



**Ethical Governance of Biological and Biomedical Research:
Chinese-European Co-operation
FINAL CONFERENCE REPORT**



**BIOMEDICAL RESEARCH IN CHINA AND EUROPE -
THE FUTURE OF RESEARCH COLLABORATIONS**

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INTRODUCTION

During the last decade, collaboration between and within China and Europe in life sciences and biomedical research has significantly intensified. Such inter-cultural research collaboration depends, on the one hand, on human subjects either as donors of human biological materials (gametes, embryos, blood, bone marrow, tissue) or as recipients of therapies in clinical research, and on the other, scientists and medical professionals who operate within their particular regulatory, institutional and cultural settings.

Scientists, biological materials, biomedical treatments, scientific equipment and/or information databases are exchanged across continents and countries. Biological samples procured in one place, are biologically cultured or biochemically/ genetically analysed in another, and finally, the information derived can be transported instantaneously throughout the world electronically. Biomedical treatments developed in one place can be transferred to another country or region for clinical testing, while the chain from donor to bench to bedside raises technical and ethical issues at each of its links.

At the same time, ever since the Nuremberg Code and Helsinki Declaration were drafted in the aftermath of World War II, countries throughout the world have been developing governance procedures to protect the safety, rights and dignity of individuals who participate in biological or biomedical research, and to make the process transparent. There have been very much national efforts to introduce legislation and to build up statutory systems of ethical review in human subjects research. What is more, recent advances in life sciences research, together with an unprecedented focus on the implications of such activities for societies, cultures and individuals have raised a number of dilemmas regarding, for example, the moral status of human embryos, the moral acceptability of research cloning, inter-species embryos and genetic modification as well as the appropriate use of genetic information. And again, each of these dilemmas has been addressed in different ways in different countries across the world.

How does such a *national diversity* of systems of ethical governance and ethical deliberation about biological and biomedical research cope with increasingly *global life science research collaborations*? The conference will address this central question by looking at the emerging patterns of scientific cooperation between two major players in the field of contemporary life sciences and biomedicine, Europe and China.

Based on the knowledge and experiences gathered through five workshops and conferences held in China in the 2007-2009 period on topics of reproductive and regenerative medicine, stem cell research, clinical trials, biobanking and genetic testing, the final BIONET conference examined some of the challenges that are emerging for international bioscience research collaborations, focusing especially on Chinese-European co-operation. Around 80 Chinese and European experts from

Research Councils, government Ministries, life science research institutions, social sciences as well as law gathered in London to discuss and debate:

- What are the challenges that an ongoing globalisation of life sciences research poses to principles and practices of ethical review, informed consent and benefit-sharing?
- What are best practices in ethical governance of international biomedical and biological research?
- How can national ethical governance systems, forms of communication, socio-economic conditions and cultural particularities be reconciled when scientists from two or more countries collaborate?

The conference also saw the presentation of a set of draft recommendations for best practice in the ethical governance of research collaborations in biological and biomedical research between Chinese and European scientists which have been prepared by the BIONET Expert Group chaired by Prof. Christoph Rehmann-Sutter and co-chaired by Prof. Qiu Renzong.

EMERGING THEMES FOR SINO-EUROPEAN COLLABORATIONS

Nikolas ROSE (from the BIOS Centre of the LSE, and lead partner in BIONET), opened the conference with a brief introduction to the intersecting developments that gave BIONET its relevance. He pointed out that the issue of the ethical governance of international research collaborations emerged at the intersection of five significant global trends: the great advances in biomedical research in reproductive technologies, stem cells and genomics; the powerful and growing presence of China in this area; the globalization of the life sciences and the key role of international research collaborations, and multi-centre research and clinical trials; the pressures to translate developments in basic science to clinical applications, placing pressure on the research/therapy/product development interfaces; and the rapid development of the global bioeconomy in which Asia in general, and China in particular was playing a key role. Rose argued that this produces exciting opportunities but also challenges for the scientists and researchers involved, for public and commercial funders of research; for regulators facing challenges of regulating in this transnational context, and for ethicists faced with ethical and cultural pluralism. This provided the context for the debates and the proposals that would be presented over the next three days.

In his opening presentation, Peteris ZILGALVIS, Head of Unit, Governance and Ethics, European Commission, Research Directorate-General pointed out that a final conference is by definition a very important one but that this could not be the end - ethics is always a work in progress, especially in relation to research. It is an area where we can learn from each other: co-operation in research requires better implementation of international ethics guidelines and this is particularly true in an

area such as biosciences. The foundation for a European ethical framework – Europe's Charter of Fundamental Rights – is based on scientific and political



responsibility, respect for the diversity of opinions and a search for balance of interests, which was particularly relevant in a globalised world of research, where European and Chinese researchers work as team. Dr. Zilgalvis argued that ethics has become an issue relevant to the place of science in society in conjunction with topics such as assisted reproductive technologies and embryonic stem cell research, as studied in the case of BIONET. Likewise, efforts have been made at the international level to provide a foundational context for the ethical aspect of the practice of science. Emerging governance structures respond to a need for the ethical oversight of science and innovation in society, but also pose a challenge to governance at a global level because of the issues of ethical diversity, as, for example in concepts of personhood and the

strongly relational concept of personhood in China. Moral education of scientists can therefore be as important or even more, than the legal regulation of science. He pointed to the importance of the EU's ethics reviews in this context, to ensure that Community-funded research undertaken anywhere in the world, including China, complies with fundamental ethical principles. These reviews use international experts, including from overseas, to review research which crosses national boundaries, on the basis of national, European and international legislation and guidelines. He gave some good examples of the role Europe has to play with its international partners in research ethics for instance in the proposed EU Code of conduct on Responsible Research and Development of Nanotechnology.

Dr. Zilgalvis spoke of the many uncertainties looming over the EU-China relationship. On the one hand, the two sides share many common interests for instance in promoting peace and development in the world; they are engaged in strategic partnership, and conduct regular policy dialogues in many fields. On the other hand and in many specific issue areas, the two partners are facing intense rivalries and conflicts. In areas such as human rights, democracy, global security, intellectual propriety rights and others, the EU can meet resistance when searching for collaborative solutions with China. The EU has to face an increasingly strong China with much greater impact on global affairs, and it is also Europe's interests to develop a progressively more effective China policy. There is a need to build the basis for a longer-term co-operation in socio-economic sciences and humanities with China, and especially the Ministry of Education. Dr. Zilgalvis concluded with a few words on global governance. Global governance needs to aim at agreeing and harmonising general ethical principles, but it must also take into account local cultures, beliefs and traditions as a vital part of the necessary dialogue. This goes beyond research to international trade and development policies. It is up to us, said

Dr. Zilgalvis, to show that we can advance with respect for ethical concerns and turn challenges into opportunities.



HE Wei, Acting Director of Bureau for Science and Education, Ministry of Health spoke on "Understanding, Trust and Collaboration" expressed the support of the Ministry of Health for the work of BIONET and the project of enhancing ethical governance of international biomedical research collaborations. His presentation gave us an excellent insight into ongoing ethical governance initiatives in China, summarizing the many developments in ethical regulation over recent years, and the need to develop a regulatory regime which both solved medical problems and promoted industrial development. He made several suggestions for EU-China cooperation, including the need to make full use of the global innovation and technology resources, mutual benefit, complementary advantages, enhance the innovative capability; to

complete high-quality research tasks; to improve research capacity, and enhance international competitiveness; and to promote personnel training, suggesting such approaches as cooperative research project; jointly held international academic conferences; international (regional) academic discussions and exchanges; and short-term foreign experts to lecture in China. He noted a number of ongoing collaborations including the NSFC-AF (Academy of Finland) Joint Research Projects undertake research in the environment and ecology, energy and other fields in 2008; NSFC-DFG invested 10 million yuan each year to support the bilateral seminar on strategic areas of collaborative research; Sino-Danish joint research projects and jointly determine the subject, joint bidding, financing the implementation of research projects; Sino-French joint research projects mainly invested in materials, nano, chemistry and other fields. He concluded by enumerating a number of challenges: the need for scientific progress; Translational study from bench to bed should be strengthened; and argued that on the basis of sufficient theoretical finding, translation and transfer of mature biomedical technology into clinic with strict ethical governance could benefit patients maximally. And he concluded by suggesting that the proposed Sino-European platform for research ethics is important for continuous improvement in research governance.

