

Restricted and Prohibited Research

1. Restricted Research >>>

Restricted Research are defined in Fourth Schedule of Human Biomedical Research Act (HBRA):

1. Human biomedical research involving human eggs or human embryos.
2. Human biomedical research involving:
 - (a) the following types of human-animal combination embryos:
 - (i) cytoplasmic hybrid embryos
 - (ii) human-animal combination embryos created by the incorporation of human stem cells (including induced pluripotent stem cells)
 - (iii) human-animal combination embryos created in-vitro by using:
 - (A) human gametes and animal gametes
 - (B) one human pronucleus and one animal pronucleus
 - (b) the introduction of human stem cells (including induced pluripotent stem cells) into a prenatal animal foetus or animal embryo
 - (c) the introduction of human pluripotent stem cells (including induced pluripotent stem cells) into a living postnatal animal but excludes the introduction of such human pluripotent stem cells into immunodeficient mice solely for the analysis of teratoma induction
 - (d) the introduction of human stem cells (including induced pluripotent stem cells) or human neural cells into the brain of a living postnatal animal
 - (e) any entity created as a result of any process referred above (b), (c) and (d).

Restricted research will require:

- ✓ Approval from IRB
- ✓ Approval from MOH
- ✓ Approval from Institutional Animal Care and Use Committee (IACUC) (if research involves the use of animals)

2. Prohibited Research >>>

Prohibited Research is defined in the Third Schedule of HBRA. These research are deemed to be unacceptable and will **NOT** be allowed in Singapore. These includes:

1. Human biomedical research involving the development of human-animal combination embryos referred to in paragraph 2(a)(i) or (iii) of the Fourth Schedule beyond 14 days or the appearance of the primitive streak, whichever is the earlier.
2. Human biomedical research involving the implantation —
 - (a) of a human-animal combination embryo mentioned in paragraph 2(a)(i) or (iii) of the Fourth Schedule into the uterus of an animal
 - (b) of a human-animal combination embryo into the uterus of a human.
3. Human biomedical research involving the introduction of human stem cells (including induced pluripotent stem cells) or human neural cells into the brain of living great apes* whether prenatal or postnatal.
4. Human biomedical research involving the breeding of animals which have had any kind of human pluripotent stem cells (including induced pluripotent stem cells) introduced into them.

Note: There are four types of great apes: gorillas, bonobos, orangutans and chimpanzees.

3. Review process of Restricted Research >>>

Institution

SingHealth

MOH

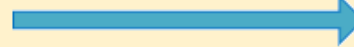
PI



CIRB

IACUC

After IRB & IACUC approval, PI
submit to MOH via institution.



MOH

- Following approval from IRB and IACUC, PI will submit the application documents to Research Office for final QC.
- Research Office Admin will work with ORIC for application to MOH along with the agreed charging.
- Please contact ORIC for more information on process for MOH approval (Restricted Human Biomedical Research - rHBR)

Takeaway message...

Restricted Research must obtain the necessary approval (IRB, IACUC (if required) and MOH) prior to conduct of research. Prohibited Research cannot be conducted according to HBRA.

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