



Guidance for CIRM Medical and Ethical Standards Regulations Governing Donation of Oocytes for CIRM-Funded Research

The CIRM Medical and Ethical Standards Regulations, Title 17 California Code of Regulations, sections 100010 – 100120, contain specific provisions governing the procurement of human oocytes. These provisions apply to all CIRM-funded research. Major requirements governing the procurement of human oocytes are summarize below.

Requirements for Intuitional Oversight (Section 100070(a))

All research proposing to procure human oocytes must be reviewed and approved by a stem cell research oversight (SCRO) committee as defined in section 100060. Since procurement also involves intervention with a living person, proposed research must also be approved by an institutional review board (IRB).

Requirements for Oocyte Donation (Section 100095)

As part of the review and approval process the SCRO committee must confirm the following conditions are met:

- The clinic performing oocyte retrieval must be a member of the Society for Assisted Reproductive Technology
- The physician attending the donor shall not be the principal investigator unless exceptional circumstances exist and the IRB has granted an exemption.
- The physician attending the donor shall not have a financial interest in the research.
- The CIRM grantee must ensure that the oocyte donor has access to no-cost medical care that is required as a direct and proximate result of donation. The donor shall not be required to claim any treatment costs through her own insurance coverage, but this provision does not preclude a donor from voluntarily opting to utilize her own provider and claiming the cost as a permissible expense (see below).
- If the primary purpose of oocyte procurement is for reproductive use (either for the donor or another woman), the procurement for research should not compromise the reproductive success of the woman undergoing infertility treatment. The woman in infertility treatment must determine that she does not require the oocytes (provided by her or another woman) for her own reproductive need.
- The original donor must consent for her oocytes to be used in CIRM-funded research.

Requirements of Oocyte Donation

- IRB / SCRO approval
- SART membership
- Attending physician is not the principal investigator
- Physician has no financial interest in the research
- Donor access to medical care
- Oocyte procurement does not compromise optimal reproductive success (when applicable)
- Original donor consents for research use
- No payments to donor beyond *permissible expenses*

Permissible Expense for Oocyte Donation (Section 100020(h))

Payments to oocyte donors are limited to direct out-of-pocket expenses incurred by the donor (permissible expenses). Permissible expenses include but are not limited to costs associated with travel, housing, child care, medical care, health insurance and actual lost wages.¹ If a donor is paid to provide oocytes for use by another woman and the original donor receives payments in excess of reimbursement for permissible expenses, then the oocytes may not be used for CIRM-funded research.

Costs Associated with Ovarian Stimulation

If a donor is providing oocytes exclusively for CIRM-funded research, CIRM funds may be used to cover cost associated with ovarian stimulation and oocyte retrieval. If a potential donor is undergoing infertility treatment, CIRM-funds may not be used to pay costs associated with ovarian stimulation and oocyte retrieval.²

Examples of Donation Scenarios

- Research only donation: If a donor is providing oocytes exclusively for research, then provisions governing optimal reproductive success are not applicable. Costs associated with stimulation and retrieval may be paid with CIRM-funds. Donor reimbursement is limited to *permissible expenses*.¹
- Donor in infertility treatment: If a potential donor is undergoing infertility treatment, then the fertility protocol must be established prior to obtaining consent for donation and donation may not compromise the reproductive success of the woman in treatment. The donor must determine oocytes donated for research are not required for infertility treatment. Failed to fertilize oocytes and oocytes in excess of clinical need may be donated to research. Donor reimbursement is limited to *permissible expenses*.¹
- Donor providing oocytes for a woman in infertility treatment: If a potential donor is providing oocytes for another woman undergoing infertility treatment, then the fertility protocol must be established prior to obtaining consent for donation and donation may not compromise the reproductive success of the woman in treatment. The original donor must consent to research donation and the woman undergoing infertility treatment must determine the oocytes are not required for infertility treatment. Failed to fertilize oocytes and oocytes in excess of clinical need may be donated to research only if reimbursement was limited to *permissible expenses*.¹

¹ See definition “permissible expenses,” Title 17 California Code of Regulations § 100020(h).

² Payment of costs associated with infertility treatment constitutes valuable consideration. See Title 17 California Code of Regulations § 100080(e)(2).