SIXTH FRAMEWORK
PROGRAMME

BIONET
Ethical Governance of Biological and Biomedical Research: Chinese European Co-operation

WORKSHOP TWO

PROGRAMME
Draft

Ethical governance of reproductive and stem cell research and stem cell banks

CAS-MPG Partner Institute for Computational Biology

Shanghai

9 – 11 October 2007

Background

In the last decade, stem cell research has become emblematic of both the hopes and fears that are associated with advanced bioscience. On the one hand, it is hoped that some of the most debilitating diseases and disorders – e.g. neurodegenerative disorders, spinal cord damage, diabetes, eye diseases, multiple sclerosis, immune disorders and blood diseases – can finally be treated if not cured. These are diseases where suffering can be long and drawn out. On the other hand, the development of effective regenerative treatment relies on stem cell research which requires the ethically controversial sourcing and manipulation of human cells to generate stem cell lines which can then be transplanted into sufferers of degenerative diseases. Such self-renewing stem cell lines can be sourced from six-day old *in vitro* fertilised human blastocysts, aborted human foetal tissues, umbilical cord blood, bone marrow, brain and other somatic sources as well. The challenge for stem cell researchers is how to generate and perpetuate these stem cell lines into the large stem cell populations that are necessary for regenerative therapy in an ethically acceptable and accountable way.

Stem cells, then, are sourced from embryos, foetuses or adults; are manipulated and cultivated in laboratories; with the hope that they can then be transplanted back into human patients in the treatment of degenerative diseases. Each of these stages of research and treatment (sourcing, manipulation and transplantation) embodies ethical challenges, and it is the goal of this second BIONET workshop on stem cell research to address these challenges in a Chinese and European context.

In Europe, there have been a diverse set of responses to the ethical challenges raised by stem cell research in different countries. The procurement of human embryonic stem (hES) cells, somatic cell nuclear transfer (popularly know as 'therapeutic cloning'), creating hybrid human-animal embryos for research purposes and distinctions between 'research grade' and 'clinical grade' stem cell lines in human treatment have been the subjects of some of the key ethical debates. Some countries allow for the *in vitro* creation of human embryos for the purpose of procuring hES cell lines, others allow for the procurement of hES cells only from so-called 'surplus embryos' (unused by a couple following infertility treatment) while still other countries prohibit procurement from human embryos. In July 2007, a Joint committee on the Human Tissue and Embryos (Draft) Bill in the United Kingdom explicitly proposed that "an inter-species embryo may only be created, kept and used under licence, subject to the 14-day rule and may not be placed either in a woman or in an animal". In most other European countries, the creation of hybrid embryos for research or other purposes is prohibited. On the therapeutic side, few (if any) clinical trials have to date been officially approved for stem cell therapies. Some clinics, for example in the Netherlands, have offered patients 'experimental' therapies for multiple sclerosis but this remains controversial in many European countries for two reasons. Firstly, there are concerns that the procedures have not been tested rigorously through clinical trials and secondly, there are safety, quality and ethical concerns as regards where and how stem cell lines used in the treatments have been procured and manipulated. Moreover, there have also been concerns that European citizens are travelling within Europe or to Asia in order to undergo often costly though 'unproven' regenerative medicine treatment.

In recent years, China has been highlighted by many scientific observers as an emerging hub for stem cell research (together with South Korea and Singapore). Research centres in Beijing, Shanghai, Changsha, Tianjin and Guangzhou have carried out stem cell research for many years in the fields of neural stem cells, cord blood stem cells as well as hES cells. The Chinese government has identified stem cell research as a key strategic field, and provides direct funding through the Ministry of Science and Technology as well as the Chinese Academy of Sciences. In China, there is both focus on laboratory research aiming to improve procedures for deriving and cultivating stem cell lines and also clinical research into potential stem cell applications in neurodegenerative diseases, muscular dystrophy as well as other diseases. In tandem with these developments, a number of guidelines and regulations have also been passed in China to address some of the many ethical challenges surrounding this research. These have included "Ethical Principles and Governance of Human Embryonic Stem Cell Research and Application" which was recommended by Centre for Applied Ethics of Chinese Academy of Social Sciences, Cnetre for Bioethics of Chinese Academy of Medical Sciences/Peking Union Medical College, Chinese Society for Philosophy of Science and ELSI Committee of Human Genome Project China and submitted to Ethics Committee of the Ministry of Health (ECMOH) on 15 September 2001, and ECMOH revised it and changed the title to "Ethical Principles and Governance of Human Embryonic Stem Cell Research", and submitted to the Ministry of Health, "Ethical Guidelines for Human Embryonic Stem Cell Research" from the Ethics Committee of the Chinese National Human Genome Center at Shanghai which were adopted on 16 October 2001 and revised on 20 August 2002, "Ethical Guiding Principles for Research on Human Embryonic Stem Cells (2003-460)" passed on 24 December 2003 by the Ministry of Science and Technology and the Ministry of Health and finally new regulations from the Ministry of Science and Technology on scientific misconduct (2006) as well as from the Ministry of Health on the ethical review of biomedical research involving human subjects (2007).

