

Conduct of Prohibited HBR is an offence under the HBRA

Conduct of Restricted HBR is permitted subject to additional approvals

Prohibited HBR

Listed in [Third Schedule, HBRA](#). Involves:

- ❖ Development of in vitro human-animal combination embryos beyond the earlier of 14 days or the appearance of the primitive streak, whichever is earlier;
- ❖ Implantation of any human-animal combination embryo into the uterus of an animal or a human;
- ❖ Introduction of human stem cells or human neural cells into the brain of living great apes; or
- ❖ Breeding of animals which have had any kind of pluripotent stem cells introduced into them.

Restricted HBR

Listed in [Fourth Schedule, HBRA](#). Involves:

- ❖ Human eggs or human embryos;
- ❖ Human-animal combination embryos;
- ❖ Introduction of human stem cells into a prenatal animal foetus or animal embryo;
- ❖ Introduction of human pluripotent stem cells into a living postnatal animal;
- ❖ Introduction of human stem cells or human neural cells into the brain of a living postnatal animal; or
- ❖ Any entity created as a result of any process referred to in above.

Before starting Restricted Human Biomedical Research, approvals needed from:

- ❖ IRB
- ❖ Institutional Animal Care and Use Committee
- ❖ MOH

Reportable Adverse Outcome (RAO) Reporting to MOH

No.	Conditions of MOH Approval	RAO Reporting Procedures	References
1.	<p>[Animal Escape]</p> <p>Appropriate barriers and safeguards must be put in place to prevent the study's animals from escaping.</p>	<p>Occurrence of escape from the animal facility must be reported to MOH <u>immediately</u> as a RAO through TIARAS.</p>	<ul style="list-style-type: none"> • See "IACUC Actions for rHBR Reportable Incident (RI) under HBRA (IACUC-SOP-016)" here. • For rHBR studies under the purview of SingHealth IACUC, please see paragraph 5.5 of NUS Research Compliance Policy Appendix 2D rHBR Workflow Guide.
2.	<p>[Animal Unexpected Atypical Behaviour]</p> <p>The animals into which human neural cells have been introduced must be monitored for any unexpected atypical behavior.</p>	<p>Occurrence of any unexpected atypical behavior must be reported to IACUC for assessment → Reported to MOH as a RAO through TIARAS <u>once the unexpected atypical behavior is confirmed</u>.</p>	