

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

**Final Report**

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# Preface and acknowledgments



This is the final report of the BIONET project, an inter-disciplinary China-Europe collaboration on the ethical governance of biological and biomedical research consisting of 20 partners from Europe and China. Over the last three years (2006-2009) we have organized a total of 6 events on key areas of advanced life science research – 4 workshops (Beijing, Shanghai, Xi’an and Shenzhen and 2 conferences (Changsha and London) covering issues of ethical governance in reproductive medicine, regenerative medicine, stem cell research, clinical trials research, biobanking and genomics research. Workshop reports from each of these events are available online at ([www.bionet-china.org/](http://www.bionet-china.org/)).

In this report, we summarise some of the key findings from the BIONET workshops and conferences. The report is presented in tandem with two other key outputs from the BIONET project – a set of recommendations on best practice in the ethical governance of life sciences research prepared by the BIONET Expert Group and a BIONET textbook on issues of ethical governance in Sino-European research collaborations edited by Ole Döring and with chapters written by workshop participants as well as BIONET’s exchange students.

This report has therefore been produced as a collective effort with input from BIONET’s partners: Nikolas Rose, Herbert Gottweis, Qiu Renzong, Lu Guangxiu, Cong Yali, Hans Galjaard, Margaret Sleeboom-Faulkner, Christoph Rehmann-Sutter, Zhai Xiaomei, Ole Döring, Alicja Laska-Formejster, Renata Salecl, Paul Unschuld, Yang Huanming, Dominique Memmi, Nick Bunnin, John Telford, Jack Price, Genevra Richardson, Peter Propping and Wolfgang Hennig. The bulk of the writing was undertaken by Dr Ayo Wahlberg, and the BIONET partners express their thanks to him for his invaluable contributions to this report, and to the work of the BIONET over the past years.

BIONET would also like to express its sincere thanks to the over 300 scientists, clinicians, lawyers, ethicists, policymakers and others who participated in and contributed to BIONET meetings. It is on the basis of discussions and debates at these events that this report has been prepared. The openness of the discussion was impressive, and the vigour of the debate shows how seriously these issues are being taken, in both Europe and China. This promises well for future collaborations.



Epidemiology research in Dai Community, Yunnan province



**Since the beginning of the 21st century, collaboration between and within China and Europe in life sciences and biomedical research has significantly intensified.**

Whether in pursuit of genomic, stem cell or clinical research to further develop forms of regenerative medicine, personalised medicine or genetic testing, scientists in China and Europe are working together in a

variety of different ways. A Sino-Danish collaboration on the genomics of cardiovascular disorders in Shenzhen, Sino-German cooperation on stem cell research in Changsha and clinical trials research in Beijing for a Swiss pharmaceutical company are but a few examples.

Ever since WWII, countries throughout the world have been developing governance procedures to protect the safety, rights and dignity of individuals who participate in biomedical research

Through such inter-cultural research collaborations, 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 the information derived can be transported instantaneously throughout the world electronically. Biomedical treatments developed in one place are 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.

Biomedical research depends, on the one hand, on human subjects – either as donors of human biological materials (gametes, embryos, blood, bone marrow, tissue) and/or biographical information, or as recipients of therapies in clinical research – and on the other, scientists and medical professionals who operate within their particular regulatory, technological, institutional and cultural settings. More generally, it depends on efficient ways to organise best research practice according to the standards of all relevant disciplines and governance bodies. The purpose of such research is the improvement of biomedicine (including conditions for research and fundamental science), the enhancement of medical technology and the well-being of patients and potential consumers.

Accordingly, 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 fair and transparent. These have been very much national efforts to introduce legislation and to build up statutory systems of ethical review, especially in human subjects research. While international scientific communities have long accepted general ethical and legal standards beyond such national focus in many

## How can a national diversity of systems of ethical governance of biological and biomedical research cope with increasingly global life science research collaborations?

areas of research, global conventions and declarations have been difficult to enforce.

In particular, 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' in life science research, the moral acceptability of research cloning, inter-species embryos and genetic modification, the appropriate use of genetic information as well as how to organise normative procedures such as 'informed consent' in different cultural contexts. And again, many of these questions have been addressed in different ways in countries and communities across the world.

