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 general Federal and State requirements for informed consent? [1]	YES	NO
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.

B. Does your informed consent form/process contain the following State requirements for subjects undergoing oocyte retrieval for research? [2]	YES	NO
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.

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

	YES	NO
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