

## 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"> <li>- 1992 Fertility Clinic Success Rate and Certification Act</li> <li>- 2001 Presidential directive on hESC research</li> <li>- FDA "Dear Colleague" letter of 2001</li> <li>- Dickey-Wicker Amendment of 1996</li> </ul>	<ul style="list-style-type: none"> <li>- Centers for Disease Control and Prevention (CDC)</li> <li>- Food and Drug Administration (FDA)</li> </ul>
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"> <li>- Prohibition of Human Cloning Act 2002</li> <li>- Research Involving Human Embryos Act of 2002</li> <li>- Ethical guidelines on the use of assisted reproductive technology in clinical practice and research of 2004</li> <li>- Code of Practice for Centres Using Assisted Reproductive Technology of 2002</li> </ul>	<ul style="list-style-type: none"> <li>- Fertility Society of Australia</li> <li>- Australian Health Ethics Committee of the National Health and Medical Research Council</li> <li>- Embryo Research Licensing Committee (ERLC)</li> </ul>
Germany	<ul style="list-style-type: none"> <li>- Embryonenschutz-Gesetz (1991 Embryo Protection Act)</li> <li>- Stammzellgesetz (2002 Stem Cell Act)</li> </ul>	<ul style="list-style-type: none"> <li>- Bundesministerium fuer Gesundheit und Soziale Sicherung (Federal Ministry of Health)</li> <li>- Zentralen Ethik-Kommission für Stammzellenforschung (Central Ethics Commission on Stem Cell Research)</li> </ul>
UK	<ul style="list-style-type: none"> <li>- 1990 Human Fertilisation and Embryology Act</li> <li>- 2001 Human Reproductive Cloning Act</li> <li>- The Human Fertilisation and Embryology (Research Purposes) Regulations 2001</li> </ul>	<ul style="list-style-type: none"> <li>- Human Fertilisation and Embryology Authority (HFEA)</li> <li>- Ministry of Health</li> </ul>
France	Loi n° 2004-800 du 6 août 2004 relative à la bioéthique	<ul style="list-style-type: none"> <li>- Ministère de Santé Public</li> <li>- Agence de la biomédecine</li> <li>- Le Comité consultatif national d'éthique</li> </ul>
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"> <li>- Law 35/1988 – Assisted Reproduction Techniques Act</li> <li>- Law 42/1988 – Donation and Use of the Embryos and Fetus, or Their Cells or Organs Act</li> <li>- Law 41/2002 – Patients’ Rights and Obligations Act</li> <li>- Law 45/2003 National Health System Act Organic Law</li> </ul>	<ul style="list-style-type: none"> <li>- Ministry of Health</li> <li>- Ethics Advisory Committee for Scientific and Technological Research</li> <li>- National Commission of Assisted Reproduction (CNRA)</li> </ul>
Sweden		National Board of Health and Welfare issues permits
Japan	<ul style="list-style-type: none"> <li>- 2000 The Law Concerning Regulation Relating to Human Cloning Techniques and Other Similar Techniques</li> <li>- No legislation governing the ART industry [check]</li> </ul>	Ministry of Education and Science
China	<ul style="list-style-type: none"> <li>- 2004 Ethical Guidance on Human Embryonic Stem Cell Research</li> <li>- 2003 Guidelines on Human Assisted Reproductive Technologies</li> <li>- 2003 Ethical Principles of Human ARTs</li> <li>- 2000 The Human Reproductive Technology Ordinance (Hong Kong)</li> </ul>	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>PGD<sup>1</sup></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 <sup>2</sup>	Unregulated	Unregulated	Unregulated	Unregulated	Unregulated	Unregulated	Unregulated	Unregulated
Canada	Regulated	Prohibited	Prohibited	Regulated <sup>3</sup>	Regulated <sup>4</sup>	Prohibited	Prohibited	Prohibited	Regulated <sup>5</sup>	Regulated <sup>6</sup>
Australia	Regulated	Prohibited	Prohibited	Regulated <sup>7</sup>	Regulated <sup>8</sup>	Prohibited <sup>9</sup>	Prohibited	Prohibited <sup>10</sup>	Regulated	Regulated <sup>11</sup>
Germany	Prohibited	Prohibited	Prohibited	Regulated <sup>12</sup>	Prohibited	Prohibited	Prohibited	Prohibited	Prohibited	Regulated <sup>13</sup>
UK	Regulated	Prohibited	Regulated	Regulated <sup>14</sup>	Regulated <sup>15</sup>	[check]	Regulated	Prohibited	Regulated <sup>16</sup>	Regulated <sup>17</sup>

<sup>1</sup> Pre-implantation genetic diagnosis.

