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## Appendices

### Appendix 1

Appendix 1 (a). Compliance and provenance determination.		
<b>(1) Embryo provenance determination</b>	<b>Code</b>	<b>Considerations</b>
▪ (a) Independent review and oversight	▪ B	▪ The protocol for obtaining gametes and embryos from living donors should be subject to independent review. Review and approval of the hESC derivation protocol may be required in some jurisdictions, but is not an essential requirement
▪ (b) Voluntary informed consent	▪ B	▪ hESC-specific consent requirements may exist or subsequent users of hESC lines may be required to obtain lines for which comprehensive consent has been obtained. Bank should seek to obtain documentation of consent protocol
▪ (c) Gratuitous donation	▪ B	▪ Banks should receive assurance that donors were not paid for embryos or storage costs
<b>(2) Compliance determination</b>	<b>Code</b>	<b>Considerations</b>
▪ (a1) Embryo was donated in a jurisdiction with no explicit prohibition on hESC derivation	▪ B	▪ Accepting embryos from jurisdictions where hESC research is restricted may incur legal liability
▪ (a2) Derivation protocol confirms to any unique legal requirements in jurisdiction where hESC derived	▪ B	▪ Jurisdiction may have unique requirements in addition to international standards for research ethics (e.g., embryo research oversight or licensing); Consistent with 1a
▪ (b) Any line derived using IVF for research purposes, parthenogenesis or SCNT is identified	▪ B	▪ The use of hESC lines derived from embryos created for research purposes are prohibited by some jurisdictions and funding bodies
▪ (c) Consent requirement for third-party gamete donors	▪ A	▪ Some donated embryos may have been created using gametes from someone other than the embryo donor; Some jurisdictions require consent from third-party donors
▪ (c1) hESC lines derived from embryos intended for reproductive use where a third-party donor(s) was contracted to provide gametes	▪ A	▪ Bank or entity performing hESC derivation should review donor/recipient contract for any conditions that would restrict research use
▪ (c2) hESC lines derived from embryos for which gamete donor(s) participated in egg sharing or exchange programs are identified	▪ A	▪ Policies regarding the use of such embryos or resulting hESC lines are variable. Bank should review egg-sharing contract or exchange policies
▪ (c3) hESC lines derived from embryos created with anonymous gamete donation are identified	▪ A	▪ Certain end-users may not be able to utilize lines derived from embryos for which gamete donors were paid or where egg sharing, exchange or anonymous donation has taken place. Documentation serves to enable end user to perform use eligibility determination
▪ (d) Donor medical history	▪ A/PU	▪ Requirement for medical history may vary depending on relationship between donor and recipient of embryo for IVF. If embryos are created specifically for research, gamete donor medical history should be obtained
Code Key:		
A	Advisable (recommended?): Level of attainment recommended at this time by the International Stem Cell Banking Initiative.	
B	Baseline: Minimum level of attainment generally consistent with the current standard of care for clinical grade stem cell lines.	
NR	Not recommended: This option not recommended at this time. Consideration subject to revision based on new information.	
PU	Potentially utility if available but not required: In certain circumstances supplemental information: medical records, biological specimens (e.g., blood or urine specimens) or quality control assays may be available or have been performed. Banks are encouraged to retain access to supplemental information. Absent evidence of utility – safety or clinical efficacy – the acquisition of supplemental information should not be required for the development of clinical grade stem cell lines.	
hESC: Human embryonic stem cell; SCNT: Somatic cell nuclear transfer.		

