

California Department of Public Health
**INFORMED CONSENT FORM CHECKLIST FOR
RESEARCH INVOLVING HUMAN OOCYTE RETRIEVAL**

NOTE: This checklist is intended to aid institutional review boards and research projects involving human oocyte retrieval in following Federal and State informed consent standards. The following is not an exhaustive list of informed consent requirements and is only provided to assist in the informed consent process for subjects undergoing oocyte retrieval.

A. Does your informed consent form contain the following <u>general</u> Federal and State requirements for informed consent? ¹	<u>YES</u>	<u>NO</u>
1. Statement that the study involves research.	_____	_____
2. Expected duration of subject's participation.	_____	_____
3. Description of the procedures to be followed.	_____	_____
4. Description of foreseeable risks or discomforts.	_____	_____
5. Description of how confidentiality will be maintained.	_____	_____
6. Whom to contact with questions about the research.	_____	_____
7. Whom to contact with questions about subject's rights.	_____	_____
8. Whom to contact in the event of a research related injury.	_____	_____
9. Statement that participation is voluntary.	_____	_____
10. Statement that refusing or discontinuing participation involves no penalty.	_____	_____
11. Statement that significant findings during the course of the research which may relate to subject's willingness to continue participating will be provided to the subject.	_____	_____
12. Statement that subject may retain a copy of the informed consent form.	_____	_____

¹ For a complete listing of requirements, please refer to Title 45 Code of Federal Regulations Part 46 and California Health and Safety Code Section 24170-24179.5.

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B. Does your informed consent form/process contain the following State requirements for subjects undergoing oocyte retrieval for research? ²	<u>YES</u>	<u>NO</u>
1. Medically accurate written summary of health and consumer issues associated with assisted oocyte production and any alternative method of oocyte retrieval (e.g., American Society for Reproductive Medicine, "Assisted Reproductive Technologies: A Guide for Patients").	_____	_____
a. Description of the manner in which the subject will receive and review the written summary.	_____	_____
b. Statement of the potential risks associated with the surgical procedure and with the drugs/medications prescribed for ovarian stimulation, such as ovarian hyperstimulation syndrome, infection, and intestinal injuries.	_____	_____
2. Statement that payment of medical expenses resulting from the procedure will be provided at no cost to the subject.	_____	_____
3. Summary informing the subject that oocytes may not be sold or transferred for valuable consideration.	_____	_____
4. Statement that donors may document their preferences regarding future uses of their donated materials.	_____	_____
5. Statement as to any professional interest of the physician/surgeon or his/her immediate family in the outcome of the research or of the oocyte retrieval procedure.	_____	_____

² For a complete listing of requirements, please refer to Chapter 2, Part 5.5 of Division 106 of the California Health and Safety Code commencing with Section 125330.

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C. Does your informed consent form contain the following recommended information per the CDPH Guidelines for Human Stem Cell Research? ³

	<u>YES</u>	<u>NO</u>
1. Statement that the research is not intended to provide direct medical benefit to the donor(s) except in the case of autologous donation.	_____	_____
2. Statement as to whether the identities of the donors will be readily ascertainable to those who derive or work with the resulting hESC lines.	_____	_____
a. If the identities of the donor(s) are retained (even coded), researchers must discuss any plans for recontact of donors of materials used to derive cell lines and obtain informed consent for recontact.	_____	_____
b. This requirement includes both recontacting donors to provide information about research findings and to ask for additional health information.	_____	_____
c. Recontact may only occur if the donor consents to recontact at the time of donation.	_____	_____
3. Statement that derived human embryonic stem cells (hESC) and/or cell lines might be kept for many years.	_____	_____
4. Statement that the hESCs and/or cell lines may be transplanted into humans or animals.	_____	_____
5. Statement that the results of research may be patentable or have commercial potential, and that the donor will not receive any financial benefit from future commercial development.	_____	_____
6. Statement that donation is being made without restriction regarding who may be the recipient of transplanted cells, except in the case of autologous donation.	_____	_____
7. Statement that neither consenting nor refusing to donate materials for research will affect the quality of any future care provided to potential donors.	_____	_____
8. Statement that embryos will be destroyed in the process of deriving hESCs.	_____	_____

³ For a complete listing of recommendations, please refer to the CDPH [Human Stem Cell Research Program homepage at http://www.cdph.ca.gov/programs/HSCR/Pages/default.aspx](http://www.cdph.ca.gov/programs/HSCR/Pages/default.aspx)