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SIXTH FRAMEWORK PROGRAMME

BIONET launches in China

Following the kick-off of the BIONET project in London last November, the first BIONET workshop on assisted reproductive technologies and informed consent was held at the Peking University Health Science Centre, 1-5 April 2007. Over 50 clinicians, scientists, policy officials, bioethicists, lawyers and patient representatives from China and Europe gathered to begin the work of 'mapping' the normative frameworks and practices concerning informed consent, good governance and best practice in research and clinical contexts.

Discussions focused on the practicalities of informed consent, commercialisation of ART, the role of ethics committees and review boards as well as on regulation. A list of key findings can be found in the workshop report available on the BIONET website: **www.bionet-china.org**


BIONET workshop

Summary of proposals from participants at first BIONET workshop

• **Standardized informed consent protocols** should be developed, that would be generally valid and adaptable according to specific requirements in given situations, combining universal ethical convictions and room for diversity of strategies to contextualise them properly. Such protocols should detail the steps of the full process, going beyond the conveying of information and communication and establishing a model of participation. They should cover not just ART treatment but also ART-related research as well as donation information and processes.

• Special **certified training programmes** should be developed and offered to practitioners, such as physicians and nurses in order to qualify them to counsel patients in informed consent. In clinical practice, sufficient time and standardised informed consent procedures should be introduced into daily hospital routines – **informed consent procedures should be institutionalised** while also allowing for individual particularities and care. In European-Chinese research collaborations, these same considerations about **informed consent should be carefully protocolled into research designs** as well as into agreements between partners so that adequate time and resources for good quality informed consent procedures could be guaranteed.

• **A separation of institutional ethics review boards from Research Ethics Committees** was necessary and these should be independent of each other. The **training of ethics committee members** was highlighted as crucial to ensure that ethics was not seen as an add-on. **Clinical eithics committees should be strengthened** and resourced to help practitioners tackle individual ethical cases as they arise.

• From the European point of view, when it came to research collaborations what was at stake was making sure that **European researchers and European funds were accountable to European standards while also adhering to national requirements** no matter where the research activities take place.

• Globalised trends toward open and hidden forms of commercialization and a general tendency to **accept economic/market capitalist rationales in medicine pose serious ethical problems and challenges** to the character of medicine that Chinese and European participants were jointly concerned about.

Professor Tu Ling


Professor Dominique Memmi

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Ethics of Chinese-European biomedical research collaborations

With growing global interest in genetic and stem cell research (both laboratory-based and clinical), cross-national research collaborations have become increasingly common. In such collaborations, European companies and/or academic institutions partner with Chinese counterparts to gain access to biological samples from China, to carry out clinical trials or to benefit from growing investment and focus on biomedical research in China. Costs can be a consideration in the establishment of such collaborations (notably lower human resource costs) though some suggest that what is viewed as more 'lax' regulation of such research may also be 'attracting' some European collaborators to China.

With a remit to address some of the ethical challenges that arise from such collaborations – including issues of informed consent, benefit sharing and ethical review – a Chinese-European Expert Group was officially constituted in Beijing on the 6th of April 2007. The BIONET Expert Group is chaired by Professor Christoph Rehmann-Sutter of the University of Basel in Switzerland and co-chaired by Professor Qiu Renzong of the Chinese Academy of Social Sciences in Beijing.

'Communication, based on listening to the concerns of others in different cultural contexts, is a root from which ethics can grow. It is itself an ethical act,' said Professor Rehmann-Sutter at the launch.

Leading stem cell scientist and member of the Expert Group, Professor Lu Guangxiu of the Hunan Institute of Human Reproduction and Stem Cell Engineering said: 'Though bioethics emerged a little late in China, in recent years our government has made great efforts to develop bioethics working with scholars in related fields. Now with the support of the government and efforts of scholars, we have seen how bioethics has really provided guidance in biomedical research and practice. I believe BIONET will improve mutual communication and help to standardise practice so that we can protect the interests of common people.'

Consisting of 10 members from the fields of medicine, ethics, law, political science and social science, the group will work towards guidelines for best practice in ethical governance of collaborative research between China and Europe, foster mutual understanding and provide opportunities to learn from each other. Results are expected within less than 3 years.

Members of the Expert Group

- **Professor Lu Guangxiu**, Institute of Human Reproduction and Stem Cell Engineering, Changsha
- **Professor Qiu Renzong**, Chinese Academy of Social Sciences (co-Chair)
- **Professor Cong Yali**, Peking University Health Science Centre
- **Professor Zhai Xiaomei**, Peking Union Medical College, Research Centre for Bioethics, Beijing
- **Dr Ole Döring**, Institute of Asian Affairs, Hamburg, Germany
- **Professor Herbert Gottweis**, Department of Political Science, University of Vienna, Austria
- **Professor Wolfgang Hennig**, Institute of Genetics, University of Mainz, Germany & CAS-MPG Partner Institute for Computational Biology, Shanghai, China
- **Professor Genevra Richardson**, School of Law, King's College, United Kingdom
- **Dr Margaret Sleeboom-Faulkner**, University of Sussex, United Kingdom
- Chairman: **Professor Christoph Rehmann-Sutter**, Unit for Ethics in the Biosciences, University of Basel, Switzerland

BIONET junior researchers network

One of the specific objectives of BIONET is to encourage and assist junior researchers from China and Europe who are working in the field of ethics in biomedical research. An informal junior researchers network has been established and the BIONET project will provide a total of 9 research stipends (each worth €2,500) to facilitate research student exchanges during the course of the three year project. The first three research students to have been awarded BIONET research stipends Li Rong of the Peking University Third Hospital, Joy Zhang of the LSE's BIOS Centre and Thomas Streitfellner of the Life Science Governance Research Platform at the University of Vienna in Austria, each made presentations at the first BIONET conference in Beijing. Moreover, in May-June 2007, Li Rong visited Germany and the United Kingdom on a study tour to learn more about informed consent at the interface of stem cell research and IVF.