**Appendix 1 (b). Informed consent and donor disclosures: compliance determination check list.**

2.1 Did the informed consent process communicate the following elements?	Yes	No	N/A
That the somatic tissue/cells would be used for the purpose of stem cell research, including the derivation of stem cell line(s).			
That genetic tests may be performed, including whole-genome sequencing.			
That research may be conducted on human transplantation.			
That the research is not intended to provide direct benefit to the donor(s) except in the case of autologous donation.			
That the cell lines might be used in research involving genetic manipulation of the cells.			
That the cell lines might be used in research involving the mixing of human and nonhuman cells in animal models.			
That the research entails both foreseeable risks and benefits.			
That any stem cell lines created may be used and stored indefinitely.			
That any stem cell lines created may be used in future unspecified research projects.			
That the decision whether to donate would not affect future medical care.			
That confidentiality will be maintained.			
That the cells would be coded or anonymized (i.e. irreversibly de-linked).			
That donor recontact may be possible (unless anonymized).			
That the donor was informed concerning the disclosure (or not) of general, individuals and/or incidental findings.			
That the donor was informed of the right of withdrawal provided this is not overridden by complete anonymization.			
That the stem cell lines derived will be deposited in a repository for long-term storage and use.			
That once the cells have been used in research, the donor will have no further control over any use of the cells or derived stem cell lines.			
That the cells may be distributed to researchers and institutions within and beyond Canada.			
That the cell lines may be used for commercial purposes but without financial benefit to the donor.			
That the donor was informed of the researchers' actual or potential conflicts of interests.			

## Appendix 2. Material transfer agreements

A material transfer agreement (MTA) is a contract that governs the transfer of tangible research materials between two organizations (the provider, who is the owner/custodian or the authorized licensee of the material and associated data, and the recipient), thereby defining the contractual rights and obligations with respect to the materials and any derivatives.

Important issues to consider when drafting or evaluating an MTA include:

- Ownership of the materials.
- Definition and legal status of original/biological materials, modifications of materials and derivatives, progeny;
- Definition of commercial purposes, non-profit organizations, investigator or researcher
- Intellectual property rights;
- Publication rights;
- Royalty fees
- Confidentiality;
- Scope of use and restrictions (e.g., non-commercial/academic vs. commercial research; ethical limitations on types of research to be conducted (e.g., limitations on research aimed at the generation of gametes);
- Use of materials in sponsored research (e.g., industry vs. industry/academic sponsored research);
- Transferability of cell line, cell products or data derived from cell products (e.g., genetic sequencing data);
- Conflicts with existing agreements;
- Compliance with laws and ethical guidelines;
- Processing, cost-recovery and other fees
- Warranties;
- Liability;
- Indemnification.

