

International Stem Cell Banking Initiative

Stem Cell Bank Questionnaire, November 2007

Name of correspondent submitting questionnaire : Shiaw-Min Hwang.

Contact details : Shiaw-Min Hwang

Director , Taiwan Stem Cell Bank

Senior Scientist, Bioresource Collection and Research Center

331 Shih-pin road

Hsinchu 30062

Taiwan

Tel: +886-3-5223191

Fax: +886-3-5224171

Email: hsm@firdi.org.tw

Name of Bank: Taiwan Stem Cell Bank

Bank Director/Head: Shiaw-Min Hwang

Director/Head Contacts: Dr. Shiaw-Min Hwang

Email: hsm@firdi.org.tw Tel: +886-3-5223191#576, Fax: +886-3-5224171

Address of Bank: 331 Shih-pin Road, Hsinchu 30062, Taiwan

Web site: <http://www.tscb.bcrc.firdi.org.tw> Tel/fax: + 886-3-5223191/Fax: +886-3-5224171

Source of funding: National Science Council (NSC), and Ministry of Economic Affairs (MOEA), Taiwan

National regulatory bodies dealing with:

1) Stem cell ethics (include website or other address)

Department of Health, Executive Yuan, Taiwan

(Bureau of Medical Affairs)

Address: No.100, Aiguo E. Rd., Jhongjheng District, Taipei City 10092, Taiwan (R.O.C.) Tel: +886-2-2321-0151

<http://www.doh.gov.tw>

http://www.doh.gov.tw/EN2006/index_EN.aspx (English version)

Policy Instructions on the Ethics of Human Embryo and Embryonic Stem Cell Research (updated at Aug 9,2007)

website:

http://www.doh.gov.tw/EN2006/DM/DM1_p01.aspx?class_no=246&now_fod_list_no=246&level_no=1&doc_no=51090

Content:

Policy Instructions on the Ethics of Human Embryo and Embryonic Stem Cell Research

1.Research on human embryos and embryonic stem cells (hereafter referred to as embryo and their stem cell research) shall be conducted under the principles of respecting and protecting human dignity and rights of life, and to maintain public order and virtuous customs.

2.Research on embryos and their stem cells shall comply with relevant laws and regulations promulgated by the government.

3.Embryo and their stem cell research shall not be conducted in the following ways:

(1) The use of somatic cell nuclear transfer techniques to produce an embryo and implant that embryo into a uterus;

- (2) The use of in vitro fertilization to produce embryos for research purposes;
- (3) The production of hybrids;
- (4) The in vitro culture of embryos with primitive streaks;
- (5) The reproduction of embryos for research purposes or implantation of embryos for research use into the uterus of humans or other species;
- (6) Reproduction of chimeras containing human germ cells; and
- (7) Injection of nuclei from other species into nucleus-free human eggs.

4. Embryos and their stem cells shall be obtained in a non-remunerative way from embryos from spontaneous abortions, embryos from induced abortions in compliance with regulations of the Genetic Health Act, embryos remaining from in vitro fertilization procedures, or embryos or embryonic tissues produced by somatic cell nuclear transfer without the presence of primitive streaks.

5. Embryos and their stem cells can only be obtained after donors are clearly informed in advance of the matters to be agreed upon, and consent in writing is signed with the full understanding of the donors and with their free will.

6. Human eggs for research on somatic cell nuclear transfer shall be eggs remaining after in vitro fertilization has been performed in accordance with the relevant laws and regulations and with the consent in writing of the couples or donors who have undertaken this procedure; or, cells can be obtained from informed adult females whose consent in writing is obtained.

Donors of the eggs mentioned in the preceding Paragraph shall possess the capacity of disposition and shall not be related in any way with the research project directors.

7. Research projects on embryos and their stem cells shall be reviewed and approved by the ethics committee of the responsible research institute or the ethics committee of other authorized institutions.

For the review mentioned in the preceding Paragraph, the following matters shall be considered:

- (1) The research project shall meet the objectives of promoting medical care and scientific development, improving human health and welfare, and treating diseases.
- (2) It would be difficult to achieve the objectives of the research projects by other research methods.
- (3) The project contents shall be scientifically qualified and meet ethical requirements.

2) Clinical application of stem cells (include website or other address)

Department of Health, Executive Yuan, Taiwan

(Bureau of Medical Affairs)

Address: No.100, Aiguo E. Rd., Jhongjheng District, Taipei City 10092, Taiwan (R.O.C.) Tel: +886-2-2321-0151

<http://www.doh.gov.tw>

http://www.doh.gov.tw/EN2006/index_EN.aspx (English version)

Following regulations are related to clinical application of stem cells in Taiwan.

(1) 人體細胞組織優良操作規範 (Regulations of human cellular and tissue-based products)

http://www.doh.gov.tw/newverprog/proclaim/content.asp?class_no=0&now_fod_list_no=&array_fod_list_no=&level_no=1&doc_no=19364.....

(2) 體細胞治療人體試驗申請與操作規範 (Regulation of somatic cell therapy in clinical trials)

<http://www.doh.gov.tw/ufile/doc/%C5%E9%B2%D3%ADM%B3W%BDD-921104%A4%BD%A7i%AA%A9.doc>

<http://dohlaw.doh.gov.tw/Chi/FLAW/FLAWDAT0202.asp>

(3) 器官保存庫管理辦法 (Regulations of organ bank)

<http://dohlaw.doh.gov.tw/Chi/FLAW/FLAWDAT0202.asp>

Types of cells distributed : human embryonic stem cells and other adult stem cells

Are cells provided for clinical treatment : No. The cells are provided for research use only now.

Is the bank accredited for supply of cells for therapy : NO.

Brief description of current work of the bank for inclusion on the International Stem Cell Forum (attach additional information if appropriate)

1. Quality control

2. Cell Characterizations
3. Storage and shipment of cells

Plans for future work

Taiwan Stem Cell Bank (TSCB) initiative (2009-2010): The aims are 1) to set up the ISCI I protocols for the qualification of collected stem cells, 2) to follow ISCBI I protocols for collecting, maintaining and quality controlling stem cells, 3) to distribute the high quality of stem cells, and 4) to provide stem cell-related training courses. We expect to finish the construction of one general laboratory and 3 good laboratory practice (GLP)-compliant stem cell operation rooms by the end of 2009. We will host 13 domestic hESC lines to TSCB. After full characterization and stringent quality control, these hESC lines will be accessed to researchers under steering committee's oversight. Besides human embryonic stem cells, TSCB is planning to extend its collection and services to cord blood and other adult stem cells.

Taiwan Stem Cell Bank is part of Bioresource Collection and Research Center (BCRC, <http://www.bcrc.firdi.org.tw>) right now.

Please highlight any information

you do NOT wish to be entered on the ISCF website.