The following minimum elements must be present in the informed consent document in order to meet Federal and California regulations, and NAS standards.

### A. BASIC REQUIRED FEDERAL ELEMENTS:

<table>
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<tr>
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<th>YES</th>
<th>NO</th>
<th>N/A</th>
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<tbody>
<tr>
<td>1. Statement that the study involves research.</td>
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<td>2. Statement that participation is voluntary.</td>
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<td>3. Expected duration of subject's participation.</td>
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<td>4. Description of how confidentiality will be maintained.</td>
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<td>5. Statement that refusing or discontinuing participation involves no penalty.</td>
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<tr>
<td>a. <em>For donors:</em> A statement that neither consenting nor refusing to donate materials for research will affect the quality of care provided to potential donors.</td>
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<td>6. 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.</td>
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<td>7. Whom to contact in the event of a research related injury (if the research is more than minimal risk¹).</td>
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<td>8. Whom to contact with questions about the research (PI).</td>
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<td>9. Is there language which asks the subject to waive his/her legal rights?</td>
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<td>10. Who to contact with questions about subject's rights.</td>
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<td>11. Statement that subject may keep a copy of the informed consent form.</td>
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</table>

¹“Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests” [45 CFR 46.102(i)].
B. CA CIRM & NAS REQUIRED STANDARD ELEMENTS:²

1. A statement that the blastocysts or gametes will be used to derive hESCs
   a. For stored IVF blastocysts: A statement that the donated embryos are no longer needed for reproductive purposes.
   b. A statement that the embryos will be destroyed in the process of deriving hESCs.
   c. A statement that the research may include research on human transplantation.

2. A statement that donation of cells (blastocysts, gametes, somatic or pluripotent) is made without any restriction or direction regarding who may be the recipient of transplants of the cells derived, except in the case of autologous donation.
   a. A statement that the research is not intended to provide direct medical benefit to the donor(s) except in the case of autologous donation.

3. A statement as to whether the identities of the donors will be readily ascertainable to those who derive or work with the resulting pluripotent lines.
   a. If the identities of the donor(s) are retained (even coded), investigators 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 recontacting donors to ask for additional health information.
   c. Donors may be recontacted in the future only if they consent to recontact at the time of donation.

4. A statement that the hESC or iPSC and/or cell lines might be used in research involving genetic manipulation of the cells or the mixing of human and nonhuman cells in animal models.

5. Disclosure of the possibility that the research results of study of the cells, somatic, gametes, hESC or iPSC may have commercial potential.

6. A statement that the donor will not receive financial or any other benefits from any commercial development of the cells.

7. A statement of the foreseeable risks involved to the donor.

² CA CIRM Regulations do not allow a waiver of any of the elements of informed consent.
8. A statement that researchers may choose to use materials only from donors who agree to all future uses of donated materials.

   a. A statement that the cells may be used in future research projects that are not foreseeable.
   
   b. A statement that derived hESC, iPSC and/or cell lines might be kept for many years.
   
   c. If the investigator wishes to restrict future uses of the cells to specific types of research, the consent document should offer subjects the option of agreeing to some forms of iPSC/hESC research but not others. If this is the case, please include a list of options for subject/donors to agree to some forms of iPSC/hESC research but not others. The list should have a line for subjects to initial agreement to specific forms of iPSC/hESC research.

9. A statement that subjects/donors may withdraw consent for the use of their donated embryos until the blastocysts are actually used in cell line derivation.

   a. A statement that subjects/donors may withdraw consent for the use of their donated embryos until the identifying donor information attached to the blastocysts are no longer retained by the researchers.

10. Payment to IVF and somatic cell donors. Information consistent with NAS Guidelines and CA regulations on payment for subject participation/donation of materials.

    IVF: No payments, cash or in-kind, may be provided for donating blastocysts in excess of clinical need for research purposes. Donors may not be reimbursed for the costs of storage prior to a decision to donate.

11. There is a signature block for both gamete donors or somatic cell donors when IVF procedures or SCNT will be used to create research cells.

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3 Payment to somatic cell, gamete, or IVF donors for donation of biological materials is not allowed. Investigators, however, are allowed to reimburse “permissible expenses” of embryo and somatic cell donors. “Permissible expenses” are defined as: “necessary and reasonable costs directly incurred as a result of donation or participation in research activities. Permissible expenses may include but are not limited to costs associated with travel, housing, child care, medical care, health insurance and actual lost wages.” 100020(h)

4 CIRM 100080(a)(2)(B): “For embryos originally created using [IVF] for reproductive purposes and are no longer needed for this purpose, “valuable consideration” does not include payments to original gamete donors in excess of “permissible expenses.”

CIRM 100082: For embryos created on or before August 13, 2008, limits on “valuable consideration” does not include payments to gamete donors in excess of “permissible expenses,” provided the embryo was originally created for reproductive purposes.”
C. OTHER ELEMENTS OF INFORMED CONSENT

1. An understandable explanation of the research purpose.  

2. An understandable description of the research procedures.  

3. A description of the reasonably foreseeable research risks or discomforts.  

4. Clearly indicate which procedures are experimental and which are standard clinical treatments.  

5. Indication that the treatment or procedure may involve risks that are currently unforeseeable.  

6. Description of anticipated benefits to subjects or others.  

7. Disclosure of alternative procedures or treatments that may be advantageous to the subject.  

8. Additional costs to subject resulting from research participation.  


11. Consequences of subjects’ early withdrawal from the study.  

12. Circumstances under which PI may terminate subject participation without subject consent.  

13. Disclosure statement that informs subjects that investigator(s) may have a conflict of interest.  

14. The consent form includes all of the IRB required boilerplate sections for tissue/blood samples and/or genetic testing.
D. SCNT, PARTHENOGENESIS, ETC

1. A statement whether the resulting cells may be available for autologous use by the somatic cell donor.  

2. A statement that the research is not intended to directly benefit the oocyte donor  

3. A lay description of the process of deriving stem cell lines, i.e., SCNT, parthenogenesis, or some other method.  

4. Stem cell lines developed from her oocytes will be grown in the lab and shared with other researchers for future unforeseeable studies.  

5. If stem cell lines derived from her donated oocytes are to be transplanted into patients, researchers might recontact her to obtain additional health information.  

6. Explanation of payment: Oocyte donors will receive no payment beyond reimbursement for permissible expenses as approved by the IRB/ESCRO.  

7. Payment: Research oocytes: Women who undergo hormonal induction to generate oocytes specifically for research, such as for nuclear transfer, may be reimbursed ONLY for direct expenses incurred as a result of the procedure, as determined by the IRB. No payments, cash or in-kind, may be provided for donating oocytes, sperm, or somatic cells for research.  

8. A statement describing the foreseeable risks involved to the donor.  

   For Women undergoing oocyte retrieval for donation:  
   a. Ovarian hyperstimulation syndrome (OHSS)  
      • Blood clots  
      • Bleeding  
      • Liver dysfunction  
      • Renal failure  
      • Cardiac disorders  
      • Memory loss  
      • Neurological dysfunction  
      • Death  
   b. Infection  
   c. Rupture of ovaries  
   d. Cysts  
   e. Anesthesia  
   f. Risks to future pregnancy, if any  
   g. Other risks.