### Model material transfer agreements.

UK Stem Cell Bank	Clinical/Commercial use <a href="http://www.ukstemcellbank.org.uk/cell_lines/eutcd_grade_stem_cell_lines/depositing_eutcd_stem_cell.aspx">http://www.ukstemcellbank.org.uk/cell_lines/eutcd_grade_stem_cell_lines/depositing_eutcd_stem_cell.aspx</a> Research Use <a href="http://www.ukstemcellbank.org.uk/legal_agreements.aspx">http://www.ukstemcellbank.org.uk/legal_agreements.aspx</a>
USA National Institutes of Health (NIH), Center for Regenerative Medicine (CRM)	Master Agreement Regarding Use of the Uniform Biological Material Transfer Agreement <a href="http://www.crm.nih.gov/researchTools/uniform_transfer_agreement.asp">http://www.crm.nih.gov/researchTools/uniform_transfer_agreement.asp</a> CRM Induced Pluripotent Stem (iPS) Cell Material Transfer Agreement <a href="http://www.crm.nih.gov/researchTools/material_transfer_agreement.asp">http://www.crm.nih.gov/researchTools/material_transfer_agreement.asp</a> Public Health Service Biological Materials License Agreement <a href="http://www.crm.nih.gov/researchTools/bio_mats_agreement.asp">http://www.crm.nih.gov/researchTools/bio_mats_agreement.asp</a>
International Society for Stem Cell Research (ISSCR)	ISSCR Sample Material Transfer Agreement <a href="http://www.isscr.org/home/publications/guide-clintrans/sample-material-transfer-agreement">http://www.isscr.org/home/publications/guide-clintrans/sample-material-transfer-agreement</a>
ATCC	General MTA <a href="http://www.atcc.org/Documents/Product%20Use%20Policy/Material%20Transfer%20Agreement.aspx">http://www.atcc.org/Documents/Product%20Use%20Policy/Material%20Transfer%20Agreement.aspx</a> Research Use <a href="http://www.atcc.org/en/Documents/Product_Use_Policy/Research_Use.aspx">http://www.atcc.org/en/Documents/Product_Use_Policy/Research_Use.aspx</a> Commercial Use <a href="http://www.atcc.org/en/Documents/Product_Use_Policy/Commercial_Use.aspx">http://www.atcc.org/en/Documents/Product_Use_Policy/Commercial_Use.aspx</a>
California Institute for Regenerative Medicine (CIRM)	<a href="http://www.cirm.ca.gov/our-funding/stem-cell-regulations-governing-cirm-grants">http://www.cirm.ca.gov/our-funding/stem-cell-regulations-governing-cirm-grants</a> BioTimes hESC Lines <a href="http://www.cirm.ca.gov/our-funding/biotime-stem-cell-lines-agreement">http://www.cirm.ca.gov/our-funding/biotime-stem-cell-lines-agreement</a>
WiCell	iPS Wisconsin MTA <a href="http://www.wicell.org/media/WiCellAgreements/WiCell-iPS-MTA.pdf">http://www.wicell.org/media/WiCellAgreements/WiCell-iPS-MTA.pdf</a> UCSF MTA <a href="http://www.wicell.org/media/WiCellAgreements/WiCell-UCSF-Material-Agreement.pdf">http://www.wicell.org/media/WiCellAgreements/WiCell-UCSF-Material-Agreement.pdf</a>
Wisconsin Alumni Research Foundation (WARF)	Agreements <a href="http://www.warf.org/home/for-industry/Agreements/agreements.cmsx">http://www.warf.org/home/for-industry/Agreements/agreements.cmsx</a>

### Appendix 3. Compliance determination: specific issues to consider for hESCs

Prior to initiation of hESC derivation protocol or intent to bank a hESC line, the following compliance issues should be considered (see Appendix 1 to 3).

Appendix 3. Compliance determination: specific issues to consider for hESCs.	
Embryo donation/ hESC derivation	Some jurisdictions explicitly prohibit the derivation of hESC from human embryos. It is not uncommon for individuals residing in prohibitive jurisdictions to inquire about research donation to outside research centers or banks. Embryos originating from prohibitive jurisdiction should not be used for the derivation of hESC lines if an explicit prohibition is/was effective at the time of donation.
