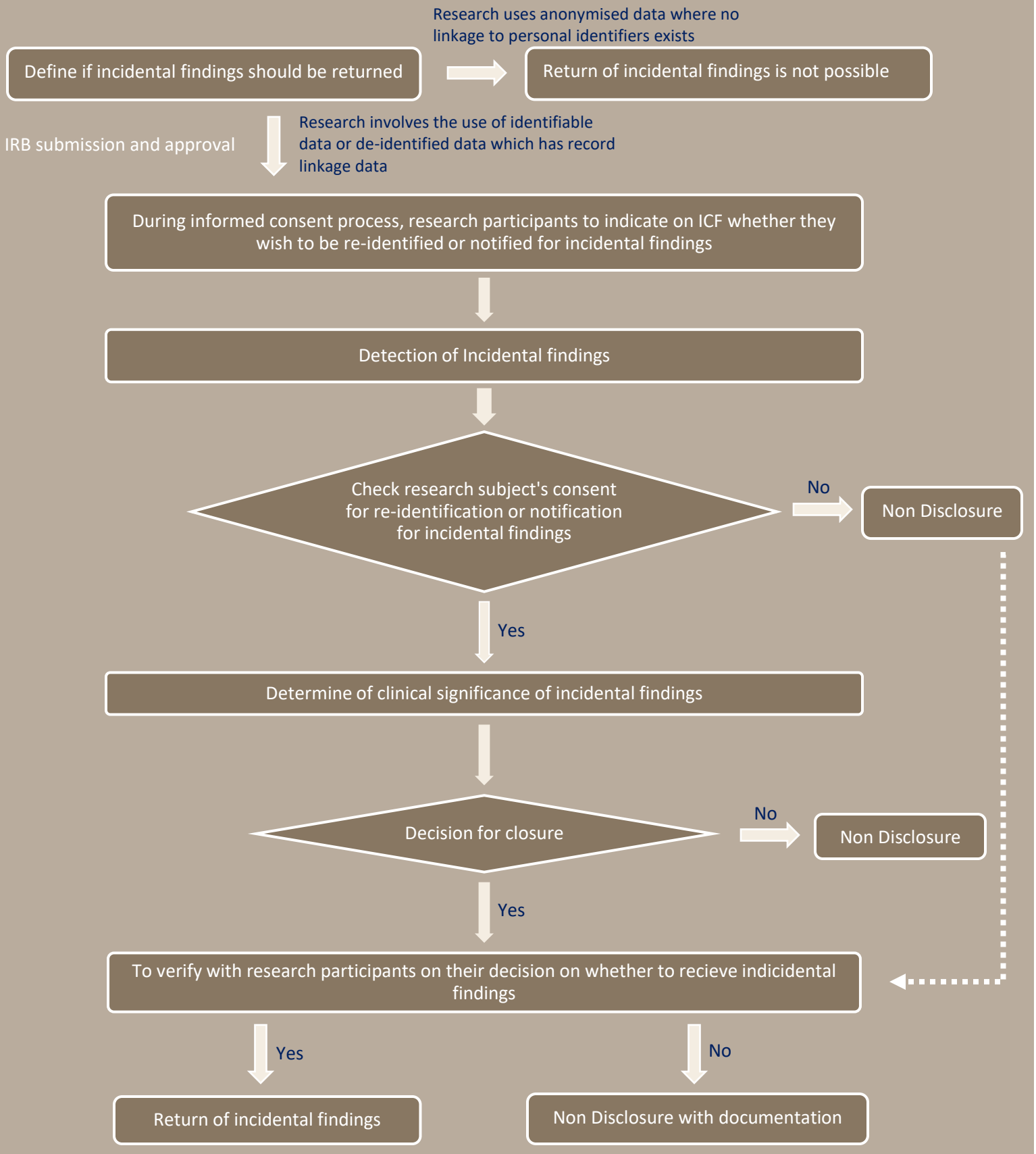
2. HBRA's requirements >>>

For HBR studies, appropriate consent must be obtained from participants.
According to HBRA, the following element(s) related to incidental findings must be included in the informed consent document.

HBRA Section 12 (1) (m)
whether the research subject would wish to be re-identified in the case of an incidental finding if the proposed biomedical research expressly provides for such re-identification.

HBRA Section 12 (2) (o)
whether the donor or the person authorised to give consent under this Part (as the case may be) would wish to be re-identified in the case of an incidental finding if the future research expressly provides for such reidentification.

3. Management of incidental finding (SingHealth Policy) >>>



Please refer to SHS-RSH-ORIC-CWP-203: Management of Incidental Findings for more information.

Takeaway message...

It is important for all research study to plan on how incidental findings would be managed. Management of incidental findings and the possible risk and impact should be communicated to the research participants during the informed consent process.

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