The first substantive session, WHY COLLABORATE?, was moderated by Ole DÖRING.

Nikolas Rose gave a short introduction to the rationale for the work of BIONET. The aim of the collaboration was to identify best practice for the governance of research

in the life sciences and biomedicine; to support development of legal frameworks, regulations, guidelines and professional codes; and to identify and try to overcome problems of implementation. He set out the structure of BIONET: Workshops and conferences; Research and training; Student exchanges, Reports on our Conferences and Workshops, together with regular newsletters a web library of key documents and an internet discussion forum. BIONET had been a productive, frank, open collaboration over three years, and, in the words of our BIONET partner Cong Yali, had been characterised by friendship, trust, tolerance, co-learning. But, as Professor Cong pointed out, there was more to do to ensure high quality collaborative research with patient protection and benefit sharing. Nonetheless, as the saying has it “A good start is half way to success!” And the report for the EC from Expert group will inform future research collaborations between the EU and China. Rose highlighted in particular one recommendation from the Expert Group: the need to establish a standing Sino-European ‘platform’ to advise on ethical and governance issues in EU-CN collaborations in biomedical research: to build on BIONET to support multiple European and Chinese research collaborations; to help build capacity in EU and China; to be able to respond rapidly to changing conditions, scientific, ethical, regulatory; to act as advisors to actual and potential research partnerships; and to help in the development and oversight of regulatory procedures and standards

This was followed by a Stakeholder Roundtable:

Catherine ELLIOT, Head Of Clinical Research Support and Ethics, Medical Research Council, United Kingdom outlined the concerns of the UK’s MRC in considering funding such joint research collaborations, and the criteria that the MRC uses in evaluating proposals, drawing attention to the recommendations of the CURE report (the report of the China-UK Research



Ethics Working Party established by the MRC), which had worked in close association with the BIONET, and whose report was launched immediately prior to the opening of this conference. It was important to examine the compatibility of the recommendations of CURE and BIONET, but the close links between the two groups had ensured that there was harmony between their approaches. The MRC would look with interest at the proposed development of the Sino-European ‘platform’ mentioned earlier.

CHU Jiayou, Professor, Institute of Medical Biology, Chinese Academy of Medical Sciences spoke on “Cooperation Research between Chinese and European scientists On Human Genome Resources”. Professor Chu discussed a number of examples of international collaboration in genomics research and gave an illuminating insight into the kinds of projects that European and Chinese scientists are engaging in. In particular he stressed that Chinese ethnic diversity provided an important resource for biomedical research. He pointed out that China has a 1.3 billions population that

accounts for 22% of the world population. There are 56 nationalities in China, each of them having independent inhabitation areas. And some of them are genetic isolated population. In the source of nationalities and genetic phenotypes, each nationality has its unique characteristics. There are very significant differences in categories, enzyme system, HLA antigen and incidences of some genetic diseases. Professor Chu



explained the role of the BioSino Genetic Diversity Database of the Chinese Population and gave some compelling examples of the importance of this research to identify genomic differences linked to disease susceptibility and longevity. He also presented information on primate research facilities in china and on vaccine development, ending by arguing that

there were no reasons not to collaborate and singling out -Cooperation on Human Genome Resources ; Ethic Issues in Vaccine Clinical Trials; and issues arising from research among Different Chinese Ethnic Groups.

Stephen MINGER, Director, Stem Cell Biology Laboratory, Wolfson Centre for Age Related Diseases at King's College London spoke on "Sino-UK collaboration in stem cell research" and gave a clear and frank presentation on the state of the art in biomedical research in China, and the key challenges faced by scientists in the UK engaging in collaboration with Chinese colleagues.



Hans WOLF, Director of Institute for Medical Microbiology and Hygiene, University of Regensburg, Honorary Professor of the Chinese Academy for Preventive Medicine, recipient of 2004 "Friendship Award" from Chinese

Prime Minister Wen Jiabao, spoke on "Chinese-European cooperation in vaccine trials". Professor Wolf gave an illuminating presentation with a number of detailed examples of collaborations with Chinese colleagues and organizations in clinical trials research, including those for HIV vaccine development, and drew many useful conclusions for the structure and funding of trials and for the development of the product pipeline. These detailed case descriptions provided participants with good insight into the kinds of projects that European and Chinese scientists are engaging in.

The next session on KEY CHALLENGES FOR COLLABORATION IN BIOMEDICINE: Lessons from BIONET, was moderated by QIU Renzong.

Herbert GOTTWEIS, Department of Political Science, University of Vienna and a BIONET partner spoke on "Towards good governance of co-operation in biomedical

research collaborations". Professor Gottweis discussed the concept of good governance; Good governance of research collaborations; Bad Governance; Strategies of Good Science Governance; and concluded by considering the implications for China-Europe research cooperation. By 'governance' he referred to the complex set of values, norms, processes and institutions by which society manages its development and resolves conflict, formally and informally. It involves not only the state, but also economic and social actors, community-based institutions and unstructured groups as well as the media, at the local, national, regional and global levels. And it achieves this through the mechanism of politics, and social deliberation. Good governance means the rule of law; transparency; accountability; respect for human rights; participation. Key to science governance was the idea of data integrity, which is supported by institutional capacity and by culture, and by practices to deal immediately with issues of scientific misconduct – hyping science is a threat to good science governance. Good governance involved mutual acceptance of legal traditions; harmonisation of private norms; independent Regulatory Agencies and open coordination, deliberative governance, mutual recognition. And Professor Gottweis put forward the notion of relational contracting as a pathway for good science governance, where parties do not agree on detailed plans of action, but on general principles, on the criteria to be used in deciding what to do when unforeseen contingencies arise: this requires exchange and communication, in particular where cultures differ greatly.



ZHAI Xiaomei, Research Centre on Bioethics, Peking Union Medical College, a BIONET partner, spoke on "Key Ethical Challenges for Co-operation in Biomedical Research: International Guidelines vs. Native Culture". She pointed to the assumptions of shared values underlying the recommendations of BIONET and similar groups, and

raised some questions about the extent to which this assumption was justified. Countering many of the criticisms of this belief in shared values, she pointed to the fact that many of the international guidelines were drawn up in collaborations between Chinese and non-Chinese researchers and regulators, demonstrating that a core of shared values did exist. She presented numerous Chinese examples of such shared values, from Mencius, Xun Zi and Confucius to the current Chinese leadership. However, she pointed out that the application of international ethical guidelines may not just a deduction from these guidelines. Even in deductive reasoning the conclusion cannot be drawn only from the international ethical guidelines as major premise, there must be another minor premise as initial condition. Thus, when applying international ethical guidelines to the case which is embedded in local culture, one meets different initial conditions. Each ethical issue (what ought to be done and how morally) is embedded in certain socio-cultural context and carries with certain socio-cultural characteristics. In particular she pointed to the relational conception of the person in Chinese culture and ethics,

which alters questions of who can give informed consent, and argued that family consent, or community consent can still be consistent with rigorous ethical principles, as can oral consent where participants have particular concerns about giving their signatures on consent or other documents. She advocated a “Reconciliation” approach: when applying international ethical guidelines we should respect the beliefs and values in native culture and try to assimilate its positive elements into our procedures in our research. This, she argued, was the only approach which makes us able to properly address the cultural tension, and effectively protect the rights and welfare of human subjects. It required distinguishing the essential core of the ethical basis of regulation, which was universal and must be adhered to across cultures, from a flexible and variable periphery involving such things as the way in which information is disclosed, the way consent is expressed, the wording of consent forms and the involvement of family and community in the process of informed consent. She concluded by suggesting that the result will be as Confucius said: 和而不同 *he er bu tong* (*Lun Yu*, chapter 13, paragraph 2): “harmonized but not identical”, or “harmonized as well as diversified”.