Other junior researchers affiliated with BIONET include Su Yeyang of the Beijing Institute of Genomics (working on ethical issues around genetic research into disease), Sui Suli of the International Institute for Asian Studies, Leiden, The Netherlands (working on the marketing and use of genetic testing in China) and Kerstin Klein of the BIOS Centre, London School of Economics (working on regulatory frameworks for stem cell research in China and Europe).

The group met in London on 19 June 2007 to discuss and exchange ideas about the ethical governance of stem cell research in an international and cross-cultural context.

Expert Group L-R: Qiu Renzong, Christoph Rehmann-Sutter and Herbert Gottweis

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BIONET junior researchers: Summary of research topics

"Informed Consent in Artificial Reproduction and Embryo Stem Cell Research in a European context"

Li Rong
PhD student, Reproductive Medical Centre, Peking University Third Hospital

All informed consents must be in writing and signed by patients who receive ART treatment. It is necessary that couples be provided with full information concerning chance of success, financial obligations and other issues. If the couples have infertility problems, we will find the main problem or problems and thereby better treatment. The doctors give the couples all information for them to be able to consents including descriptions of the treating procedure – ovulation induction agents, ultrasound monitoring, collection of sperm, oocyte retrieval, luteal support and monitoring of early pregnancy. There are some problems that maybe arise during this cycle such as poor response to ovulation induction agents, unsuccessful oocyte retrieval, abnormal oocytes, fertilizing failure, failure of implantation or loss/damage to oocytes or embryos. The success rates of the clinical centre and possible complications during pregnancy should also be communicated. At the same time, research on embryonic stem (ES) cells should be actively pursued, since their potential value for clinical treatment is very great. Human ES cells have been induced to differentiate in vitro into a variety of different cell types. The derivation of embryonic stem cells involves the destruction of a blastocyst-stage embryo. Embryos that are produced by IVF for an infertile couple but are no longer required for their own or any other couple's reproductive purposes may be donated by them for research. Without transferring to a uterus, the embryos would die within a few days. The aim of my student exchange is to see how informed consent is regulated and practiced in European countries at the IVF-stem cell interface.

"China Stem Cell Research Policy and Related Ethical Issues"

Joy Zhang
PhD student, BIOS Centre, London School of Economics and Political Science

My research will be conducted with the social background that China is now a rising power in the bio-science field yet current regulation on stem cell research is still at its initial stage. At the same time, however, China has realized the importance of an efficient regulation system to balance scientific and social benefits and to resolve conflicts. By visiting stem cell laboratories, stem cell banks, hospitals and interviewing medical researchers and patients, this research will define the core moral and ethical issues at stake in the Chinese context, and give suggestions for ethical protocols to govern the future regulation of its own stem cell research community.

"Hybrid Hierarchies: Governing Regenerative Medicine as Practice in Europe and Asia"

Thomas Streitfellner
PhD Student, Life Science Governance Research Platform, University of Vienna, Austria

This work analyses a contemporary project of biomedical governance through field research on two regenerative medicine research centres. Regenerative medicine is conceptualised as a transnational project with "translational stem cell research" as its platform, which aims at moving science from research to health, from basic research start-ups to the applied level of healthcare economy. In analysing this as performance, the dissertation looks at two project sites: a reproductive stem cell engineering centre in a southern Chinese province and a centre for age related diseases in the inner London area. How is stem cell research shaped as a bio-political-economic project in these two spaces? How are these two spaces connected? How do hybrid hierarchies emerging from these systems replace traditional top-down approaches to science and health care governance?

In order to answer these questions, policy making is conceptualised as deliberative practice of multi-level renegotiation of systemic boundary conditions rather than as a top-down engineering activity. Looking at transnational performances as confined in spatial-temporal micro-systems the study aims at evaluating policy as deliberative practice of distinct political epistemic communities in probing their relation to the respective macro-systems. The underlying theoretical framework considers a governance system as distinct assemblage of discursive and non-discursive elements connecting aspects of virtuality and actuality through practice. In applying a policy-focussed ethnographic approach, film footage from public speeches, meetings, conferences, visits at biotech-sites, policy documents and research interviews are utilised to introduce elements of everyday practice's immediacy into the comparative analysis of hybrid governance systems.

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2nd Workshop:

Stem cell research in China and Europe

9-12 October, Shanghai

The initial focus on reproductive medicine in clinical practice for the first BIONET workshop will be followed up in the second workshop which will focus on stem cell research. The second workshop is set to take place in Shanghai, 9-12 October 2007. The workshop aims to bring together stem cell scientists, policy makers, bioethicists and social scientists from Europe and China to discuss such issues as informed consent in the procurement of embryos for human embryonic stem cell research, therapeutic use of stem cells and publication ethics stemming from data quality and reliability.

Workshop participants visit botanical gardens in Beijing

BIONET Roadmap

Workshops

Workshop 1
ART clinical practice
Beijing, April 2007

Workshop 2
ART and stem cell research
Shanghai, October 2007

Conference

Conference 1
Ethical governance of reproductive technologies, therapeutic stem cells, and stem cell banks
Changsha, April 2008

Ethical governance
Informed consent
Benefit sharing

Workshops

Workshop 3
Bio-banking
July 2008

Workshop 4
Genomic research
January 2009

Conference

Conference 2
Genomic research, biobanking and benefit sharing
Beijing, August 2009