This sharing of work between states, scientific and medical communities, civil society organisations and others has taken place without much attention to the question of how ethical governance of research can be established for the benefit of all in situations where cross-cultural and international differences are concerned. Over the last three years, BIONET, an interdisciplinary and multinational China-Europe co-operation on the ethical governance of biological and biomedical research has been examining emerging patterns and consequences of growing scientific co-operation between two major regional players in the field of contemporary life

sciences and biomedicine, Europe and China. A key question for BIONET has been: How can a *national diversity* of systems of ethical governance and ethical deliberation about biological and biomedical research cope with increasingly *global life science research collaborations*?

In this report, key findings are presented from 5 workshops and conferences held in Beijing, Shanghai, Changsha, Xi'an and Shenzhen on the topics of reproductive and regenerative medicine, stem cell research, clinical trials, biobanking and genetic testing. Each event examined ethical issues arising in these fields of research while also mapping out existing practices of ethical governance. During these events, discussions were organized with individual scientists and stakeholders who had been invited to speak to selected topics and in view of issues that might arise for international collaborations. These inputs form the material basis and limitation of BIONET's findings.

The report begins by providing an overview of the kinds of biological and biomedical research involving human subjects that have been the focus of BIONET as well as the key ethical challenges surrounding them. As already noted, such research relies on human subjects as either donors of biological samples and/or biographical information for laboratory-based biological research or as recipients of innovative therapies in clinic-based research.

Forms of ethical deliberation, ethical regulation, ethical oversight and ethical interaction are crucial for the ethical governance of life science research in any given country let alone in international collaborations

The report then maps out different 'layers' or 'spheres' of governance when it comes to international bioscience cooperation, from global to national, institutional and local contexts of life sciences research. Forms of ethical deliberation, ethical regulation, ethical oversight and ethical

interaction are identified as crucial for the ethical governance of life science research in any given country let alone in international research collaborations. The report concludes by looking at how global life science collaborations must increasingly navigate through a plurality of ethical governance systems.

BIONET workshop on reproductive technologies, April 2007, Beijing



# The new biology and its human implications



**It was around the mid-20th century that a 'new' biology emerged powered by new microscopy technologies and biochemical techniques.** Ever since the elucidation of the molecular basis of heredity in 1953, impressive developments have taken place both in basic research and in applications of gene technology in a variety of areas. New insights have been gained in the way the DNA code is translated into proteins that determine the structure and functions of cells and the processes of cell division. Consequently, differentiation and embryonic development are much better understood. It has become possible to transfer (parts of) DNA from one organism to another and to switch off or change a single gene. In 1990, the first approved gene therapy to repair a genetic error was given to a child suffering from severe combined immunodeficiency. By the turn of the millennium, the complete human genome had been sequenced and by 2009 the genomes of hundreds of plants, microorganisms and (higher) animals had been sequenced.

All of these developments – some speak of a 'genetic revolution' – have also led to practical applications: in agriculture, the study of evolution, forensic medicine, (prenatal) diagnosis of human disease, the prediction of individual susceptibilities for specific diseases and the prediction of response to treatment in the design of new medicines. Some even expect that the emerging field

of synthetic biology – where life is molecularly engineered 'from scratch' – will play a role in cleaning up the environment and in the production of energy. BIONET has limited itself to the implications of new life sciences research in the biomedical field.

The last three decades have also seen often unexpected developments in reproductive technology. In 1978 the first child was born following in vitro fertilisation (IVF) involving a couple who could not conceive without assistance. Today, in many countries, thousands of IVF procedures are performed annually accounting for 1-2 per cent – in some cases up to 6 per cent – of total births. The method of pre-implantation genetic diagnosis made use of the IVF technique by allowing for the removal of a single cell from in vitro fertilised embryos for genetic diagnosis before deciding which embryos should be implanted. In 1990, the world's first child was born following preimplantation selection of an embryo not carrying the genetic mutation that causes Cystic Fibrosis. Six years later the world's first cloned mammal (Dolly the sheep) was born using a technique known as somatic cell nuclear transfer (SCNT) whereby an egg cell's nucleus is removed (leaving an 'empty' shell) only to have an adult cell injected into it which is then shocked into dividing using a direct current pulse thereby creating an embryo which is (practically) genetically identical to the donor of the adult cell. Two years later, in 1998, the first successful human

## Developments in the life sciences have raised concerns and emotional debates about their social, psychological and ethical implications

embryonic stem cell line was derived by American investigators raising hopes that regenerative medicine (therapeutic use of stem cells) might be able to cure human diseases like diabetes, heart muscle failure or neurodegenerative disorders.