IVF for research purposes & parthenogenesis	Some national, sub-national jurisdictions or funding organizations impose limits on hESC line eligibility. For example, certain jurisdictions have adopted explicit policies determining which hESC lines may be used in research, including requiring that such lines only be derived from embryos that were created using <i>in vitro</i> fertilization for reproductive purposes and were no longer needed for this purpose. This reproductive use requirement prevents the use of IVF to develop hESC lines specifically for clinical application or the use of parthenogenetic lines. Consequently, lines derived from oocytes (parthinodes) or embryos created for non-reproductive use should be identified as such.
Special considerations for third-party gametes	<p>Most established hESC lines have been derived from embryos that were created using <i>in vitro</i> fertilization for reproductive purposes and were no longer needed for this purpose. Gametes used in the creation of reproductive embryos frequently come from intimate partners. There are, however, a proportion of embryos created with gametes from third-party donors. The conditions surrounding the procurement of third-party gametes may influence the compliance determination and should be documented to the extent feasible. Potential factors to consider include the following:</p> <ul style="list-style-type: none"> <li>• Paid gamete donation: oocyte and sperm donors are routinely financially compensated. Some policies limit the use of hESC lines derived from embryos for which gamete donors were paid [3]. Banks should be aware of any payment or financial compensation restrictions in their jurisdiction. In addition, it should be noted that certain funding organizations have restrictions on the use of hESC lines derived from embryos where gamete donors were financially compensate beyond the reimbursement of expenses.</li> <li>• Use restrictions: it is also advisable to review the donor contract to support provenance determination and ensure there is no clause in the contract that the resulting embryos be used exclusively by the couple to which they were donated or otherwise restricting research use.</li> <li>• Oocyte sharing/exchange programs: various mechanisms exist for the financing of fertility treatment. One mechanism is 'egg sharing' where fertility treatment costs are reduced for the donor who consents to donating a portion of her oocytes to other women seeking treatment for infertility. Jurisdictional variations exist in the interpretation of this kind of arrangement as a financial incentive, compensation or payment.</li> </ul> <p>It is important to note that the applicability of the above factors relating to third-party gametes will vary by national, local or supra-national jurisdictions. For instance, all embryos created using <i>in vitro</i> fertilization for reproductive purposes and no longer needed for this purpose are potentially eligible in some jurisdictions regardless of third-party donor payment or exchange. However, in other jurisdictions hESC lines derived from embryos for which a gamete donor(s) were paid are not eligible for research or funding. Documentation of the factors above by the banking entity will enable end users to determine if specific lines are eligible for use in their jurisdiction, but such documentation should not be viewed as essential prerequisite for banking.</p>

