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| **Title** | Research on Assisted Procreation Activities |
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# Purpose

This standard operating procedure (SOP) clarifies the ethics review process for research projects on assisted procreation activities that are carried out in institutions in the Québec Health and Social Services Network (RSSS).

# Scope

This SOP pertains to Research Ethics Boards (REBs) at RSSS institutions that review human participant research in compliance with applicable regulations and guidelines.

# Responsibilities

All REB members and designated REB staff are responsible for ensuring that the requirements of this SOP are met.

# Definitions

See Glossary of Terms.

# Legislative Framework

Section 8 of the *Act respecting clinical and research activities relating to assisted procreation* states as follows[[1]](#footnote-1): “A research project concerning assisted procreation activities or using embryos that resulted from such activities but were not used for that purpose must be approved and monitored by the research ethics committee established by the Minister under article 21 of the Civil Code.”

Section 2 of the Act defines assisted procreation activities as follows:

“Any support given to procreation by medical or pharmaceutical techniques or laboratory manipulation, whether clinical, to create a human embryo, or in the field of research, to improve clinical procedures or acquire new knowledge.

The following activities are targeted in particular: the use of pharmaceutical procedures to stimulate the ovaries; the removal, treatment, *in vitro* manipulation and conversation of human gametes; artificial insemination with a spouse’s or a donor’s sperm; preimplantation genetic diagnosis; embryo conservation; embryo transfer in a woman.

However, the surgical procedures to restore normal reproductive functions in a woman or a man are not targeted”

## Review by the Committee Established by the Minister of Health and Social Services.

Research projects involving only the following must be reviewed by the research ethics committee established by the Minister of Health and Social Services:

* The use of pharmaceutical procedures for ovarian stimulation in the course of assisted procreation activities;
* The collection, processing, *in vitro* manipulation and storage of human gametes in the course of assisted procreation activities;
* Artificial insemination with a spouse’s or a donor’s sperm in the course of assisted procreation activities;
* Preimplantation genetic diagnosis in the course of assisted procreation activities;
* Embryo storage in the course of assisted procreation activities;
* Embryo transfer in a woman in the course of assisted procreation activities.

## Review by Institutional REBs

All research projects that do not involve assisted procreation activities must be reviewed by REBs of RSSS institutions, including:

* Chart review research projects;
* Research projects on fertility;
* Research projects in endocrinology;
* Research projects on the impact of an exercise program on fertility;
* Research projects on the impact of a nutrition program on fertility;
* Research projects on the impact of lifestyle on fertility;
* Research projects on surgical procedures to restore normal reproductive functions in a woman or a man;
* Research projects on gamete conservation;
* Research projects on the repercussions of chemotherapy on fertility;
* Research projects on the psychological consequences of assisted procreation.

# Procedures

Before or when submitting a request for ethics review of a research project, the REB Chair or designee will determine whether the research project should be reviewed by the institution’s REB or by the research ethics board established by the Minister of Health and Social Services.

# References

See footnotes.

# Revision History

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| **SOP Code** | **Effective Date** | **Summary of Changes** |
| REB-SOP 504-001 | YYYY-MM-DD | Original version |
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# Appendices

1. Act respecting clinical and research activities relating to assisted procreation, c. A-5.01. [↑](#footnote-ref-1)