CHICKEN SOUP FOR THE BUSY COORDINATOR

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MANAGEMENT OF INCIDENTIAL FINDINGS – PER HBRA REQUIREMENT

According to the Human Biomedical Research Act (HBRA), "incidental findings" (IFs) '*is a finding, in relation to human biomedical research, means a finding about a research subject that has potential health or reproductive importance to the research subject and is discovered in the course of conducting research but is unrelated to the purposes, objectives or variable of the study.*' (HBRA 2015, Part 1, Section 3).

To facilitate better understanding, here are a few examples of IFs that may arise from different research domains:

- An unexpected mass at the base of the lung discovered in computed tomography (CT) colonography
- An IF on a genomic microarray suggesting a genetic or chromosomal variant of potential clinical importance beyond the variants or genotype phenotype associations directly under study
- Signs of physical abuse or suicidality in studies unrelated to those phenomena
- Abnormal blood pressure or blood chemistry during the baseline screening for eligibility

The HBRA mandates that Research Institutions formulate a policy to determine if a research participant should be re-identified and informed in the case of an IF, and that policy communicated to all Institutional Review Boards (IRB) and researchers under its purview. Researchers should thus refer to their respective Research Institutions and comply with the requirements of their IF Policy.

The HBRA also mandates that the informed consent process must inform and seek the research participant's decision if they would wish to be re-identified in the case of an IF, if re-identification was practicable.

In this respect, researchers must first identify during their research design, whether the research could possibly result in IFs. A plan for disclosing and managing IFs should be included as part of the protocol submitted to the IRB for review. The IRBs are then expected to evaluate and assess the adequacy of the plan. You may wish to check with the IRB of review on the type of information that should be included in the plan.

If IFs are not to be returned, the researcher must provide reasons for the non-return as the IRB would want to ensure that the non-return is ethical.

For researchers under NHG Research Institution, you may refer to the "NHG Management of Incidental Findings Policy here.

Note: NHG readers are encouraged to refer to the NHG Research Website (https://www.research.nhg.com.sg) and/or Sharepoint (https://mynhg.nhg.com.sg/dept/rcu) for the latest announcements and information on the NHG Management of Incidental Findings.

Reference:

- Human Biomedical Research Act 2015
- Human Biomedical Research Regulations 2017
- NHG Management of Incident Findings (v040119)

Article Contributed By: **NHG RDO**
Edited By: NHG-RDO