

Appendix H – Legislative Initiatives at the International Level

Statutes

Countries	<i>Relevant Statutes</i>	<i>Administering Agencies</i>
United States	<ul style="list-style-type: none"> - 1992 Fertility Clinic Success Rate and Certification Act - 2001 Presidential directive on hESC research - FDA "Dear Colleague" letter of 2001 - Dickey-Wicker Amendment of 1996 	<ul style="list-style-type: none"> - Centers for Disease Control and Prevention (CDC) - Food and Drug Administration (FDA)
Canada	Bill C-6: An Act Respecting Assisted Human Reproduction and Related Research (2004)	Assisted Human Reproductive Agency of Canada
Australia	<ul style="list-style-type: none"> - Prohibition of Human Cloning Act 2002 - Research Involving Human Embryos Act of 2002 - Ethical guidelines on the use of assisted reproductive technology in clinical practice and research of 2004 - Code of Practice for Centres Using Assisted Reproductive Technology of 2002 	<ul style="list-style-type: none"> - Fertility Society of Australia - Australian Health Ethics Committee of the National Health and Medical Research Council - Embryo Research Licensing Committee (ERLC)
Germany	<ul style="list-style-type: none"> - Embryonenschutz-Gesetz (1991 Embryo Protection Act) - Stammzellgesetz (2002 Stem Cell Act) 	<ul style="list-style-type: none"> - Bundesministerium fuer Gesundheit und Soziale Sicherung (Federal Ministry of Health) - Zentralen Ethik-Kommission für Stammzellenforschung (Central Ethics Commission on Stem Cell Research)
UK	<ul style="list-style-type: none"> - 1990 Human Fertilisation and Embryology Act - 2001 Human Reproductive Cloning Act - The Human Fertilisation and Embryology (Research Purposes) Regulations 2001 	<ul style="list-style-type: none"> - Human Fertilisation and Embryology Authority (HFEA) - Ministry of Health
France	Loi n° 2004-800 du 6 août 2004 relative à la bioéthique	<ul style="list-style-type: none"> - Ministère de Santé Public - Agence de la biomédecine - Le Comité consultatif national d'éthique
Italy	Norme in materia di procreazione medicalmente assistita no. 40, 2004 (2004 Norms Regarding Medically Assisted Reproduction)	Ministry of Health

Countries	<i>Relevant Statutes</i>	<i>Administering Agencies</i>
Spain	<ul style="list-style-type: none"> - Law 35/1988 – Assisted Reproduction Techniques Act - Law 42/1988 – Donation and Use of the Embryos and Fetus, or Their Cells or Organs Act - Law 41/2002 – Patients’ Rights and Obligations Act - Law 45/2003 National Health System Act Organic Law 	<ul style="list-style-type: none"> - Ministry of Health - Ethics Advisory Committee for Scientific and Technological Research - National Commission of Assisted Reproduction (CNRA)
Sweden		National Board of Health and Welfare issues permits
Japan	<ul style="list-style-type: none"> - 2000 The Law Concerning Regulation Relating to Human Cloning Techniques and Other Similar Techniques - No legislation governing the ART industry [check] 	Ministry of Education and Science
China	<ul style="list-style-type: none"> - 2004 Ethical Guidance on Human Embryonic Stem Cell Research - 2003 Guidelines on Human Assisted Reproductive Technologies - 2003 Ethical Principles of Human ARTs - 2000 The Human Reproductive Technology Ordinance (Hong Kong) 	Ministry of Health/Ministry of Science and Technology
Singapore		Bioethics Advisory Committee (BAC)
S. Korea	2004 Life Ethics Law	Ministry of Health and Welfare

Table 16: Governing statutes.

Key Provisions

	<i>Embryo Research</i>	<i>Reproductive Cloning</i>	<i>Research Cloning</i>	<i>Stem Cell Research</i>	<i>PGD¹</i>	<i>Creation of Chimeras</i>	<i>Creation of Hybrids</i>	<i>Germ-line Genetic modifications</i>	<i>Surrogacy</i>	<i>Trade/Sale of Gametes and Embryos</i>
United States	Unregulated	Prohibited ²	Unregulated	Unregulated	Unregulated	Unregulated	Unregulated	Unregulated	Unregulated	Unregulated
Canada	Regulated	Prohibited	Prohibited	Regulated ³	Regulated ⁴	Prohibited	Prohibited	Prohibited	Regulated ⁵	Regulated ⁶
Australia	Regulated	Prohibited	Prohibited	Regulated ⁷	Regulated ⁸	Prohibited ⁹	Prohibited	Prohibited ¹⁰	Regulated	Regulated ¹¹
Germany	Prohibited	Prohibited	Prohibited	Regulated ¹²	Prohibited	Prohibited	Prohibited	Prohibited	Prohibited	Regulated ¹³
UK	Regulated	Prohibited	Regulated	Regulated ¹⁴	Regulated ¹⁵	[check]	Regulated	Prohibited	Regulated ¹⁶	Regulated ¹⁷

¹ Pre-implantation genetic diagnosis.