Each of these developments has raised concerns and emotional debates about the social, psychological and ethical implications of the new life sciences. In many countries this has resulted in legislation restricting some kinds of research. At the international level, the UN Education, Science and Culture Organisation (UNESCO), the World Health Organisation (WHO), the Council of Europe and other organisations have published declarations and guidelines aiming to ensure respect for human rights and dignity and to secure the individual safety of those participating in biomedical research.

In UNESCO's Universal Declaration on Bioethics and Human Rights (Paris, 19 October 2005), governments from all over the world take note of:

*the rapid developments in science and technology, which increasingly affect our understanding of life and life itself [and]... the ever-increasing dilemmas and controversies that science and technology present for humankind.*

Moreover, protests against so-called 'designer babies', human-animal cybrids/chimeras and cloning technologies have been staged throughout Europe and

other parts of the world. Recent controversies surrounding life sciences research have in large part concerned fears that scientists are somehow 'tampering' as they seek to manipulate, reprogram and direct human life through genetic and/or reproductive technologies. Commentators have argued that being able to do something (eg, genetic manipulation or cloning) does not mean that we should be doing it.

As successful and controversial as the new biology has been, neither has it escaped scandal. In 1999, Jesse Gelsinger was offered an experimental gene therapy for ornithine transcarbamylase deficiency (a relatively mild liver disorder) by clinical investigators at the University of Pennsylvania. He died four days later following a rapid deterioration of his organ functions. The Food and Drug Administration later ruled that the responsible clinical investigators had not informed Gelsinger sufficiently about potential serious side effects. A few years later in 2006, the 'Hwang scandal' broke in South Korea which has reverberated since. A whistleblower informed an investigative television programme in Korea that acclaimed stem cell scientist Hwang Woo Suk had in fact faked data which apparently demonstrated the first successful use of SCNT technology using human eggs and adult cells to create patient-specific embryonic stem cell lines. It also transpired that Hwang had used over 2,000 human eggs procured

from some 120 female donors some of which were paid and some of which were his junior staff members. In both cases, principal researchers were ruled to have violated principles of informed consent and research participant protection first laid out in the Nuremburg Code (1947) and Helsinki Declaration (1964) and since made enforceable through national regulations and ethical review procedures throughout the world.

As such, one might distinguish between three key areas of concern emerging out of the new biology:

**Manipulation** – advances in genetic technology have allowed scientists to manipulate living organisms at the level of DNA, the so-called ‘building blocks of life’. Genetically modified animals and plants are now commonplace and ongoing development of gene therapies suggest that genetic manipulation of humans may also become possible. At the same time, reproductive technologies allow scientists to manipulate human gametes and to initiate human conception in laboratories. Resulting embryos can also be manipulated and probed in order to generate human embryonic stem cell lines. Human or animal eggs can be enucleated and injected with adult cells to generate ‘clones’ or to create human-animal cybrids. As a result, questions are raised about what forms of biological manipulation of human life (if any) should be restricted in controlled laboratory settings. In the context of

international collaboration, the ways in which different countries control and limit the biological manipulation of human life need to be explained and synchronised.