#### Appendix 4. Donor screening protocols for assisted reproductive treatments

The majority of existing hESC lines have been derived from embryos intended for assisted reproductive treatments (ART). Cells differentiated from hESC lines have been utilized in clinical trials after extensive safety evaluation by national regulatory bodies. These evaluations incorporate the donors' medical history and tests that are required in the context of ART treatments for screening low-risk donors of gametes. Consequently, there is no evidence at this time to support the need for further screening of donors of embryos used to derive clinical grade hESC lines [8].

Screening assays occurring prior to hESC derivation should be documented. It is sufficient to verify testing was performed in accordance with prescribed regulatory requirements. For instance, gamete donation (from non-intimate partners) is generally regulated as a biological product and, therefore, subject to both donor infectious disease testing and sample screening (21 CFR part 1271, subpart C, Directive 2004/23/EC of the European Parliament and of the Council as regards certain technical requirements for the donation, procurement and testing of human tissues and cells). Verifying tests performed (as opposed to obtaining quantitative results) is sufficient. Testing and screening regulations have evolved over time, so the bank should seek to document the specific screening requirements in place at time of gamete donation.

ART embryos created with anonymous gametes donors should be acceptable for clinical use provided that first, the donor contract is sufficient to support provenance determination (see section 1 Governance and Ethics); and second, gametes and/or gamete donor were subject to any required screening and testing for relevant communicable disease agents and diseases (see section 4).

#### Appendix 4. hESC lines: additional donor screening and medical records.

Third-party (allogeneic) donation from ART	In the case of gamete donation for the purpose of embryo creation, medical history requirements may vary depending on the relationship between the donors and the individuals undergoing ART treatment as well as jurisdictional policy. A third-party gamete donor would typically undergo medical screening and a medical history will be obtained. Entities deriving hESC lines have demonstrated the ability to obtain third-party medical history information ( <a href="http://www.cirm.ca.gov/CIRMCellLines">www.cirm.ca.gov/CIRMCellLines</a> ). Researchers deriving new hESC lines should inquire about the availability of medical history information. Due to privacy and contractual considerations it is generally not possible to re-contact third-party donors. Again, it should be noted that donor-screening requirements have evolved over time, so it is critical to document the time when gamete donation occurred.
Self (autologous) donation from ART	Embryos created from the gametes of sexually intimate partners for self-reproductive use are not necessarily subject to the same screening requirements as third-party (allogeneic) donation. Resulting ART embryos are generally regulated in a manner consistent with requirements for autologous human transplantation. In this case, the individual(s) donating the embryo(s) for hESC derivation are the gamete donors. A medical history is generally performed in the context of ART treatment and may be available. A medical screening and history may also be obtained at time of embryo donation with donor consent. There is evidence from hESC derivation protocols that donors may consent to (1) being re-contacted in the future or (2) allow linkage to their medical records [8]. Consequently, entities deriving or banking clinical grade lines should examine the possibility of donor re-contact and record linkage options when possible.
Gamete donation for research purposes	Blastocysts may also be made specifically for research using assisted reproductive technologies. In this case, it is recommended to obtain a medical history at the time of gamete donation to inform risk assessment. When available, banks should associate anonymous medical history with the banked hESC lines. Banks may also seek to determine whether the donor(s) of gametes used to derive the hESC line underwent a previous medical screening or history consistent with requirements for tissue intended for allogeneic human transplantation. The nature and extent of such screening should be documented.