YANG Huanming, Beijing Genomics Institute at Shenzhen gave a lively and challenging presentation on “Scientific challenges for cooperation in biomedicine”. After a discussion of the achievements of Charles Darwin, Professor Yang put forward the two challenging theses of current molecular biology – that life is digital, and written in two codes – the code of the four bases of DNA, CAGT, and the binary code of computers, zeros and ones – therefore, as the saying goes, the answer indeed was 42, in this case 4 and 2. This led to the revelation that life was in fact contained in a sequence, and that we can move from reading the code of life, in genomics, to writing the code of life, in synthetic biology. He pointed to the huge advances in sequencing technology made at his own Institute, the Beijing Genomics Institute, and the creation of the new BGI ‘SOAP’ software for sequencing, with major technical advances and advances in speed and accuracy, which extended to sequencing the transcriptome, the epigenome and to meta-genomics. He argued that we faced three great challenges in contemporary biomedicine – the rise of personal genomics, the emergence of technologies based on induced pluripotent stem cells not derived from embryos, and synthetic biology and “man made life”. The great reduction in the cost of gene sequencing and the huge investment in, and profits to be made in, sequencing technologies had come to fruition in 2007 and we were now moving towards the realistic prospect of sequencing the transcriptome of individual cells and to analyzing many individual genomes and also the genomes of many new species. After a discussion of the great strides made by synthetic biology, Professor Yang



ended by calling for a bioethics that avoided dual standards, was not driven by politics, and supported good science, so that bioethicists and scientists could work together to support the public good. Science was best when ethical, escorted and advocated by bioethicists.



LU Guangxiu, Reproductive and Genetic Hospital CITIC-Xiangya and a BIONET partner, spoke on “Key scientific challenges for co-operation in biomedical research”. She gave some troubling examples of very bad practice in attempts at research collaboration by non-Chinese scientists with Chinese researchers, and argued compellingly that it was unethical for the Chinese researchers to be seen merely as collectors of materials to be researched and analysed outside China. What was crucial were agreements that showed mutual respect, with genuine collaboration on the intellectual and analytical aspects of the research, sharing in publication credit, and in benefits, both financial and intellectual.

Only in that way would the benefits of international collaboration be properly and ethically achieved.

Ole DÖRING, German Institute of Global and Area Studies and a BIONET partner, spoke on “Key translational challenges in bioethics”. He structured his presentation around four challenges of translation - from Donor to Bench to Bedside; from one Language to Another, from one Regulatory System to Another; from one Culture to Another. After exploring each of these issues, he concluded by arguing (a) in respect of translation from Donor to Bench to Bedside we required a medical system which embraces the donors / patients, research and application. A field for social work where communicative skills are required for successful translation; (b) from one Language to Another we needed to address cultures of “applying” norms and creating meaning; different readings of reference language (English); use of alien concepts in key normative texts (laws, declarations, guidelines), Philosophical texts (ethics and science), and Sociological texts and narratives; (c) from one Regulatory System to Another: When building an ethical governance system, the original context should be accounted for. Alien elements need to be adapted properly; (d) from one Culture to Another: The Key Levels for Improvement of Ethical Governance are Institutions (Adaptors), Process (Interaction), Intervention (Catalyst). Governing best biomedical practice between China and Europe, Dr Döering concluded, requires proper understanding and special skills in the complex dynamics of translation(s). - ethical Governance can be created through translational processes that mobilise cultural, structural and conceptual resources, to ensure legitimacy, best practice and continued dialogue.

SESSION THREEE was devoted to presentations by the BIONET Expert Group of their RECOMMENDATIONS ON BEST PRACTICE FOR COOPERATION IN THE BIO-MEDICAL SCIENCES:



Genevra RICHARDSON introduced the twelve general recommendations of the BIONET Expert Group:

1. Regulatory coherence: International ethical standards to protect human research subjects should be reflected in national regulation. The ethical review standards that must be adhered to in multinational projects need to be clarified transparently and publicly.
2. Conflict of interests: Appropriate precautions should be taken against potentially harmful conflicts of interest. Names of members of supervising ethics committees should be made publicly available and any potential conflicts of interests should be disclosed. Therapy-research interfaces need special attention. Patients with life threatening or untreatable diseases are particularly vulnerable.
3. Gaps in regulations: Clear responsibility and accountability within the organization of the project should be assigned to one person or one department in each participating country. National regulations should make this assignment of responsibility an obligatory requirement for conducting collaborative research/trials . A clear assignment of responsibilities between collaborating partners in different countries should be a requirement.
4. Implementation of ethical standards on the ground: Countries should have a system of independent research ethics committees established with ethical, medico-scientific and local knowledge. The research ethics committees should be accountable and have good working standards that include a maximum length of time for their reviews. They should also have the capacity to review informed

consent documents before they are handed out to patients and might have an additional monitoring function.

5. Education and Training: Learning opportunities arising from each international collaborative research project should be explored. This should be done by including opportunities for the exchange of views and experience. International bodies should be encouraged to co-operate in the systematic collection of lessons learnt from the conduct of multinational projects.
6. Awareness of social and ethical implications of decisions: Decision-makers and researchers on all levels need support and empowerment through adequate training. Training should include medico-scientific as well as socio-cultural knowledge, and the skills required to plan and perform informed consent procedures. Before any research collaborations are approved or begin, participating researchers must receive the necessary training focusing on the particularities of the kind of research at stake (e.g. donation or participation in a trial).
7. Therapeutic misconception, undue inducement: Adequate education and training of all those who are involved in recruitment decisions, including the study participants, will protect against therapeutic misconception. Undue inducements to participate in a research study are not acceptable. Study participants should be selected from groups who understand what it means to participate in the study, and are able to make free decisions. Exceptions from this rule should be carefully described and justified. A “coercion audit” must be prepared in advance.
8. Control and monitoring; Appropriate control and monitoring systems in all participating countries should be established. Research institutions who want to participate in multinational projects need to fulfil minimal requirements relating to institutional capabilities and individual professional qualifications. The disclosure and publication of ethical governance procedures should be a condition of peer reviewed publication of research findings in scientific journals
9. Cooperation between research ethics committees: The establishment of platforms for mutual exchange of experience and insight (including across national borders), and the clarification of responsibilities for reviewing multicenter studies should enhance co-operation between ethics committees. Special attention should be paid to the fairness of selection of patients. When research collaborations involving both Chinese and European partners have to be reviewed by ethics committees on both sides the committees should work towards a joint opinion whenever feasible.
10. Understanding the effects of governance: Empirical research into the realities of ethical governance of research should be encouraged
11. Data sharing: Frameworks should be created that allow the sharing of data among the partners while ensuring privacy of research participants and confidentiality of their personal data
12. Continuous bioethics collaboration: A Sino-European platform for research ethics should be established

ZHAI Xiaomei spoke on the aspect of the recommendations that referred to Special Protections of Vulnerable. The set of 30 concrete recommendations) should help to prevent the exploitation of unclear standards in transnational research collaborations

and to protect those research participants and patients who become vulnerable in such settings. In particular they argued that Patients with life threatening or untreatable diseases are vulnerable against offers of unproven and potentially unsafe treatments in research and commercial contexts. Here, proper counselling and a tight regulatory framework with an appropriate level of public or state supervision of the providers will be a necessary step. After a review of the ways in which the key bioethical declarations addressed this issue of vulnerability, She then turned to a consideration of the meaning of the notion of vulnerability and argued that the central problem presented by research plans to involve vulnerable persons as research subjects is that such plans may entail an inequitable distribution of the burdens and benefits of research participation. So special justification and safeguards are required for protecting their rights, interests and welfare – and particularly significant in this respect are infertile women going to ART clinics, egg donors who may be under pressure to make donations, and desperate patients, who may be vulnerable to false promises of treatment. She argued that partnerships with community groups offered a way to redress the power imbalance, and also maximize potential benefits to the vulnerable, reduce or minimize risks to them, obtain genuinely informed consent by communicating effectively with patients/potential subjects, take other appropriate measures to ensure that consent is truly voluntary, foster compliance, and help interpret data correctly. This could take a number of forms ranging from informal discussion aimed at mutual understanding and adjustment of the proposed protocol (where appropriate), involving the negotiation of every aspects of the study (goals, identification of subjects population, ownership of data, and publication) or treatment (goals, design, procedures, payment etc).