Notwithstanding this increasing regulatory focus on stem cell research, just as has been the case in Europe, a number of concerns have been raised in China about the enforcement of regulations, especially regarding the provision of 'unproven' stem cell treatments. Also, some Chinese commentators have suggested that the regulations on scientific misconduct from 2006 were much needed, as they raised questions about whether the current system of scientific peer review was sufficient to ensure good quality results and to deter misconduct.

It is with these many ethical challenges surrounding stem cell research in mind, that 50 Chinese and European experts will meet in Shanghai on 9-11 October to discuss and exchange views on issues of ethical oversight and governance in stem cell research.

Objectives
BIONET workshops have a number of objectives:

- To provide a platform for scholars with different cultural and academic backgrounds to improve understanding

- To provide capacity building for a range of professionals across China who are involved in research, research ethics and decision making in these areas, including members of ethics review boards
- To explore differences in approaches, and current themes around, ethical review and regulation, particularly around informed consent
- To enhance understanding of the strengths and weaknesses of different approaches to the regulation of biomedical research and practice
- To gather evidence of problems, cases and practices in the ethical governance of research in this area, as they are experienced on the ground by different professional groups in different regions in relation to different issues.
- To define lines of future studies in the clinics of doctor/patient relationships, and on other issues which may arise
- To facilitate the development of evidence based social scientific research on ethics, and awareness of the need to research the experience and views of patients and research subjects.
- To learn from each other about the ethical governance of stem cell research.

Participants
About 50 participants from China and Europe will take part in the BIONET workshop on stem cell research. These include stem cell researchers, bioethicists, lawyers, social scientists as well as government representatives.

Organisation of the workshop

The workshop will last 3 days. Participants will discuss particular concerns of different groups: patients and research subjects, biomedical research institutions (hospitals and research units), policy-makers, law enforcement officials, educators, and Chinese experts in ethics and culture. While it will be important for participants to be made aware of the formal legal and regulatory structure, and their normative basis, the focus of the workshop will be on enabling participants to relate these frameworks to practical problems and cases in clinical and research settings, rather than teaching a single normative position. The workshop will consist of presentations, group discussions, case discussions, site visits, and will cover different cultural contexts.

VENUE & Hotel

[To be confirmed]

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PROGRAMME

Monday, October 8

Arrivals and registrations

10.00 - 12.00	Meeting of BIONET Core Management Group
14.00 - 16.00	First meeting of BIONET Steering Committee
16.00-18.00	*Expert Group*
18.30	Informal dinner and *Steering Committee working dinner*

Tuesday, October 9

Morning Sessions 8.30 – 12.00

CHAIRS

8.30 – 9.00 Opening and Introductions of the programme

Lu, Rose

Session 1 Stem Cell Research: State of the Art

9.00 - 9.20	PEI Duanqing (Guangzhou)
9.20 - 9.40	Martin JOHNSON (Cambridge)
10.00-10.20	JIN Ying (Shanghai)
10.20-10.40	Jack PRICE (Institute of Psychiatry, London)
10.40 – 11.10	Coffee / tea break

Session 2 Stem Cell Research and Regenerative Medicine – key regulatory and ethical issues

11.10 – 11.30	LU Guangxiu (Changsha):
11.30 – 11.50	Christiane WOOPEN
11.50 – 12.10	LIU Bin (Beijing)
12.10 – 12.30	Erica Haimes (Newcastle)
11.40 – 12.10	Discussion (Guiding questions to be formulated!)
12.10-14.00	Lunch break

Afternoon Sessions 14.00- 17.15

Session 3 Stem Cell Research: Governance and Regulations Cong, Doering

14.00 – 14.20	PEI Xuetao (Beijing)
14.20 – 14.40	Herbert GOTTWEIS (Vienna)
14.40 – 15.00	LIU Yinliang (Beijing)
15.00 – 15.30	Discussion (Guiding questions to be formulated!)