**Appendix 5. Donor selection, eligibility, release criteria and screening procedures: normative and institutional documents**

Appendix 5.	
CANADA	<p>Standard Z.900.1 "Cells, Tissues and Organs for Transplantation: General requirements". Canadian Standards Association. (2nd edition under review)</p> <p>Safety of Human Cells, Tissues and Organs for Transplantation Regulations (SOR/2007–118) (Enabling Statute is the Food and Drug Act)</p> <p><a href="http://www.laws.justice.gc.ca/en/SOR-2007-118/FullText.html">http://www.laws.justice.gc.ca/en/SOR-2007-118/FullText.html</a></p> <p>Guidance Document for Cell, Tissue and Organ Establishments (Safety of Human Cells, Tissues and Organs for Transplantation- April 6th, 2009)</p> <p><a href="http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/brgtherap/cell/cto_gd_ld-eng.pdf">http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/brgtherap/cell/cto_gd_ld-eng.pdf</a></p> <p>Transplantation Registration Application Form</p> <p><a href="http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/compli-conform/frm_0171-eng.pdf">http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/compli-conform/frm_0171-eng.pdf</a></p> <p>Annex E (normative) Exclusionary Criteria for Risk Factors Associated with HIV, HBV, and HCV</p> <p><a href="http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/brgtherap/cto-reg-annexe-eng.pdf">http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/brgtherap/cto-reg-annexe-eng.pdf</a></p> <p>Regulations Amending the Food and Drug Regulations (1024—Clinical Trials)</p> <p>(Division 5: Drugs for Clinical Trials Involving Human Subjects)</p> <p><a href="http://www.hc-sc.gc.ca/dhp-mps/compli-conform/clini-pract-prat/reg/1024-eng.php">http://www.hc-sc.gc.ca/dhp-mps/compli-conform/clini-pract-prat/reg/1024-eng.php</a></p> <p>Canadian Institute for Health Research Updated Guidelines for Human Pluripotent Stem Cell Research 2010.</p>
FRANCE	<p>Bioethics Law (2004)</p> <p>Arrêté du 21 décembre 2005 pris en application des articles R. 1211–14, R. 1211–15, R. 1211–16 et R. 1211–21 du code de la santé publique</p> <p><a href="http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000000456466&amp;dateTexte=">http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000000456466&amp;dateTexte=</a></p> <p>Décret n° 2005–1618 du 21 décembre 2005 relatif aux règles de sécurité sanitaire portant sur le prélèvement et l'utilisation des éléments et produits du corps humain et modifiant le code de la santé publique (partie réglementaire)</p> <p><a href="http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000000636261&amp;dateTexte=">http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000000636261&amp;dateTexte=</a></p> <p>Arrêté du 11 avril 2008 relatif aux règles de bonnes pratiques cliniques et biologiques d'assistance médicale à la procréation</p> <p><a href="http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000018829426&amp;dateTexte=">http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000018829426&amp;dateTexte=</a></p> <p>Décret n° 2008–588 du 19 juin 2008 transposant en matière de don de gamètes et d'assistance médicale à la procréation la directive 2004/23/CE du Parlement européen et du Conseil du 31 mars 2004</p> <p><a href="http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000019060568&amp;dateTexte=">http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000019060568&amp;dateTexte=</a></p>
UNITED STATES	<p>Guidance for Industry. Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)</p> <p><a href="http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Tissue/ucm091345.pdf">http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Tissue/ucm091345.pdf</a></p> <p>International Compilation of Human Research Standards (2012)</p> <p><a href="http://www.hhs.gov/ohrp/international/intlcompilation/intlcompilation.html">http://www.hhs.gov/ohrp/international/intlcompilation/intlcompilation.html</a></p>
SINGAPORE	<p>Guidelines for Healthcare Institutions Providing Tissue Banking: Regulation 4 of the Private Hospitals and Medical Clinics Regulation</p> <p><a href="http://www.moh.gov.sg/mohcorp/uploadedFiles/Publications/Guidelines/institutions_providing_tissue_banking_guidelines.pdf">http://www.moh.gov.sg/mohcorp/uploadedFiles/Publications/Guidelines/institutions_providing_tissue_banking_guidelines.pdf</a></p> <p>Medicines Act (Chapter 176, ss. 18 and 74) Medicines (Clinical Trials) Regulations</p> <p><a href="http://www.hsa.gov.sg/publish/etc/medialib/hsa_library/health_products_regulation/legislation/medicines_act.Par.41439.File.dat/MEDICINES%20(CLINICAL%20TRIALS)%20REGULATIONS.pdf">http://www.hsa.gov.sg/publish/etc/medialib/hsa_library/health_products_regulation/legislation/medicines_act.Par.41439.File.dat/MEDICINES%20(CLINICAL%20TRIALS)%20REGULATIONS.pdf</a></p> <p>Medical (Therapy, Education and Research) Act</p> <p><a href="http://statutes.agc.gov.sg/non_version/cgi-bin/cgi_retrieve.pl?actno=REVED-175&amp;doctitle=MEDICAL%20%28THERAPY%2c%20EDUCATION%20AND%20RESEARCH%29%20ACT%0a&amp;date=latest&amp;method=part">http://statutes.agc.gov.sg/non_version/cgi-bin/cgi_retrieve.pl?actno=REVED-175&amp;doctitle=MEDICAL%20%28THERAPY%2c%20EDUCATION%20AND%20RESEARCH%29%20ACT%0a&amp;date=latest&amp;method=part</a></p> <p>Human Organ Transplant Act</p> <p><a href="http://statutes.agc.gov.sg/non_version/cgi-bin/cgi_retrieve.pl?actno=REVED-131A&amp;doctitle=HUMAN%20ORGAN%20TRANSPLANT%20ACT%0a&amp;date=latest&amp;method=part&amp;sl=1">http://statutes.agc.gov.sg/non_version/cgi-bin/cgi_retrieve.pl?actno=REVED-131A&amp;doctitle=HUMAN%20ORGAN%20TRANSPLANT%20ACT%0a&amp;date=latest&amp;method=part&amp;sl=1</a></p>