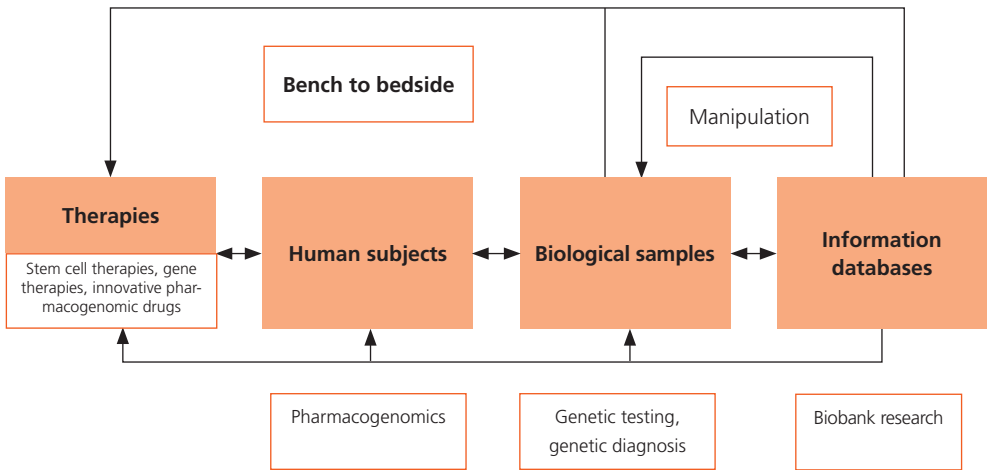
**Selection** – developments in genetic research have allowed researchers to ascertain causal relationships between certain rare diseases and localised genetic mutations on different chromosomes. Combining this knowledge with developments in reproductive technology has made possible new forms of genetic carrier testing (to see whether a couple is at risk of transmitting a certain disease to offspring), preimplantation genetic diagnosis (to select desired genetically ‘healthy’ embryos by identifying and discarding undesired embryos) as well as prenatal diagnosis (to determine whether a foetus has a certain genetic condition or disease in order to allow prospective parents to decide whether they wish to continue or terminate a pregnancy in countries where this is a legal option). It has also made it possible to select embryos for implantation which will result in an offspring whose umbilical cord blood can be used to harvest stem cells for the treatment of a sick sibling (so-called saviour siblings). Concerns have been raised that some parents will use such technologies to ‘design’ their babies and that private companies will exaggerate the feasibility of such aspirations. As such the new biology has generated questions about what forms of selection (if any) should be allowed. In the context of international collaboration, the

ways in which different countries control and limit the freedom to select human life need to be explained and synchronised.

**Exploitation** – since advanced biological and biomedical research relies on human subjects as donors of biological samples/biographical

information or recipients of experimental therapies, and since patients or clients are the targets of powerful commercial campaigns, possibilities for exploitation are ever present. For example, genetic and stem cell science have raised hopes for many persons suffering from currently untreatable conditions and

### Ethical Governance of Biological and Biomedical Research



### Some key ethical governance issues

- |   |  |  |   |
|---|--|--|---|
| <ul style="list-style-type: none"> <li>• Safety and quality</li> <li>• GMP</li> <li>• Plausibility</li> <li>• Relevance</li> <li>• Clinical trials</li> <li>• Ethical codes of conduct</li> <li>• Experimental therapies</li> </ul> | <ul style="list-style-type: none"> <li>• Informed consent</li> <li>• Genetic counselling</li> <li>• Good Clinical Practice</li> <li>• Therapeutic misconception</li> <li>• Inducement, vulnerability</li> <li>• Donation, benefit-sharing</li> <li>• Follow-up, feedback</li> <li>• Trust, exploitation</li> </ul> | <ul style="list-style-type: none"> <li>• Storage – biobanks</li> <li>• Bio-safety</li> <li>• Quality assurance</li> <li>• Donor screening</li> <li>• Traceability</li> <li>• Cultivation</li> <li>• Manipulation (GM, inter-species, IPS)</li> <li>• Status of embryo</li> </ul> | <ul style="list-style-type: none"> <li>• Data retention</li> <li>• Privacy</li> <li>• Confidentiality</li> <li>• Traceability</li> <li>• Re-consent or blanket consent</li> <li>• Discrimination</li> </ul> |
|---|--|--|---|

Most gene and stem cell therapies are at this stage unproven, yet in an age of internet and cheap air travel some patients are travelling long distances to get treatment at often high costs

assisted reproductive technologies provide many infertile couples with the possibility of having genetically-related offspring. Such patients can be particularly vulnerable as they may not have any other treatment options available. Experimental gene and stem cell therapies are at this stage unproven, yet in an age of internet and cheap air travel some patients are travelling long distances to get treatment often at very high costs. Donors of biological samples can also be at risk, especially female donors of gametes who must follow a regime of pharmaceutical ovarian stimulation as well as an invasive procedure to collect eggs. Finally, socio-economically disadvantaged persons, especially those with little or no access

to healthcare, can also be particularly vulnerable as they may be misled into taking research for healthcare. In this sense, the new biology generates concerns about 'health tourism', 'therapeutic misconception' (that is to say a participant's belief that the principle purpose of the activity is therapy rather than research or a clinical trial) and patient/donor vulnerability and therefore about what forms of safeguards and protections should be in place for research to be carried out responsibly and ethically. And, in the context of international collaboration, the ways in which different countries protect their citizens from exploitation need to be explained and synchronised, especially in view of cross-border activities.



