

[Update] Is My Study Human Biomedical Research?

Background

The Human Biomedical Research Act was passed in 2015 to set out the regulatory frameworks for Human Biomedical Research (HBR), and Human Tissue for use in research. The objectives of the HBR framework are to regulate human biomedical research, to protect the safety and welfare of human research subjects and to regulate the conduct of certain types of human biomedical research that are considered more ‘sensitive’.

The purpose of this article is to help researchers understand what constitutes as HBR studies in 3 steps.

Tips and Recommendations

Step 1: Determine if your study falls under ‘Restricted Research’.

Does my study involve any of these?

- Human gametes or human embryos; or
- Cytoplasmic hybrid embryos; or
- The introduction of any human-animal combination embryo into an animal or human; or
- The introduction of human stem cells (Inc. induced pluripotent stem cells *but exc. the introduction of such human pluripotent stem cells into immunodeficient mice solely for the analysis of teratoma induction*) or human neural cells into an animal at any stage of the development (Inc. prenatal animal foetus or animal embryo)

IF YES

This study falls under ‘Restricted* Research’ and is under the scope of HBR.

**Restricted research will be subjected to additional HBR requirements.*

Step 2: Identify if your study objective falls within the scope of HBR.

Does the intent of my study involve:

- 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.

IF NO

This study does not fall under the scope of HBR.

IF YES

Proceed to Step 3.

Step 3: Identify if the methodology employed also falls under the scope of HBR.

Does my study methodology involve:

- Subjecting an individual to any intervention (including any wilful 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

This study falls under the scope of HBR.

**Please note that your study falls under HBR only if you have answered ‘Yes’ in both steps 2 and 3.*

IF NO

This study is not HBR as it does not deploy the methodology as listed under step 3.

For more information about the Human Biomedical Research Act, please refer to the Ministry of Health website via the link below:

https://www.moh.gov.sg/content/moh_web/home/legislation/legislation_and_guidelines/human-biomedical-research-act.html

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