Appendix 5.	
SPAIN	<p>Real Decreto 1301/2006 (10 Noviembre, 2006) por el que se establecen las normas de calidad y seguridad para la donación, la obtención, la evaluación, el procesamiento, la preservación, el almacenamiento y la distribución de células y tejidos humanos y se aprueban las normas de coordinación y funcionamiento para su uso en humanos.</p> <p>Ley 14/2006 (26 Mayo, 2006) sobre técnicas de reproducción humana asistida.</p> <p>Real Decreto 65/2006 (30 Mayo, 2006) por el que se establecen requisitos para la importación y exportación de muestras biológicas.</p> <p>Plan Nacional de Sangre de Cordón Umbilical.</p> <p><a href="http://www.ont.es/infesp/DocumentosDeConsenso/plannscu.pdf">http://www.ont.es/infesp/DocumentosDeConsenso/plannscu.pdf</a></p> <p>Programa de Garantía de Calidad en el proceso de donación. Organización Nacional de Transplantes.</p> <p><a href="http://www.ont.es/infesp/Paginas/ProgramadeGarantiadeCalidad.aspx">http://www.ont.es/infesp/Paginas/ProgramadeGarantiadeCalidad.aspx</a></p> <p>Real Decreto 2132/2004 begin_of_the_skype_highlightingend_of_the_skype_highlighting, de 29 de octubre, por el que se establecen los requisitos y procedimientos para solicitar el desarrollo de proyectos de investigación con células troncales obtenidas de preembriones sobrantes (BOE 30 octubre).</p> <p>Ley 14/2007, de 3 de julio, de Investigación biomédica.</p> <p>ORDEN SCO/393/2006, de 8 de febrero, por la que se establece la organización y funcionamiento del Banco Nacional de Líneas Celulares.</p> <p>Banco Nacional de Líneas Celulares requisitos para depósito y acceso</p> <p><a href="http://www.isciii.es/htdocs/terapia/terapia_bancoelular.jsp">http://www.isciii.es/htdocs/terapia/terapia_bancoelular.jsp</a></p> <p>Requisitos que debe cumplir la Hoja de Información a los Participantes y el Consentimiento Informado para investigaciones que impliquen la generación de células pluripotentes inducidas (iPS)</p> <p><a href="http://www.isciii.es/htdocs/terapia/terapia_comiteetica.jsp">http://www.isciii.es/htdocs/terapia/terapia_comiteetica.jsp</a></p> <p>Real Decreto 1527/2010 (noviembre, 2010) por el que se regulan la Comisión de Garantías para la Donación y Utilización de Células y Tejidos Humanos y el Registro de Proyectos de Investigación</p> <p><a href="http://www.boe.es/boe/dias/2010/12/04/pdfs/BOE-A-2010-18654.pdf">http://www.boe.es/boe/dias/2010/12/04/pdfs/BOE-A-2010-18654.pdf</a></p>
INDIA	<p>Guidelines for Stem Cell Research and Therapy. Department of Biotechnology and Indian Council for Medical Research (2013)</p> <p>The Assisted Reproductive Technologies (Draft Regulation), Rules – 2010. Ministry of Health and Family Welfare, Government of India.</p> <p>The Assisted Reproductive Technologies (Draft) Bill. Ministry of Health and Family Welfare, Government of India</p>
AUSTRALIA	<p>Therapeutic Goods (Charges) Amendment Act 2010 (No. 53, 2010). An Act to amend the Therapeutic Goods (Charges) Act 1989, and for related purposes.</p> <p>Australian code of good manufacturing practice for human blood and blood components, human tissues and human cellular therapy products (2013)</p> <p>National Statement on Ethical Conduct in Human Research (2007), developed jointly by National Health and Medical Research Council, Australian Research Council and Australia Vice-Chancellors' Committee</p> <p>Ethical Guidelines on the use of assisted reproductive technology in clinical practice and research (June, 2007), National Health and Medical Research Council.</p> <p>NHMRC Embryo Research Licensing Committee, Information Kit, National Health and Medical Research Council (2008).</p>
UNITED KINGDOM	<p>UKSC Bank, MRC, Code of Practice for the use of Human Stem Cell Lines (April, 2010)</p> <p>HFEA Code of Practice (8th edition), HFEA (2009)</p> <p>The Human Fertilisation and Embryology Act (2008)</p> <p>UK Stem Cell Tool Kit <a href="http://www.sc-toolkit.ac.uk/home.cfm">http://www.sc-toolkit.ac.uk/home.cfm</a></p> <p>Data and Tissues Tool Kit <a href="http://www.dt-toolkit.ac.uk/home.cfm">http://www.dt-toolkit.ac.uk/home.cfm</a></p> <p>HTA Code of Practice on Research (2009)</p> <p>Human Tissue Act (2004)</p> <p>Human Tissue (Quality and Safety for Human Application) Regulations 2007</p> <p>British Standards Institute (BSI) Publicly Available Specification PAS 83:2012 Developing human cells for clinical applications in the European Union and the United States of America. Guide</p> <p>BSI Publicly Available Specification PAS 84:2012 Cell therapy and regenerative medicine. Glossary</p> <p>BSI Publicly Available Specification PAS 93:2011. Characterization of human cells for clinical applications. Guide</p>