LU Guangxiu and Herbert GOTTWEIS presented the aspects of the recommendations that referred to clinical trials, biobanks, stem cells and ethics. Discussing clinical trials, they argued that the following points are of particular importance; Overlap of innovative therapy and research; Clarification of distinction of clinical trials from experimental therapy; a Register of clinical trials; Regulatory oversight, public disclosure of study designs and results through a clinical trial register and certification system for research ethics committees; Procedures for a suspension of a trial in cases of scientific misconduct ; Publication of all clinical trial data regardless of the outcome or the location of study site

Discussing research in the fields of genetics, genomics and biobanking, they argued that the following points are of particular importance: Accountability and appropriate governance structures of biobanks; informed consent and ethical value; Agreement about the kind of donors' informed consent that will be asked for; Confidentiality of samples and related data and protection of privacy of sample donors; Transparency and clarity to donors and the public regarding the purpose and use of a biobank. A change of the purpose (e.g. forensic use of a research biobank) requires consent by the donors; Transparency and clarity to donors and the public regarding the purpose and use of a biobank. A change of the purpose (e.g. forensic use of a research biobank) requires consent by the donors. Guidelines for access to samples and clinical data; a distributive justice of profit with fair benefit-sharing; Clear and transparent rules regarding the feedback of individual

information to donors as part of the informed consent. Pharmacogenomic information considered in drug development and dosage

Discussing stem cell research, reproductive and regenerative medicine they argued that the following points are of particular importance: Investigation of the safety and efficiency of experimental treatments with stem cells in state-of-the-art trials before offering them commercially to patients; public compliance, discrepancies in the legal status of embryo between different legal systems; adherence to the laws of the countries involved, without necessarily downgrading regulation to the most restrictive partner country: clarification of what is allowed to be done to an embryo in vitro and clarification of what is allowed to be done to an embryo before implanting it in the uterus of a woman: Transparency regarding under which conditions germ cells, embryos or embryonic tissue has been collected; quality standards about 'clinical grade' stem cells.

Christoph REHMAN-SUTTER spoke on the Potential and Limits of the Recommendations. He pointed out that ethics, in contemporary societies, cannot steer the progress of science and technology in biomedicine into desirable directions.

Research ethics can help to protect the rights, the wellbeing and health of those human subjects, with whom research is conducted. Therefore the

BIONET „recommendations for best practice in the ethical governance of biological and biomedical research collaborations between Chinese and European scientists“ were a ‚road map‘. They point out key points to consider and need to be developed further and continually. They need also to be complemented by a larger and more comprehensive reflection on the role of biomedicine in market-driven societies.

Ethical governance of research, he argued, starts in the ways we discuss it, and **how we meet**, encounter and address each other. It is not an operation that starts from theoretical principles but a task of common perception and translation.

Recommendations are only recommendations, not prescriptions. They only have the force of advice, which rests on recognition, argued Professor Rehman-Sutter, quoting Hans Georg Gadamer's remark: „You can only give advice to friends.“ Therefore the recommendations mostly concern **procedures** (where to regulate, how to work toward a solution, where international guidelines can be particularly helpful, how to improve the self-regulatory capacities of those involved, down to the doctors and patients), how to protect those research participants and patients who become vulnerable in research settings.

QIU Renzong spoke on Building an ethical framework for collaborative research. He argued that we need to build an ethical framework for evaluating any conduct which will be taken in collaborative research between EU and China, underlain by a set of ethical principles or a set of core values shared and committed by professionals and



regulators who engage in collaborative research between EU and China. Professor Qiu set out a number of key principles that should underpin such recommendations. Principle 1: the fundamental purpose of collaborative research in biological and biomedical fields between EU and China with advantages of both sides is to promote human health, quality of life and interests with safer, more effective, and more advanced bio-science/technology. Principle 2: Collaborative research between EU and China should maintain high standards of responsible research, i.e. adhering research integrity and committing safeguarding and protecting patients/subjects' rights and interests. Principle 3: in the case of conflict, the priority should be put to interests of patients/human subjects over scientific interests, social interests, and commercial interests in particular, and conflict of interest should properly be dealt with by both sides. Principle 4: Mutual respect means respect for laws, regulations or guidelines of the other side, respect for the autonomy of the other side and the commitment that any issue (regulatory gap, or disagreement among scientists/bioethicists) in one side will be properly resolved by themselves. Mutual respect should be based on mutual understanding and each side needed to develop cultural competence. Principle 5: reciprocity: Benefits-sharing between two sides (including scientists/institutions, donors or vulnerable communities), involving Authorships; Royalties; Patents; Access to data or/and samples and profits. Principle 6: Accountability and transparency in which both sides in collaborative research between EU and China are accountable/responsible for their people. The information on collaborative research between EU and China should be made transparent to other colleagues as well as the public, i.e. taxpayers of both sides. A website of biological and biomedical research between EU and China should be established. Principle 7: Public engagement and the needs to take measure to facilitate public understanding of science and lead to public consultation, engagement or involvement.. Principle 8: Equal, equitable and just relationships; Preventing exploitation: inadequate regulatory infrastructures and independent oversight processes as well as poverty, limited access to health-care services, illiteracy, and limited understanding of the nature of scientific research of patients/subjects in one side may increase the possibility of exploitation. Capacity building both in science and ethics is imperative in collaborative research between EU and China.

In conclusion Professor Qiu drew attention to a number of Pitfalls in Implementation of Recommendations, for instance the belief that sciences is always good, that ethics may hamper the development of good science, the submerging of ethics into red tape and bureaucracy, and the use of ethics as cosmetics to legitimate ventures undertaken solely or mainly for profit.

This was followed by Panel and General Discussion with members of BIONET EXPERT GROUP

SESSION FOUR consisted of RESPONSES TO THE BIONET ECOMMENDATIONS and was moderated by ZHAI Xiaomei



Andre SYROTA, Chairman and CEO of INSERM (The National Institute of Health and Medical Research), France, Member of EUROHORC European Association of the heads of research funding organisations spoke on “Ethics of biomedical research - clinical trials: an EU prospective”, He argued that ethical research was research that was relevant for the study population; scientifically sound and meets universal ethical standards. He argued that while

patients ability to give fully informed consent varied with many factors, with age, education and cultural beliefs involving family and community, individual written informed consent must remain the rule. There must be ethical review in BOTH countries, by committed with Independence from research team and from sponsor, with clear rules for membership, and with formal operating processes, including record-keeping. And he argued that post study benefits for patients, subjects and communities were crucial and were required by international guidelines. He continued by expressing concern about the proliferation of contract research organizations undertaking clinical trials for profit. And he concluded by presenting different models of collaborating on clinical trials research, showing how some requests for funding had been turned down on ethical grounds, and others provided models of good practice, thus providing us with some criteria to distinguish between failed and successful models. Professor Syrota concluded with a telling quote from Marcia Angell, former editor of the New England Journal of Medicine: “Ethical lapses are almost never cases of bad people, doing bad things, for no good reason. Rather, they are good people, doing bad things, for good reasons.”