On-site sampling for biobank research, Yunnan province

# The new challenge of international governance



While the UNESCO Declaration meets growing need for international ethical standards it is still up to States to create legal texts and instruments appropriate to their cultures and tradition

**When the Universal Declaration on Bioethics and Human Rights was adopted by member states in 2005, UNESCO pointed out that while 'the Declaration meets a genuine and growing need for international ethical standards [and] can help 'globalize' ethics in the face of the increasingly globalized sciences... it is still up to States to create legal texts and instruments appropriate to their cultures and tradition' (UNESCO 2005).**

It is exactly this potential paradox that has been at the heart of BIONET's work:

- What happens when a German scientist approaches stem cell scientists in China about possibilities to collaborate on research projects in which human embryonic stem cell lines are created (illegal in Germany yet legal in China)?
- Should a randomised controlled trial carried out in China as part of an international multicentre clinical trial commissioned by a European pharmaceutical company be ethically reviewed in Europe, in China or both?
- How should benefits arising from Sino-Danish collaboration on the genomics of metabolic disorders be shared?
- How can European researchers working in China ensure that informed consent procedures and forms are adapted to the particular

cultural, socio-economic, regulatory and linguistic context they are working in?

- What factors should the United Kingdom's Medical Research Council take into consideration before granting funds for Sino-British clinical research to develop innovative stem cell therapies?
- What guarantees should the Chinese Human Genetic Resources Administration Office require of European scientists wishing to export biological samples out of China for genetic research?
- Who are the responsible governance bodies that can ensure best practice in Sino-European research collaborations? How do they collaborate across borders?
- What role do international scientific journals have in ensuring that data emerging out of international science collaborations are not only scientifically rigorous but also ethically sound?

These have been some of the many questions tackled through BIONET's workshops and conferences which were attended by Chinese and European scientists, clinicians, lawyers, ethicists, regulators and social scientists. As a practice, global science collaboration raises important issues, on the one hand, around harmonisation and standardisation, and on the other around translation and communication. Through our workshops and conferences, we have identified

numerous 'layers' or 'spheres' that are relevant when thinking about the ethical governance of global biological and biomedical research collaborations. Each layer or sphere, and the various ways in which they overlap and interact, forms a part of ethical governance systems or regimes.

First, through debates among BIONET partners and discussions between participants at our workshops it became clear that the specific terms for national ethical governance systems are aided by some form of **ethical deliberation** – a kind of deliberative space in which science directions and national legislative frameworks for ethical governance can be debated and fixed. Each country has defined its ethical and scientific agenda which have to be communicated and, in cases of collaborations, sometimes negotiated. There are no formulas for ensuring the 'best' or 'most inclusive' forms of deliberation, but with a wealth of experiences in different countries there are plenty of lessons learned and best practices. Many countries have established national Ethics Commissions or Councils in order to stimulate and facilitate national debate, but there are also other forms of public engagement taking place led by patient organisations or civil society organisations in Europe. What matters most for the governance of research collaboration between Europe and China and also within these regions, is that all research should take place accountably within clear national

regulations and ethical frameworks. This was the starting assumption of the BIONET.

Second, the question of **ethical regulation** was often raised. Through the experiences of scientists and clinicians participating in BIONET workshops, it became clear that laws and regulations were a necessary part of any ethical framework. Distinctions were made between 'soft' and 'hard' regulation. Yet, it was also abundantly clear that gaps between regulation and implementation were often wide. Moreover, the ways in which normative documents (laws, conventions, guidelines, etc) are translated into practice and into foreign languages can be very different sometimes leading to misunderstandings. At the same time, it became equally clear that regulation was only one part of ethical governance systems which were better thought of as governance networks consisting of scientists, clinicians, regulators, patients, publics, civil society organisations, venture capitalists, research councils, biotechnology companies, scientific journals, etc.

