Beyond the Permissibility of HESC Research: Substantive and Procedural Requirements

California’s Stem Cell Initiative: Confronting the Legal and Policy Challenges

Berkeley, March 4th 2006

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Countries Surveyed

1. Australia
2. Austria
3. Argentina
4. Belgium
5. Bulgaria
6. Brazil
7. Canada
8. China
9. Colombia
10. Costa Rica
11. Denmark
12. Estonia
13. Finland
14. France
15. Georgia
16. Germany
17. Greece
18. Hungary
19. Iceland
20. India
21. Ireland
22. Israel
23. Italy
24. Japan
25. Latvia
26. Lithuania
27. Netherlands
28. New Zealand
29. Norway
30. Panama
31. Peru
32. Poland
33. Portugal
34. Romania
35. Russia
36. Singapore
37. Slovakia
38. Slovenia
39. Spain
40. South Africa
41. South Korea
42. Sweden
43. Switzerland
44. Tunisia
45. Thailand
46. Turkey
47. Ukraine
48. United Kingdom
49. United States
50. Vietnam
Survey of National Policies on Embryonic Stem Cell Research

- 32 countries prohibit human cloning for therapeutic or research purposes by law, 05 by guidelines.

- 6 countries allow for the creation of embryos for research purposes by law, 01 country by guidelines.

- 15 countries allow the procurement of hESC from surplus embryos by law, 04 by guidelines.

- 05 countries prohibit the procurement of hESC by law, but 1 country allow for their importation.

- 33 countries have signed (19 have ratified) the European Convention on Human Rights and Biomedicine, which prohibits the creation of embryos for research purposes.
Substantive Requirements (I)

1. Constrain research to practices that serve important and worthwhile goals, such as medical therapy (e.g. diagnostic and preventive purposes)

2. Prohibit research with non-therapeutic or “trivial” goals (e.g. enhancement, eugenic purposes)
3. Identify the circumstances under which hESC and cloning research is ethically justified and establish:

- A hierarchy and/or an order of priority among embryos used for research (surplus vs. SCNT; embryos low quality vs. not suitable to be placed in the body)

4. Prohibit developing, implanting or conducting research on embryos beyond 14 days (from fertilisation) or until formation of primitive streak.
Procedural & Ethical Safeguards (I)

1. Stages of embryonic development:
   - Alternative sources.
   - Traceability of stem cell lines with respect to their source.
   - Prohibition on the creation of animal/human chimeras.
Procedural & Ethical Safeguards (II)

2. **Donors** (e.g. blastocysts, gametes, somatic cells):
   - Free and informed consent.
   - Prohibition of financial incentives.
   - Safeguards against conflicts of interest.
   - Protection of confidentiality and privacy.
Procedural & Ethical Safeguards (III)

3. Research Governance:

- Ethics review
- Government oversight
- Enforcement mechanisms
- Transparency regarding research results