15.30 – 16.00	Coffee / tea break
16.00 – 16.30	Case discussions in 2 working groups
16.30 – 17.00	Report from groups and discussion
17.00 – 17.15	Summary and conclusion of the day
18.00-19.30	Welcome Dinner

Wednesday, October 10

Morning Sessions 8.30 – 12.00

Session 4 Stem Cell Research: Projects and Applications Sleeboom-F, Zhai

8.30 – 8.50	ZHU Jianhong (Shanghai)
8.50 – 9.10	Nick Bunnin (Oxford)
9.10 – 9.30	XU Rongxiang (Beijing)
9.30 – 10.00	Discussion
10.00 – 10.30	Coffee / tea break
10.30 – 11.30	Case discussions in 2 working groups
11.30 – 12.00	Reports from groups and discussion

Lunch break 12.00 – 14.00

Afternoon Sessions 14.00- 17.15

Session 5 Stem Cell Research: Ethical Issues Qiu, Wahlberg

14.00 – 14.20	FAN Minsheng (Shanghai)
14.20 – 14.40	TBA (EU)
14.40 – 15.00	ZHAO Chunhua (Beijing)
15.00 – 15.20	Christoph REHMANN-SUTTER (Basel)
15.20 – 15.50	Discussion (Guiding questions to be formulated!)
15.50 – 16.20	Coffee / tea break
16.20 – 16.50	Case discussions in 2 working groups
16.50 – 17.20	Report from groups and discussion
17.20 – 17.30	Summary and conclusion of the day
18.00 – 19.00	Dinner
(19.30 – 20.30	Evening presentation: QIU Renzong (Beijing): “The historical, social and philosophical background of Chinese policies regarding human embryonic stem cell research”)

Europe (NN)

Thursday, October 11

Morning Sessions 8.30 – 12.00

Session 6 Issues in International Research Collaboration
Moderators Hennig, Yang

8.30 – 8.50	Introducing the Issues ZHAI Xiaomei: "Challenges that require governance and regulatory responses – China"
8.50 – 9.10	Paul UNSCHULD (Berlin) "Translating Ethical Key Texts"
9.10 – 9.30	ZHUO Xiaoqin (Beijing) "An International Research Cooperation Case"
9.30 – 9.40	Commentary (perspective of *science*) NN
9.40 – 9.50	Commentary (perspective of *ethics*) NN
9.50 – 10.00	Commentary (perspective of *governance and regulation*) NN
10.00 – 10.45	Discussion (Guiding questions to be formulated!)
10.45 – 11.15	Coffee / tea break
11.15 – 12.00	Reporting research findings (BIONET researchers)
11.15 – 11.35	Joy Zhang (London) "Societal and Cultural Factors in Stem Cell Research: China"
11.35 – 11.55	Thomas STREITFELLNER (Vienna) "Societal and Cultural Factors in Stem Cell Research: Europe"
12.00 – 14.00	Lunch break

Afternoon Sessions 14.00- 17.30

Session 7 Taking forward the BIONET Agenda:
Liu Bin, Rose

14.00 – 14.20	"A Chinese View on Expectations Towards Governance of Research Collaborations with Europe" NN
14.20 – 14.40	"A European View on Expectations Towards Governance of Research Collaborations with China" NN
14.40 – 15.30	Working session: Suggestions for amendments (all participants) "Which topics, issues, perspectives should be added?"
15.30 – 16.00	Coffee / tea break

16.00 – 17.00	Structured discussion (With guiding questions set towards the BIONET agenda) Recommendations in preparation of the Changsha conference Recommendations for the Expert Group
17.00 – 17.30	Summary and conclusion of the workshop

Dinner and Farewell activity

(Steering Committee 20.00 – 21.30)

Friday, October 12

Schedule to be further elaborated in cooperation with local co-organiser
Site visits 9.00 – 12.00
Shanghai tour (all afternoon), with dinner

Expert Group 19.00 – 21.00

Steering Committee Meetings
Oct. 8, 14.00 – 16.00
Oct. 8, working dinner (6.30 pm – 9.00 pm)
Oct. 11, formal discussions and decisions (20.00 – 21.30)

Expert Group Meetings
Oct. 8, 16.00 – 18.00
Oct. 12, 19.00 – 21.00