Third, **ethical oversight** mechanisms such as institutional review boards (IRBs) or ethics review committees (ERCs) are important parts in established models of ethical governance as it is these institutions that scientists will be in direct contact with and who respond to societal and political concerns. And again,

Acquiring genuine informed consent is a complex act embedded in communicative practice, which depends on special human skills and knowledge about interacting between cultures and languages

the way in which such institutions are organised can vary widely both within nations and regionally. The important point is to ensure that effective systems are in place to ethically review any advanced biomedical or biological research proposals involving human subjects before research commences, and that these systems are adequately capacitated and accountable. With countries throughout Europe and Asia currently being in the midst of building up such systems of ethical oversight,

there were plenty of lessons learned and best practices which should be shared through capacity building with a particular focus on international cooperation initiatives. Also, science journals had a particularly important place in systems of ethical oversight, as published research should not only be scientifically rigorous but also ethically sound.

Fourthly, when it comes to human subjects research, the most visible internationally-established ethics mechanism is the signed 'informed consent' form, as a legal requirement preceding any involvement in a research study or clinical intervention. Notwithstanding numerous shortcomings identified around formal informed consent procedures and forms, these symbols that represent due procedure nevertheless remain important tools for organising and guiding **ethical interaction** between researchers and research subjects. It

became very clear that each specific form and site of research raises particular concerns about potentials for exploitation. As a result, research could be helped by detailed analyses of factors that can lead to coercion, inducement or undue influence of potential research participants. Moreover, acquiring *genuine* informed consent is a complex act embedded in communicative practice, which depends on special human skills and knowledge about interacting between cultures and languages. Empirical social science studies can play a central role here, and indeed, many presentations by social scientists at BIONET workshops focused on these questions. It also raises questions about capacity building for researchers specifically to build ethical interaction competences which take into consideration the kind of research taking place (clinical research, basic science research, etc), the kinds of human subjects to be recruited (patients, socio-economically vulnerable subjects, healthy donors, etc), languages and traditions of communication, as well as the forms of risk to which research participants would be exposed.

Ethical governance of biological and biomedical research, then, emerges as these different spheres – ethical deliberation, ethical regulation, ethical oversight and ethical interaction – interact. It is a mix of top-down and bottom-up since as a form of *governance* (rather than government) it is 'non-hierarchical',

working through systems of mutual collaboration, coordination and negotiation among and between not just state organizations (such as ministries, municipalities or judiciaries), but also a whole range of non-governmental institutions, organizations and bodies (science institutions, clinics, lawyers, academic journals, patient groups, etc). It depends upon co-operation between different agents, and systems of sharing of tasks and responsibilities which are flexible and adaptable. As such, it does not only concern written regulations and rules, but also informal working practices, peer oversight and the like. *Ethical governance* adds a qualitative element as a fundamental orientation in governance towards ethical principles, reaching beyond technical paradigms such as functionality and effectiveness.

While there may be broad consensus about what the objectives of ethical governance systems are – protection of individuals and societies from potentially negative consequences of biological and biomedical research and related medical business – there is no such agreement on just what it is that makes deliberation, regulation, oversight and interaction ethical. This then is the new challenge of international ethical governance: how to cope with a multiplicity of regulatory systems, cultural understandings, socio-economic circumstances, research quality assurance standards, forms of communication and languages? Where does such ‘ethical difference’ come from and how is it expressed and how can over-reaching governance be achieved?



Scientist at work,  
Beijing Genomics  
Institute, Shenzhen



# Ethical deliberation – stewardship and science directions in China and Europe

**One of the key discussions in the BIONET workshops has been around how deliberations about direction in scientific research take place in different countries.**

The ways in which national ‘consensus’ has emerged in each country has been very different. Moreover, national consensus can express different views or interests on different levels, such as those of the public, the government, powerful stakeholders, etc, which might not be directly comparable between countries.

In Europe, over the past decades a new form of ‘participatory governance’ in the life sciences arena has begun taking shape. As argued by members of the European PAGININI project: ‘Areas of administration and governance that were previously the exclusive domain of technical experts and of meetings behind closed doors are being opened up to public scrutiny and participation. Increasingly, government agencies are arranging for opportunities to interact with lay persons on what appear to be highly technical questions vis-à-vis regulation’<sup>1</sup>. Biology is no longer – if it ever was – an esoteric subject restricted to the laboratories, clinics, university departments, journals and academic conferences which consume the daily lives of biological and biomedical researchers. Instead, debates about whether it should be permissible to manipulate and

experiment on human zygotes or whether or not enucleated rabbit eggs should be filled with human adult cells have become public affairs.