QI Guoming, Vice-Chair, Chinese Medical Association (CMA) spoke on “Sino-European cooperation in biological and bio-medical research ethics”. He agreed that the proposed Sino-European platform for research ethics is important, but he also pointed out that its functions should be clearly specified, and if it was to play important functions, the participants should be qualified, and it should be authoritative and have its own budget. Dr. QI also gave comments and feedback on the BIONET Expert Group's recommendations which highlighted a number of key points for the revision and development of these recommendations.

Jochen TAUPITZ, Chair of Civil Law, University of Mannheim and member of the German Ethics Council EU: “The BIONET Draft Recommendations - some remarks from outside”. Prof Taupitz subjected the draft recommendations to detailed scrutiny and made many excellent suggestions for improvement and clarity which proved very productive for the BIONET Expert Group.

HU Qing-li, Director of the Independent Ethics Committee, Shanghai Clinical Research Center, Member of the Ethics Committee, Ministry of Health China and former Assistant Director-General of WHO spoke on “Comments on the best practice in ethical governance of biological and biomedical research collaboration between

Chinese and European Scientists". He pointed in particular to the urgent need to address the problem of unproven stem cell interventions being marketed directly to patients. A study group had been supported by the Ministry of Health and the Ministry of Science and Technology, which had led to the Management Practice for Clinical Application of Medical Technology, issued on 16 March 2009 and coming into force on 1 May 2009. It is hope this managerial practice will put a stop to such unauthorized medical practices as stem-cell interventions and brain surgeries. The initiative is welcomed by the medical community in and outside China. "It is a step in the right direction", However, it was considered that the impact of the regulation will depend on its effective implementation.

The new regulation divides medical treatments into three categories. Type I and type II categories include those that have proved to be safe and effective, with type II therapies carrying higher risks and entailing potential ethical issues. Individual hospitals are responsible for overseeing type I interventions, whereas provincial health bureaus regulate those falling into type II category. More importantly, the new regulation bans the use of xeno-transplantation of stem cells, human somatic-cell cloning, and cross-species gene therapies in clinical application. The ministry will directly regulate so-called type III interventions procedures. Prof. Hu pointed out that attempts to develop a stem cell-based intervention into an accepted standard of medical practice are particularly difficult processes and that attention should be paid to ensure the quality and safety of stem cell and its derived products. In particular there was a need strictly to distinguish pre-clinical research, clinical Research, innovative interventions (experimental therapy) and clinical Applications.

Professor Hu drew our attention to the forthcoming international symposium, supported by the MOH and the MOST, to be held in Shanghai from 10-12 Dec. 2009 with delegates from WHO, UNESCO, NIH, FDA, and expertise from abroad and Hang Kong. The major agenda of this event will cover the Establishment and Evaluation of the Bioethics Committee; governance of Ethics Committees; Standard Operation Procedures; Continuing Training of the EC Member; Informed Consent and Some Special Issues related to consent; Multinational Clinical trials and Foreign Investigator in China; and the proposal for an International Clinical Trial Registry. He concluded by expressing some concern about the difficulties of regulation of the burgeoning new field of personal genomics. He also made some specific suggestions for amendment and improvement of the BIONET draft recommendations.

This was followed by presentations of the CASE STUDIES ON STEM CELL AND GENOMIC RESEARCH BIONET EXCHANGE STUDENTS Introduced and Chaired by Ayo WAHLBERG. He Jing, CITIC-Xiangya Reproductive and Genetic Hospital presented some findings from her research on "Psychosocial aspects of IVF patients - China- Denmark comparison". Achim Roseman, University of Sussex introduced his research on "Narratives of life, value, hope an death - Disentangling the IVF embryo in China". Anika Mitzkat presented some findings from her work on "Donation of 'spare' embryos for stem cell research - Experiences and views of couples undergoing IVF at CITIC-Xiangya Hospital. Zhang Yueyue, BIOS Centre, London School of Economics spoke on Reproduction and Genetics", "Government?

Governance.- A case study of hematopoietic stem cell banks in Beijing”. Chen Haidan, Zhejiang University spoke on “Stem Cell Governance in China: from Bench to Bedside?”. Thomas Streitfellner, Life Science Governance Research Platform, University of Vienna spoke on “Imagined regulation: comparing human: embryonic stem cell research in China and the UK”. Su Yeyang, Beijing Genomics Institute introduced her views on the nature of “Scientist – Public Engagement: a start to understand the new partnerships in today’s biomedical research”,



The final session of the conference was on the topic of CHALLENGES OF IMPLEMENTATION, and was moderated by Herbert GOTTWEIS

YU Xiucheng, Ministry of Health, P.R. China spoke on “Biotechnology and life science research”. After reviewing both the Asian and European tradition of ethics, YU Xiucheng emphasised the mutual influence of social development and technological advancement had on each other. He further pointed out in the recent century China’s medical ethics has been in line with major international conventions. He proposed more substantial and frequent dialogues between bioethicists and scientists in order to ensure scientific and social development being achieved with harmony and efficiency.

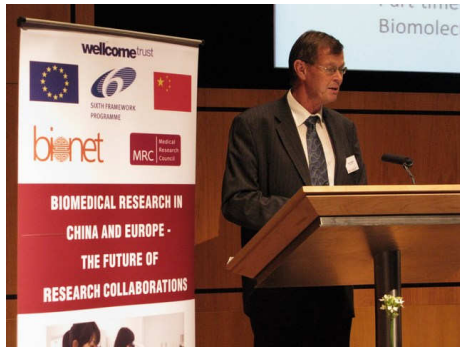
This was followed by a panel discussion. LIU Wei, Hunan Institute for Stem Cell Engineering argued for the importance of self-discipline among all the participants in international collaborations, effective and regular communication; cultural, social, legal, religious and economic understanding between participants, mutual respect and the wish to seek common ground on major issues while reserving differences on minor ones – or, as the Chinese phrase has it 和而不同(Harmony in diversity) while avoiding the problems of multiple standards.

ZHU Wei, Associate Professor at in the Department of Social Sciences of Fudan University, Member of Ethics Committee, Shanghai Municipal Bureau for Health and Member of Board of Directors, Chinese Society for Bioethics, spoke on the topic of “Gender Perspective on the Implementation of the Recommendation”. She argued strongly that the structural position of women in China and other developing countries made them a special category among the vulnerable. In particular, the female population will become more central to the development of the regenerative medicine industries. In circumstances of gender inequality, women from developing countries, who are involved in stem cell research are bearing a double or even a triple burden, compared to those from developed countries. She suggested that the BIONET Expert Group’s recommendations should clarify the researchers’ responsibility and accountability for protecting women’s rights and interests and must take account of this special vulnerability, and more generally of the importance of gender when working to protect human subjects.

Finally, Nick BUNNIN, University of Oxford, made the point that both bioscience and bioethics are both changing with astonishing speed and that concerns will alter as these fields mature. We should not be content with implementing static rules for static science. He argued that there are different layers of bioethics, each with its own problems. We will be blind to important ethical questions if we focus on some layers and ignore others. Gaps and overlaps occur among the layers as well as between Chinese and European implementation and between implementation in different European states. Ethical regulation must be understood as a whole, with specialist domains, such as 'donor's ethics' or 'investigator's ethics', seen in the wider context. Also, bioethical considerations (regarding benefit sharing, for example) should force business ethics to widen its concerns as bioscience leads to products and treatments of commercial value. Bioethical regimes can gain coherence, intelligibility and legitimacy through the influence of current interdisciplinary developments in the theory of regulation.



