

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 oocyte retrieval in following Federal and State informed consent standards.

A. BASIC FEDERAL AND STATE REQUIREMENTS:¹	<u>YES</u>	<u>NO</u>	<u>N/A</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. Who to contact with questions about the research.	_____	_____	_____
7. Who to contact with questions about subject's rights.	_____	_____	_____
8. Who 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. Is there language which asks the subject to waive her legal rights?	_____	_____	_____
13. Statement that subject may retain a copy of the informed consent form.	_____	_____	_____

¹ These requirements are specified in Title 45 Code of Federal Regulations Part 46 and California Health and Safety Code Section 24170-24179.5.

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B. CDPH REQUIREMENTS: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. A description of the manner in which the subject will receive and review the written summary.	_____	_____
2. Statement that derived hESCs and/or cell lines might be kept for many years.	_____	_____
3. 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.	_____	_____
4. Statement that the hESCs and/or cell lines might be used in research involving genetic manipulation.	_____	_____
5. Statement that the hESCs and/or cell lines may be transplanted into humans or animals.	_____	_____
6. Statement that the research is not intended to provide direct medical benefit to the donor(s) except in the case of autologous donation.	_____	_____
7. 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.	_____	_____
8. Summary informing the subject that oocytes may not be sold or transferred for valuable consideration.	_____	_____

² These requirements are specified in Part 5.5 of Division 106 of the California Health and Safety Code, Chapter 2 (commencing with Section 125330) and the CDPH Guidelines for Human Stem Cell Research.

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	<u>YES</u>	<u>NO</u>	
9. Statement that donation is being made without restriction regarding who may be the recipient of transplanted cells, except in the case of autologous donation.	_____	_____	
10. Statement that neither consenting nor refusing to donate materials for research will affect the quality of any future care provided to potential donors.	_____	_____	
11. Donors should be offered an opportunity to document their preferences regarding future uses of their donated materials.	_____	_____	
12. Statement that embryos will be destroyed in the process of deriving hESCs.	_____	_____	
13. Statement of the potential risks involved in oocyte retrieval, including:	<u>YES</u>	<u>NO</u>	<u>N/A</u>
a. Ovarian hyperstimulation syndrome (OHSS)	_____	_____	_____
• Blood clot	_____	_____	_____
• Liver dysfunction	_____	_____	_____
• Renal failure	_____	_____	_____
• Cardiac disorders	_____	_____	_____
• Memory loss	_____	_____	_____
• Neurological dysfunction	_____	_____	_____
• Death	_____	_____	_____
b. Anesthesia	_____	_____	_____
c. Infection	_____	_____	_____
d. Rupture of ovaries	_____	_____	_____
e. Cysts	_____	_____	_____
f. Risks to future pregnancy, if any	_____	_____	_____
14. Statement that payment of medical expenses resulting from the procedure will be provided at no cost to the subject.			