² De facto.

³ Permitted on donated, supernumerary embryos.

⁴ Exclusively for therapeutic applications.

⁵ Non-commercial services allowed.

⁶ Commercial sale of gametes and embryos prohibited.

⁷ Allowed on donated, supernumerary embryos.

⁸ Therapeutic applications recommended.

⁹ Creation of chimeric animals allowed.

¹⁰ Creation of transgenic animals allowed.

¹¹ Commercial trade of gametes and embryos prohibited.

¹² Stem cell lines can be imported if derivation consistent with German provisions and research is deemed important.

¹³ Oocyte donation prohibited, sperm donation permitted.

¹⁴ Allowed on donated, supernumerary embryos.

¹⁵ Some therapeutic uses permitted.

¹⁶ Commercial offerings prohibited.

¹⁷ Commercial trade of gametes and embryos prohibited.

	<i>Embryo Research</i>	<i>Reproductive Cloning</i>	<i>Research Cloning</i>	<i>Stem Cell Research</i>	<i>PGD¹</i>	<i>Creation of Chimeras</i>	<i>Creation of Hybrids</i>	<i>Germ-line Genetic modifications</i>	<i>Surrogacy</i>	<i>Trade/Sale of Gametes and Embryos</i>
France	Regulated ¹⁸	Prohibited	Prohibited	Regulated ¹⁹	Regulated ²⁰	Prohibited	Prohibited	Prohibited	[check]	Regulated ²¹
Italy	Prohibited	Prohibited	Prohibited	Prohibited	Prohibited	Prohibited	Prohibited	Prohibited	Prohibited	Prohibited
Spain	Regulated ²²	Prohibited	Regulated ²³	Regulated ²⁴	Regulated ²⁵			Prohibited	Prohibited	Regulated ²⁶
Sweden		Prohibited ²⁷	Prohibited ²⁸	Regulated ²⁹	Regulated ³⁰			Prohibited		Regulated ³¹
Japan		Permitted	Permitted	Unregulated ³²		Regulated ³³	Regulated ³⁴		Unregulated	

¹⁸ Research on in vitro embryos prohibited, however studies permitted where research does not harm the embryo.

¹⁹ Donation of embryos for research purposes allowed, provided the research contributes to therapeutic progress – provision valid for the next five years.

²⁰ Allowed only to prevent serious inheritable disease.

²¹ Commercial sale of gametes and embryos prohibited.

²² Research on excess in vitro embryos at least five years old permitted – assuming they are no longer viable.

²³ Permitted on surplus embryos that have passed their legal date for implantation.

²⁴ Research on excess in vitro embryos at least five years old permitted – assuming they are no longer viable.

²⁵ Permitted to diagnose and prevent hereditary diseases

²⁶ Gamete and embryo donation permitted.

²⁷ Ban on implantation effectively precludes human cloning for either reproductive or research purposes

²⁸ (Ban on implantation effectively precludes human cloning for either reproductive or research purposes.

²⁹ Non-therapeutic research allowed on embryos of up to fourteen days development.

³⁰ Allowed for prevention of sex-linked hereditary diseases.

³¹ Consent is required of egg and sperm donors

³² Does not address development of human embryonic stem cells

³³ Embryo creation permitted, but implantation prohibited.

³⁴ Embryo creation permitted, but implantation prohibited

	<i>Embryo Research</i>	<i>Reproductive Cloning</i>	<i>Research Cloning</i>	<i>Stem Cell Research</i>	<i>PGD¹</i>	<i>Creation of Chimeras</i>	<i>Creation of Hybrids</i>	<i>Germ-line Genetic modifications</i>	<i>Surrogacy</i>	<i>Trade/Sale of Gametes and Embryos</i>
China	Regulated ³⁵	Prohibited	Permitted	Regulated ³⁶	Regulated ³⁷	Prohibited ³⁸	Prohibited	Prohibited	Prohibited	Regulated ³⁹
Singapore	Unregulated	Prohibited	Permitted	Regulated ⁴⁰	Unregulated					Unregulated
S. Korea	Regulated	Prohibited	Permitted	Regulated ⁴¹	Regulated ⁴²	Prohibited	Prohibited	Prohibited		

Table 17: Key statutory provisions.

³⁵ Research allowed with informed consent

³⁶ Research allowed on supernumerary IVF embryos, aborted fetal tissue, donated germ cells. Creation of embryos for research prohibited. 14-day limit for embryo research.

³⁷ Prohibits sex selection without medical indications.

³⁸ Research on human chimeric embryos prohibited.

³⁹ Purchase or sale of human gametes, embryos or fetal tissue prohibited.

⁴⁰ Creation of embryos for research prohibited.

⁴¹ Creation of embryos for research prohibited. Research on supernumerary embryos permitted.

⁴² Restricted to treatment of hereditary diseases.