<sup>2</sup> De facto.

<sup>3</sup> Permitted on donated, supernumerary embryos.

<sup>4</sup> Exclusively for therapeutic applications.

<sup>5</sup> Non-commercial services allowed.

<sup>6</sup> Commercial sale of gametes and embryos prohibited.

<sup>7</sup> Allowed on donated, supernumerary embryos.

<sup>8</sup> Therapeutic applications recommended.

<sup>9</sup> Creation of chimeric animals allowed.

<sup>10</sup> Creation of transgenic animals allowed.

<sup>11</sup> Commercial trade of gametes and embryos prohibited.

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

<sup>13</sup> Oocyte donation prohibited, sperm donation permitted.

<sup>14</sup> Allowed on donated, supernumerary embryos.

<sup>15</sup> Some therapeutic uses permitted.

<sup>16</sup> Commercial offerings prohibited.

<sup>17</sup> 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>PGD<sup>1</sup></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 <sup>18</sup>	Prohibited	Prohibited	Regulated <sup>19</sup>	Regulated <sup>20</sup>	Prohibited	Prohibited	Prohibited	[check]	Regulated <sup>21</sup>
Italy	Prohibited	Prohibited	Prohibited	Prohibited	Prohibited	Prohibited	Prohibited	Prohibited	Prohibited	Prohibited
Spain	Regulated <sup>22</sup>	Prohibited	Regulated <sup>23</sup>	Regulated <sup>24</sup>	Regulated <sup>25</sup>			Prohibited	Prohibited	Regulated <sup>26</sup>
Sweden		Prohibited <sup>27</sup>	Prohibited <sup>28</sup>	Regulated <sup>29</sup>	Regulated <sup>30</sup>			Prohibited		Regulated <sup>31</sup>
Japan		Permitted	Permitted	Unregulated <sup>32</sup>		Regulated <sup>33</sup>	Regulated <sup>34</sup>		Unregulated	

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

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

<sup>20</sup> Allowed only to prevent serious inheritable disease.

<sup>21</sup> Commercial sale of gametes and embryos prohibited.

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

<sup>23</sup> Permitted on surplus embryos that have passed their legal date for implantation.

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

<sup>25</sup> Permitted to diagnose and prevent hereditary diseases

<sup>26</sup> Gamete and embryo donation permitted.

<sup>27</sup> Ban on implantation effectively precludes human cloning for either reproductive or research purposes

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

<sup>29</sup> Non-therapeutic research allowed on embryos of up to fourteen days development.

<sup>30</sup> Allowed for prevention of sex-linked hereditary diseases.

<sup>31</sup> Consent is required of egg and sperm donors

<sup>32</sup> Does not address development of human embryonic stem cells

<sup>33</sup> Embryo creation permitted, but implantation prohibited.

<sup>34</sup> Embryo creation permitted, but implantation prohibited

	<i>Embryo Research</i>	<i>Reproductive Cloning</i>	<i>Research Cloning</i>	<i>Stem Cell Research</i>	<i>PGD<sup>1</sup></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 <sup>35</sup>	Prohibited	Permitted	Regulated <sup>36</sup>	Regulated <sup>37</sup>	Prohibited <sup>38</sup>	Prohibited	Prohibited	Prohibited	Regulated <sup>39</sup>
Singapore	Unregulated	Prohibited	Permitted	Regulated <sup>40</sup>	Unregulated					Unregulated
S. Korea	Regulated	Prohibited	Permitted	Regulated <sup>41</sup>	Regulated <sup>42</sup>	Prohibited	Prohibited	Prohibited		

Table 17: Key statutory provisions.

<sup>35</sup> Research allowed with informed consent

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

<sup>37</sup> Prohibits sex selection without medical indications.

<sup>38</sup> Research on human chimeric embryos prohibited.

<sup>39</sup> Purchase or sale of human gametes, embryos or fetal tissue prohibited.

<sup>40</sup> Creation of embryos for research prohibited.

<sup>41</sup> Creation of embryos for research prohibited. Research on supernumerary embryos permitted.

<sup>42</sup> Restricted to treatment of hereditary diseases.

