

Section 500:	Reviews Requiring Special Consideration
Title:	REB Review of Biological and Reproductive Materials
SOP Code:	502.002
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Site Approvals

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1.0 PURPOSE

This SOP describes the special considerations for the REB review process with respect to human biological materials, including materials related to human reproduction.

2.0 SCOPE

This SOP pertains to the REB that reviews human participant research in compliance with applicable regulations, guidelines and current and emerging best practices.

3.0 RESPONSIBILITIES

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

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURES

Special ethical considerations must be given to the access, use and potential privacy concerns with respect to human biological materials. For the purpose of this policy, human biological materials include tissues, organs, blood, plasma, skin, serum, DNA, RNA, proteins, cells, hair, nail clippings, urine, saliva, other body fluids, embryos, fetuses, fetal tissue, and reproductive materials.

For the purpose of the SOP the following definitions apply:

- Embryo means a human organism during the first 56 days of its development following fertilization or creation, excluding any time during which its development

has been suspended, and includes any cell derived from such an organism that is used for the purpose of creating a human being.

- Fetus means a human organism during the period of its development beginning on the 57th day following fertilization or creation, excluding any time during which its development has been suspended, and ending at birth.
- Fetal tissue includes membranes, placenta, umbilical cord, amniotic fluid and other tissue that contains genetic information about the fetus.
- Human reproductive materials means a sperm, ovum or other human cell, or a human gene, and includes a part of any of them.

5.1 REB Review of Collection and Use of Human Biological Materials

5.1.1 REB review is required for research involving the collection and use of human biological materials;

5.1.2 Consent is required from the participant who will donate the biological materials or from a third party of a participant that lacks the capacity to consent or is deceased, or from a deceased participant if donation decision is made prior to death;

5.1.3 All aspects of seeking consent outlined in SOP 701 Informed Consent Form Requirements and Documentation must be followed when seeking consent for the use of biological materials and in addition the following criteria may apply:

- type and amount of biological materials to be taken,
- manner in which biological materials will be taken, and the safety and invasiveness of the procedures for acquisition,
- intended uses of the biological materials, including any commercial use,
- measures employed to protect the privacy of and minimize risks to participants,
- length of time the biological materials will be kept, how they will be preserved, location of storage (e.g., in Ontario, outside of Canada), and process for disposal, if applicable,
- any anticipated linkage of biological materials with information about the participant,
- Researchers' plan for handling results and findings, including clinically relevant information and incidental findings;

5.1.4 The process for requesting withdrawal of human biological materials must be clearly explained, as well as any conditions where Researchers would not be able to withdraw a participant's data.

5.2 Consent and Secondary Use of Human Biological Materials for Research Purposes

5.2.1 See SOP 701 Informed Consent Form Requirements and Documentation - section 5.12.

5.3 Storage and Banking of Biological Materials

5.3.1 Institutions and Researchers that maintain biobanks must:

- use appropriate facilities, equipment, policies and procedures to store human biological materials safely, and in accordance with applicable standards,
- establish physical, administrative and technical safeguards that protect human biological materials and any information about participants.

5.4 Research Involving Human Reproduction Materials

5.4.1 Research using reproductive biological materials in relation to an anticipated or ongoing pregnancy cannot be conducted if the knowledge can be reasonably obtained using alternate methods;

5.4.2 Reproductive biological materials for research cannot be obtained through commercial transaction, including exchange for services.

5.5 Research Involving Human Embryos

5.5.1 Research on in vitro embryos already created and intended for implantation to achieve pregnancy is acceptable if:

- the research is intended to benefit the embryo,
- the research will not compromise the care of the woman, or the subsequent fetus,
- the safety and comfort of the woman and the safety of the embryo will be closely monitored,
- the gamete donors provided consent;

5.5.2 Research involving embryos that have been created for reproductive or other purposes permitted under the Assisted Human Reproduction Act (Appendix 1), but are no longer required for these purposes, may be acceptable if:

- the ova and sperm from which they are formed were obtained in accordance with SOP 502 REB Review of Biological and Reproductive Materials section 5.5.1,
- the gamete donors provided consent,
- embryos exposed to manipulations not directed specifically to their ongoing normal development will not be transferred for continuing pregnancy, and
- research involving embryos will take place only during the first 14 days after their formation by combination of the gametes, excluding any time during which embryonic development has been suspended.

5.6 Research Involving Fetuses and Fetal Tissue

5.6.1 Requires the consent of the woman;

5.6.2 Will not compromise the woman's decision making ability with respect to continuation of her pregnancy.

5.7 Research Involving Pluripotent Stem Cells

5.7.1 Research involving human pluripotent stem cells from an embryonic source that will be grafted or transferred in any other form into humans or non-human animals requires review and approval by the Stem Cell Oversight Committee (SCOC) and ethical clearance from the REB;

5.7.2 Evidence of the SCOC approval must be provided to the REB;

5.7.3 Embryos no longer needed for reproductive purposes may be donated in research, including research to derive and study human embryonic stem cells and other human cells or cell lines of pluripotent nature, as long as the donors have been informed of all available options with respect to embryo use and consent of the donors is sought again;

5.7.4 When seeking consent for human embryonic stem cell research, in addition to the information outlined in SOP 701 Informed Consent Form Requirements and Documentation section 5.12., Researchers must explain that:

- cell line(s) will be anonymized or coded,
- research participants are free to not participate and have the right to withdraw at any time before an anonymized or coded cell line is created,
- the research could result in the production of a stem cell line that could be maintained for many years, distributed to other parts of the world, and used for various research purposes,
- research participants will not benefit directly financially from any future commercialization of cell lines; nor will there be any personal benefit in terms of dispositional authority over any embryonic cell lines created (i.e., there will be no directed donation of the cells or cell lines to particular individuals),
- once an anonymized or coded cell line is created, it may have a wide distribution, making withdrawal of materials almost impossible.

5.8 Creation of Excess Embryos

5.8.1 No more embryos can be created than necessary for the optimum chance of reproductive success.

5.9 National Registry

5.9.1 Any institutions that are eligible to receive Agency funds for stem cell lines derived directly from embryonic sources must be

registered with the Canadian SCOC national registry of stem cell lines, and the stem cell lines must be made available to all Researchers, subject to reasonable cost-recovery charges.

5.10 Privacy and Confidentiality

5.10.1 All human pluripotent stem cell lines shall be anonymized or coded unless the research only involves the directed donation of induced pluripotent stem cells;

5.10.2 All Researchers who make stem cell lines available to other academics shall ensure that the cell lines are anonymized or coded.

5.11 Conflict of Interest

5.11.1 Members of the health care team who may influence a donor's decision to donate embryos may not be included on the stem cell research team;

5.11.2 When Researchers/institutions have, or acquire, financial interests in the outcome of the stem cell research it must be disclosed to the SCOC, the REB and current and prospective research participants;

5.11.3 Researchers and/or their institutions may be asked to come up with a management plan for any such conflicts of interest;

5.11.4 Copies of contracts between Researchers, institutions and industry sponsors, as well as budgets must be submitted to the SCOC and the REB for review.

6.0 REFERENCES

See References.

7.0 APPENDICIES

None.

8.0 REVISION HISTORY

SOP Title	Version	Updates
REB Review of Biological and Reproductive Materials	v.502.001 2015MAY25	Original: Based on TCPS2 Chapter 12: Human Biological Materials Including Materials Related to Human Reproduction, v. December, 2014
Review of Biological and Reproductive Materials	v.502.002 2022JAN06	<ul style="list-style-type: none">• Removed HSREB from title of SOP• Updated Site approvals• Replaced 'HSREB' with 'REB'