Internalisation of bioethical rules for Sino-European research, BUNNIN said will fail if they are seen as special rules, on the model of nineteenth-century Western extra-territoriality, rather than rules used for domestic as well as collaborative bioscience. Just like collaboration between Chinese and foreign economists provided intellectual grounding for the Chinese economic transformation over the last three decades, collaboration in bioethics can help to guide the regulation of Chinese and international bioscience. Like Francois Jullien, who studies Chinese philosophy in order to understand European philosophy, Western participants in a Sino-European Bioethical Research Platform can learn much about bioethics in Europe by helping to develop bioethics in China. In particular, we can move beyond the concern of the Confucian small person for profit to the concern of the Confucian sage for humanity who argued for the value of further Chinese-European collaboration.



The conference closed with a talk from Eero VUORIO, Professor of Molecular Biology and Chancellor, University of Turku, Chair, National Advisory Board for Research Ethics, Chair of the European Research Council identification committee, Executive Manager of BBMRI. His presentation on “Challenges Of Implementation” was a frank and detailed discussion on the challenges faced when implementing different kinds of ethical

guidelines in scientific research practice which was of great value to the BIONET Expert Group. Pointing to some of the challenges, such as agreement on terminology and the difficulty of communicating complex biological information to lay participants in research, and the growing issue of ensuring data integrity. He stressed the role of research funders setting conditions for funding of international collaborative research & mobility: adherence to international (and national) ethical guidelines and legislation; adherence to international guidelines for good scientific practice/responsible conduct of research; agreement on methodology to investigate alleged misconduct; agreement on sharing of samples and data; agreement on publication of results and data, and on protection of research subjects. And he highlighted the importance of ensuring that guidelines are formulated in a manner that makes them practicable.

Closing the conference, Nikolas Rose, for the BIONET consortium thanked all delegates and participants for their stimulating contributions and commented on the great strides that BIONET had made, as a practical experiment in international research collaboration, over some five years since the consortium began to be established. He pointed to the necessity for care and commitment if trust, communication and collaboration was to be built, and the role of friendship in ensuring that disagreements could be aired and overcome, and differences embraced within a continuing collaborative endeavour. He remarked in particular on the enduring partnerships established by the BIONET exchange students, which provided a very good basis for the future of collaborations, and were examples of the kinds of empirical investigations that were necessary to examine the ways in which bioethical guidelines and procedures actually worked in practice, which was a key to the development of effective implementation. In particular, it was necessary to accept the reality of the context in which contemporary biomedical research takes place, and neither to ignore or condemn the intrinsic economic context within which such research is situation, but to understand and regulate these economic factors. In conclusion, he outlined the future steps that would be taken before the formal ending of the BIONET on 30th September 2009. these included the preparation of a Conference Report which would be available on our website, and the revision of the Recommendations in the light of the very helpful discussions. It was clear that the key principles of research collaboration were widely shared, and provided a ‘hard core’ around which such collaborations could build, recognising the need for flexibility around that core to adapt to local circumstances. While our good start was certainly half way to success, the task for the future was to make sure that our shared

understandings of good ethical governance of biomedical research collaborations were implemented, and expressed his hope that the proposal of a Sino-European Platform for Biomedical Research Ethics would prove an effective way to take forward the work of the BIONET and of all those who had participated in our workshops and conferences.

September 4, 2009

Tighter controls needed on ‘stem cell tourism’ say European and Chinese experts

Vulnerable patients who travel abroad for unproven and potentially unsafe stem cell treatments need to be better protected says a report published by a team of expert researchers from Europe and China today (Friday 4 September).

The report calls for countries to develop more effective regulation of experimental stem cell procedures by insisting on rigorous clinical studies and ethical reviews before they can be offered as treatments.

The proposals come from a group of 10 Chinese and European experts, from the fields of medicine, ethics, law, political science and social science. Their Expert Group is an independent part of the BIONET project, a Sino-European collaboration based at the London School of Economics and Political Science (LSE).

The BIONET Expert Group report sets out 30 recommendations for the ethical and structural development of European-Chinese collaborative research in the biological and biomedical sciences. The recommendations are based on a series of five workshops and conferences organised by BIONET in Beijing, Shanghai, Xi’an, Changsha and Shenzhen. These covered the topics of stem cell research, clinical trials and genomics research and involved participation from leading scientists, ethicists, lawyers and policy makers from Europe and China.

The growing global stem cell tourism economy has been fuelled by claims of treatments for hitherto untreatable conditions, the formation of patient networks, falling travel costs and the establishment of high quality medical facilities combined with undeveloped or non-existent national regulations.

While most stem cell therapies have not undergone clinical trials, clinics throughout the world, including Europe, Asia and the Americas, are offering patients – who are often extremely vulnerable and have exhausted all other options – expensive and unproven treatments.

Qiu Renzong, Professor of Bioethics at the Chinese Academy of Social Sciences and the co-chair of the BIONET Expert Group, said: ‘Stem cell research is tremendously exciting and may lead to potential treatments. However its development must be governed in an ethical and responsible way if it is to fulfil its potential and not experience a backlash from public opinion.’

‘Many countries, including China and those in the EU, are now starting to regulate these therapies. However, if patients are to be properly protected, regulation needs to be enforceable and effective.’

The BIONET Expert Group's report makes a number of other recommendations on Sino-European research collaborations including greater clarity and more precise regulation of clinical trials, international agreements about the ethics and transparency of biobanking – the storing of human blood and tissue for research purposes – and the establishment of a permanent China-Europe partnership on research ethics.

Christoph Rehmann-Sutter, co-Chair of the Expert Group and Professor of Bioethics, said: 'European and Chinese research teams are collaborating on some really exciting bioscience. As with all relationships that reach across cultures, difficult issues can arise because of social, moral, political and other differences. Our recommendations are intended to sketch out where these problems can arise and how to prevent them. We hope this will allow research to be steered in an ethically sound way.'

BIONET has spent three years examining developments in biological and biomedical research and practice in Europe and China. The BIONET Expert Group's recommendations are being presented for approval at the project's final conference in London from 2 - 4 September.

Ends

NOTES TO EDITORS

BIONET is a Consortium of 21 European and Chinese partners examining the challenges facing the ethical governance of research in the life sciences and biomedicine in China and the EU. It is funded under the European Commission Sixth Framework programme with support from the United Kingdom's Medical Research Council.

The BIONET conference is taking place at the Wellcome Collection Conference Centre in Euston Road, London NW1 from 2-4 September 2009.

The BIONET Expert Group report – *Draft recommendations for best practice in the ethical governance of biological and biomedical research collaborations between Chinese and European scientists* is available to journalists from the LSE press office.

For more information contact:

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MEDIA RESPONSE

The screenshot shows the BBC News homepage. At the top, there is a search bar and a 'Low graphics Help' link. The main navigation bar includes 'NEWS' and 'Watch ONE-MINUTE WORLD NEWS'. A sidebar on the left lists various news categories such as Africa, Americas, Asia-Pacific, Europe, Middle East, South Asia, UK, Business, Health, Medical notes, Science & Environment, Technology, Entertainment, and Also in the news. The main content area features the article 'Safety call over stem cell trips' with a sub-headline: 'A clampdown on unproven and potentially unsafe stem cell research is being called for by an expert group.' The article text discusses Bionet, a group of expert Chinese and European doctors, lawyers, and bioethicists, who argue that countries worldwide must develop more effective regulation for this emerging science. A photograph of pink, spherical stem cells is included. To the right of the article, there are sections for 'SEE ALSO' (listing related articles like 'Cancer hope over stem cell drug'), 'RELATED INTERNET LINKS' (listing Bionet and UK National Stem Cell Network), and a disclaimer: 'The BBC is not responsible for the content of external internet sites.'

