

# CHICKEN SOUP FOR THE BUSY COORDINATOR

**February 2018**

## HOW TO DETERMINE IF A STUDY FALLS UNDER THE HUMAN BIOMEDICAL RESEARCH PURVIEW

### Scenario

Dr Gilbert is planning to start a new study. Its aim is to determine the underlying causes of a genetic condition. This study requires the collection of personal medical history data and 6ml of blood from subjects at two separate visits. However, Dr Gilbert is unsure if this study falls under the Human Biomedical Research (HBR) purview. He decided to seek assistance from the centre's Clinical Research Coordinator (CRC), Violet, for her advice on this matter. Violet used the following checklist to assess if Dr Gilbert's study will fall under the HBR framework.

### Step A: Identify if Dr Gilbert's study objective falls within the scope of HBR

Dr Gilbert's study's aim is to determine the underlying cause of a genetic condition.

- The prevention, prognostication, diagnosis or alleviation of any disease, disorder or injury affecting the human body; or
- The restoration, maintenance or promotion of the aesthetic appearance of human individuals through clinical procedures or techniques; or
- The performance or endurance of human individuals

**Proceed to Step B**

### Step B: Identify if Dr Gilbert's study methodology employed also falls under the scope of HBR

Next, Dr Gilbert's study (methodology) requires the collection of personal medical history data and the collection of blood sample to determine the diagnosis of a medical condition.

- Subjecting an individual to any intervention (including any willful act or omission) that has a physical, mental or physiological effect (whether temporary or permanent) on the body of the individual; or
- The use of any individually-identifiable biological material obtained from the human body; or
- The use of any individually-identifiable health information.

If "Yes" (✓) to any of the points in Step A **and** Step B; this study falls under the scope of HBR.

Therefore, according to the checklist, Dr Gilbert's study falls under the scope of the HBR.

Violet went on to share with Dr Gilbert the studies which are **excluded** from HBRA (HBRA 2015, fifth schedule).

Normal human psychological response and behaviours	NOT designed or intended to study psychiatric or psychological disorders; and involve <u>no more than minimal risk</u> to the research subject.
Measure human intelligence	NOT designed or intended to study mental or intellectual disability; and which involve <u>no more than minimal risk</u> to the research subject.
Public Health Research for Infectious Diseases	In accordance to Disease Act
Collection and compilation of health information	For epidemiological or statistical purposes in accordance with the National Registry of Diseases Act For statistical purposes in accordance with the Statistics Act
Clinical Trials	Of Health / Medicinal products conducted in accordance with the Health Products Act/ Medicines Act

### References:

- [https://www.moh.gov.sg/content/moh\\_web/home/legislation/legislation\\_and\\_guidelines/human-biomedical-research-act.html](https://www.moh.gov.sg/content/moh_web/home/legislation/legislation_and_guidelines/human-biomedical-research-act.html)
- <https://www.research.nhg.com.sg/wps/wcm/connect/romp/nhgromp/06+conducting+research/human+biomedical+research+act+-+hbra>
- <https://www.research.nhg.com.sg/wps/wcm/connect/a254bd80441ad8099b2edb8a28763803/QLT2018-68.pdf?MOD=AJPERES>

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*\*Disclaimer: All characters appearing in this article are fictitious. Any resemblance to real persons is purely coincidental. Best practices may differ between institutions. Readers are encouraged to follow their institution's policies/guidelines relating to the above scenarios/case study.*

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