

OFFICE OF HUMAN RESEARCH PROTECTION PROGRAMME
(OHRPP)

13ai. ADDRESSING COMMON ERRORS IN
THE DSRB ROAM APPLICATION FORM
MAIN PAGE - HBR DECLARATION

Reference:

NHG ROAM – Online DSRB Application Form Guidebook for Biomedical Study

NHG Group Research

Version November 2022



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HBR Declaration for Biomedical Domain

I declare that the study falls under the purview of the Human Biomedical Research Act. [*Click here for help](#)

- Yes
 No

Please tick all the boxes that apply:

My human biomedical research is intended to study -*

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

Definition of HBR

Where the research involves -*

- (i) 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;
 (ii) the use of any individually-identifiable human biological material; or
 (iii) the use of any individually-identifiable health information.

My human biomedical research involves -*

- (a) human gametes or human embryos;
 (b) cytoplasmic hybrid embryos;
 (c) the introduction of any human-animal combination embryo into an animal or human;
 (d) the introduction of human stem cells (including induced pluripotent stem cells) or human neural cells into an animal at any stage of development (including a prenatal animal foetus or animal embryo); or
 (e) any entity created as a result of any process referred to in paragraph (c) or (d).
 (f) None of the Above

Definition of Restricted Research

This section is the definition of a HBR research. If your study meets either one of this and either one of this, then it is a HBR study.

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Determination of HBR (defined in HBRA) study for Biomedical Domain

Common error :

Discrepancy in selection criteria.

How does this delay my DSRB application?

- Under HBRA, the IRB is required to make a determination and review the study according to the regulations. The criteria may differ as compared to other studies (e.g. non-HBRA studies).

It is important for the PI to know whether his/ her study is a HBRA study and to comply with the HBRA requirements.

Questions?

Refer to www.research.nhg.com.sg

Or contact the NHG Research
Education Unit @
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