The header for Nature News features the 'naturenews' logo in white on a red background. Below the logo is a navigation bar with tabs for 'nature news home', 'news archive', 'specials', 'opinion', 'features', 'news blog', and 'events'.

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Published online 4 September 2009 | Nature | doi:10.1038/461157a

News

Ethics scrutiny needed for Chinese–European projects

Panel calls for joint advisory body to monitor research.

[Daniel Cressey](#)

Biomedical research collaborations between Europe and China need greater ethical oversight to combat unregulated stem-cell therapies and prevent the exploitation of clinical-trial participants. That's the message from a group of bioethics experts who are part of the Chinese–European BIONET project, a partnership set up to examine scientific collaborations between the regions. Over the past three years, it has run a series of workshops in China to produce a set of best-practice guidelines for scientists working in fields such as reproductive and regenerative medicine, stem-cell research and human-tissue biobanking.

China cracks down on stem cell tourism

› 00:01 04 September 2009 by [Andy Coghlan](#)

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Chinese and European researchers have today published ethical guidelines aimed at discouraging Chinese doctors from offering patients unproven or sham treatments based on stem cells.

The authors hope the move will reinforce legal curbs on [stem cell](#) treatments introduced on 1 May by China's ministry of health.

The launch follows [new allegations of fraud](#) in stem cell research, and the arrest of individuals in Hungary [allegedly offering bogus treatments](#).

Untested therapies

Since May, Chinese institutions have been forbidden from commercialising stem cell treatments without first proving that they work through proper clinical trials.

"Now you must get approval from the health ministry first," says Qiu Renzong, vice president of the Chinese ministry of health's ethics committee, and co-author of the [new European-Chinese guidelines](#) launched today in London.

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Tighter Controls Needed On 'Stem Cell Tourism' Say European And Chinese Experts

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Vulnerable patients who travel abroad for unproven and potentially unsafe stem cell treatments need to be better protected says a report published by a team of expert researchers from Europe and China today.

The report calls for countries to develop more effective regulation of experimental stem cell procedures by insisting on rigorous clinical studies and ethical reviews before they can be offered as treatments.

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in FOCUS

LSE: Tighter controls needed on 'stem cell tourism' say European and Chinese experts

By The FINANCIAL 04/09/2009 14:48 (4 Day 01:38 minutes ago)

The FINANCIAL – Vulnerable patients who travel abroad for unproven and potentially unsafe stem cell treatments need to be better protected says a report published by a team of expert researchers from Europe and China on September 4.

The report calls for countries to develop more effective regulation of experimental stem cell procedures by insisting on rigorous clinical studies and ethical reviews before they can be offered as treatments. The proposals come from a group of 10 Chinese and European experts, from the fields of medicine, ethics, law, political science and social science. Their Expert

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PROGRAMME

Monday, 31 August 2009	
All day	Arrival of BIONET partners (Melia White House Hotel)
7.00 – 9.00	Informal Dinner for BIONET partners
Tuesday, 1 September 2009	
9.00 – 10.00	BIONET Steering Committee (Melia White House Hotel)
10.00 – 1.00	BIONET Expert Group (Melia White House Hotel)
1.00 – 2.00	Lunch
2.00 – 5.30	CURE (UK Medical Research Council's China UK Research Ethics) Workshop (Wellcome Trust) (Programme and details circulated separately)
6.00 – 7.00	Reception organized by CURE
All day	Arrival of non BIONET conference participants
Day 1: Wednesday, 2 September 2009	
9.00 – 9.30	Registration and Coffee
8.45 – 9.30	Press Conference
9.30 – 10.15	Conference Opening Nikolas ROSE (BIONET) EU: Pēteris ZILGAVIS , Head of Unit, Governance and Ethics, European Commission, Research Directorate-General, European Research Area : Science, Economy and Society CN: “Understanding, Trust and Collaboration” , HE Wei , Acting Director of Bureau for Science and Education, Ministry of Health
SESSION ONE	WHY COLLABORATE? MODERATOR: Ole DÖRING
10.15 – 10.30	The rationale for the work of BIONET Nikolas ROSE
10.30 – 12.00	STAKEHOLDER ROUNDTABLE Catherine ELLIOT , Head Of Clinical Research Support and Ethics, Medical Research Council, United Kingdom “Cooperation Research between Chinese and European scientists On Human Genome Resources” , CHU Jiayou , Professor, Institute of Medical Biology, Chinese Academy of Medical Sciences “Sino-UK collaboration in stem cell research” Stephen MINGER , Director, Stem Cell Biology Laboratory, Wolfson Centre for Age Related Diseases at King's College London “Chinese-European cooperation in vaccine trials” , Hans WOLF , Director of Institute for Medical Microbiology and Hygiene, University of Regensburg, Honorary Professor of the Chinese

	Academy for Preventive Medicine, recipient of 2004 "Friendship Award" from Chinese Prime Minister Wen Jiabao
12.00 – 1.00	PANEL DEBATE & GENERAL DISCUSSION
1.00 – 2.30	Lunch
SESSION TWO	KEY CHALLENGES FOR COLLABORATION IN BIOMEDICINE: Lessons from BIONET MODERATOR: QIU Renzong
2.30 – 3.10	"Towards good governance of co-operation in biomedical research collaborations" Herbert GOTTWEIS, Department of Political Science, University of Vienna
3.10 – 3.50	"Key Ethical Challenges for Co-operation in Biomedical Research: International Guidelines vs. Native Culture" ZHAI Xiaomei, Research Centre on Bioethics, Peking Union Medical College
3.50 – 4.10	Coffee and tea
4.10 – 4.50	"Scientific challenges for cooperation in biomedicine" YANG Huanming, Beijing Genomics Institute at Shenzhen
4.50 – 5.30	"Key scientific challenges for co-operation in biomedical research" LU Guangxiu, Reproductive and Genetic Hospital CITIC-Xiangya
5.30 – 6.10	"Key Translational Challenges in Bioethics" Ole DÖRING, German Institute of Global and Area Studies
6.15 – 7.30	Reception and Buffet Supper (at the Wellcome Trust)

Day 2: Thursday, 3 September 2009	
SESSION THREE	RECOMMENDATIONS ON BEST PRACTICE FOR COOPERATION IN THE BIO-MEDICAL SCIENCES: Key results from the BIONET project MODERATOR: Nikolas ROSE
9.00 – 10.30	BIONET Expert Group General recommendations, Genevra RICHARDSON Special Protections of Vulnerable, ZHAI Xiaomei Clinical trials, biobanks, stem cells and ethics, LU Guangxiu and Herbert GOTTWEIS Potential and Limits of these Recommendations, Christoph REHMAN-SUTTER Building an ethical framework for collaborative research, QIU Renzong
10.30 – 11.00	Coffee and Tea
11.00 – 11.45	Panel and General Discussion with members of BIONET EXPERT GROUP: Christoph REHMANN-SUTTER, University of Basel QIU Renzong, Chinese Academy of Social Sciences LU Guangxiu, Central South University, Changsha

	<p>ZHAI Xiaomei, Peking Union Medical College Ole DÖRING, German Institute of Global and Area studies Herbert GOTTWEIS, University of Vienna Genevra RICHARDSON, King's College London</p>
11.45 – 12.45	GENERAL DISCUSSION
12.45 – 2.00	Lunch
SESSION FOUR	RESPONSES TO THE BIONET RECOMMENDATIONS MODERATOR: ZHAI Xiaomei
2.00 – 3.15	<p>EU: “Ethics of biomedical research - clinical trials: an EU prospective”, Andre SYROTA, Chairman and CEO of INSERM (The National Institute of Health and Medical Research), France, Member of EUROHORC European Association of the heads of research funding organisations</p> <p>CN: “Sino-European cooperation in biological and bio-medical research ethics”, QI Guoming, Vice-Chair, Chinese Medical Association (CMA)</p> <p>EU: “The BIONET Draft Recommendations - some remarks from outside”, Jochen TAUPITZ, Chair of Civil Law, University of Mannheim and member of the German Ethics Council</p> <p>CN: “Comments on the best practice in ethical governance of biological and biomedical research collaboration between Chinese and European Scientists”, HU Qing-li, Director of the Independent Ethics Committee, Shanghai Clinical Research Center, Member of the Ethics Committee, Ministry of Health China and former Assistant Director-General of WHO</p>
3.15 – 4.00	GENERAL DISCUSSION
4.00 – 4.20	Coffee and tea
4.20 – 5.45	<p>CASE STUDIES ON STEM CELL AND GENOMIC RESEARCH BIONET EXCHANGE STUDENTS Introduced and Chaired by Ayo WAHLBERG</p> <p>“Psychosocial aspects of IVF patients - China- Denmark comparison”, He Jing, CITIC-Xiangya Reproductive and Genetic Hospital</p> <p>“Narratives of life, value, hope an death - Disentangling the IVF embryo in China”, Achim Roseman, University of Sussex</p> <p>“Donation of ‘spare’embryos for stem cell research - Experiences and views of couples undergoing IVF at CITIC-Xiangya Hospital of Reproduction and Genetics”, Anika Mitzkat</p> <p>“Government? Governance.- A case study of hematopoietic stem cell banks in Beijing”, Zhang Yueyue, BIOS Centre, London School of Economics</p> <p>“Stem Cell Governance in China: from Bench to Bedside?” Chen Haidan, Zhejiang University</p> <p>“Imagined regulation: comparing human: embryonic stem cell research in China and the UK”, Thomas Streitfellner, Life Science</p>

	Governance Research Platform, University of Vienna "Scientist – Public Engagement: a start to understand the new partnerships in today's biomedical research", Su Yeyang, Beijing Genomics Institute
7.00 – 9.00	Conference Dinner (at the White House Melia Hotel)

Day 3: Friday, 4 September 2009	
SESSION FIVE	CHALLENGES OF IMPLEMENTATION MODERATOR: Herbert GOTTWEIS
9.00 – 10.00	EU: "Challenges Of Implementation" Eero VUORIO , Professor of Molecular Biology and Chancellor, University of Turku, Chair, National Advisory Board for Research Ethics, Chair of the European Research Council identification committee, Executive Manager of BBMRI CN: "Biotechnology and life science research", YU Xiucheng , Ministry of Health, P.R. China
10.00 – 10.45	GENERAL DISCUSSION
10.45 – 11.15	Coffee and Tea
11.15 – 12.45	Panel and General Discussion: Challenges for implementation "Best Practice". LIU Wei , Hunan Institute for Stem Cell Engineering, Central South University, Changsha "Gender Perspective on the Implementation of the Recommendation", ZHU Wei , Department of Social Sciences, Fudan University Nick BUNNIN , University of Oxford
12.45 – 1.15	Closing Ceremony
1.15 – 2.15	Closing Lunch

Friday, 4 September 2009: AFTERNOON	
BIONET PARTNERS ONLY	BIONET meetings at Melia White House Hotel
2.30 – 4.30	BIONET EXPERT GROUP – FINAL MEETING
4.30 – 5.30	BIONET STEERING COMMITTEE – FINAL MEETING

Saturday , 5 September 2009	
Morning	Free time
Afternoon	Cultural visit and end of project event for BIONET partners and students 1.30pm – meet at Melia White House Hotel 2.30 – 4.30 Trip to Kew Gardens 6.00 – River boat dinner cruise back to London city centre 9.00 – Drop off at Embankment in central London

SPEAKER BIOGRAPHIES

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Nikolas ROSE is Martin White Professor of Sociology, and the Director of the LSE's BIOS Centre for the Study of Bioscience, Biomedicine, Biotechnology and Society. He was originally trained as a biologist before switching to psychology and then to sociology. His books include *The Psychological Complex: Psychology, Politics and Society in England, 1869-1939* (Routledge, 1984), *Governing the Soul: The Shaping of the Private Self* (Routledge, 1989, Second Edition, Free Association Press, 1999), *Inventing Our Selves: Psychology, Power and Personhood* (Cambridge University Press, 1996), *Powers of Freedom: Reframing Political Thought* (Cambridge University Press, 1999) and *The Politics of Life Itself : Biomedicine, Power, and Subjectivity in the Twenty-First Century* (Princeton University Press, 2006). His most recent book, written with Peter Miller, is *Governing The Present* (Polity Press, 2008). His current research is on the social implications of the life sciences, with a focus on recent developments in the brain sciences and neurotechnologies. He is also working on changing conceptions of life associated with synthetic biology, and is a Principal Investigator for a research Centre for Synthetic Biology and Innovation, jointly between LSE and Imperial College, London. He is a member of numerous advisory groups including the Nuffield Council on Bioethics, and Chair of the European Neuroscience and Society Network.

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André SYROTA was appointed Director General of Inserm, the French national institute of health and medical research, in October 2007 becoming in March 2009 Chairman and CEO. He received a mandate from the Ministers of Higher Education and Research, and Health in November 2007 to reorganize and coordinate all biological and health sciences research programmes in France. To meet the challenge posed by government – the development of a viable scientific strategy for France that is more visible and reactive – Inserm has created eight thematic institutes covering broad topics in the major areas of biomedical research. An M.D., Ph.D., and Professor of Biophysics and Nuclear medicine at the University of Paris-Sud, he was head of the Service Hospitalier Frédéric Joliot (CEA, Orsay), one of the leading European nuclear medicine and medical imaging research institutes (1984-2007). He was Director of the Life Sciences Division of the French Atomic Energy Commission between 1993 and 2007. André Syrota is the author of more than 200 articles and 40 book chapters. He is a member of various boards at the Ministry of research and of national institutes. He is also a member of scientific assessment committees in the fields of biophysics and medical technology.

Jochen TAUPITZ, Professor Dr., studied law in Göttingen and Freiburg from 1973–1978. He received his doctoral degree from the University of Göttingen in the year 1981, passed the higher state examination in law in 1982 and became a university lecturer in Göttingen. In 1988 he received his habilitation from the University of Göttingen with a post-doctoral thesis on the professional codes of ethics. From 1988 to 1989, he was a university professor in Göttingen. Since 1990 he has held the position of a full professor for civil law, civil procedure law, private international law and comparative law at the University of Mannheim. From 1996 to 2002 he also performed secondary duties as a judge at the Higher District Court (Oberlandesgericht) of Karlsruhe. In addition, since October 1998, he has been the Managing Director of the Institute for German, European and International Medical Law, Public Health Law and Bioethics of the Universities of Heidelberg and Mannheim. He has rejected offers of a university chair at the universities of Kiel (1993), Bonn (1997) and Heidelberg (2003) and also declined the position of Director of the Swiss Institute for Comparative Law (2003). Among other appointments, he is a member of the German Ethics Council, member of the Board of Directors of the Central Ethics Committee at the German Medical Association, member of the Ethics Committee for the Medical Faculty of Heidelberg University, member of the Board of Directors of the German Association of Medical Ethics Committees, head of the Advisory Council on Questions of Principle of the German Association of Medical Ethics Committees, member of the Board of Directors of the Academy for Ethics in Medicine as well as member of the European Academy of Sciences and Arts.

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BIOMEDICAL RESEARCH IN CHINA AND EUROPE:

THE FUTURE OF RESEARCH COLLABORATIONS

BIONET FINAL CONFERENCE, 2-4 SEPTEMBER 2009, LONDON

HENRY WELLCOME AUDITORIUM, WELLCOME TRUST

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