On the one hand, national ethics commissions and councils have been created throughout Europe to watch over developments in the life sciences as well as to generate public debate. Their members not only consist of ‘expert’ scientists but also ethicists, religious leaders, lawyers and in some cases also laypersons, etc depending on the country and kind of institution. Their terms of reference have similar outlines:

*the National Ethics Council [is] a national forum for dialogue on ethical issues in the life sciences. It is intended to be the central organ for interdisciplinary discourse between the natural sciences, medicine, theology and philosophy, and the social and legal sciences, and to express views on ethical issues relating to new developments in the field of the life sciences and on their consequences for the individual and society. The National Ethics Council has up to 25 members, who represent the scientific, medical, theological, philosophical, social, legal, ecological and economic worlds and are appointed for a four-year term by the Federal Chancellor. As a rule the members hold monthly meetings in Berlin. (Germany)*

<sup>1</sup> PAGININI Project (2007) *Participatory Governance and Institutional Innovation: The New Politics of Life*, available at [www.univie.ac.at/LSG/paganini/](http://www.univie.ac.at/LSG/paganini/)

*The Nuffield Council on Bioethics was established in 1991 to identify, examine and report on the ethical questions raised by recent advances in biological and medical research. The Council is committed to developing explicit ethical frameworks, norms, and principles that can be applied coherently and consistently to the issue in hand. (United Kingdom)*

*The Irish Council for Bioethics [is] an independent, autonomous body to consider the ethical issues raised by recent developments in science and medicine. It aims to identify and interpret the ethical questions raised by biological and medical research in order to respond to and anticipate questions of substantive concern. It investigates and reports on such questions in the interests of promoting public understanding, informed discussion and education. (Ireland)*

On the other hand, public consultations and debates have been organised on issues such as genetic testing, reproductive medicine and stem cell research. Civil society actors such as religious groups, patient groups and professional organisations have been particularly vocal, so much so that some have proposed distinctions between ‘interested publics’ and ‘disinterested publics’ (ie, those with no specific stakes in a particular issue). The media has also played an important role in covering life science issues, often contributing to the controversial tone of some debates by emphasising for and against positions.

What is more, European social scientists have in recent years in earnest begun exploring ‘lay person’ or ‘patient’ views concerning such matters as genetic testing, biobanking or embryo donation for stem cell research. Such research has involved participant observation and in depth interviews with donors and research subjects as well as with scientists carrying out the research, and has therefore also brought to light the views of research participants.

In China, the situation has been different and it does not appear that such a new form of participatory governance has emerged around life sciences research in the same way. As in many European countries, a National Ethics Committee has been established in China. It is under the Ministry of Health and its mandate is to ‘develop guidelines and regulations on issues like Biomedical Research Involving Human Subjects, Administration of Genetic Resources and Ethical Guidelines on Stem Cell Research’. At the BIONET workshop on stem cell research held in Shanghai in October 2007, workshop participants debated what would constitute ‘public opinion’ (eg, on the status of the human embryo) on stem cell research in China in the absence of large-scale or longitudinal national surveys, focus group research or qualitative research among the public or donors. What is more, since China is such a large nation, some participants questioned whether it would be possible to identify a single ‘public view’.

Nevertheless, ethical issues concerning life sciences research have been introduced to China's public arenas. A growing bioethics community in China – with many of its members participating in BIONET workshops – has begun engaging not only with scientists and clinicians through capacity building workshops but also with the public by calling for more deliberation about biological research. The Ministry of Health's Ethics Committee is planning to publish its findings and opinions to encourage discussion among scientists, clinicians as well as the public. Also, initial questionnaire and interview-based research has been carried out concerning lay people's or medical practitioners' views on such issues as participation in clinical trials, the moral status of embryos or genetic databases. BIONET's own student exchange programme also promoted qualitative research among donors and participants in biomedical research.

In 2008, BIONET supported a satellite training workshop called 'Reporting Bioethics' for journalists during its international conference on ethical governance of stem cell research which was organised by SciDev.Net in Changsha. The context for the training workshop was summarised by its organisers:

*Despite the rising urgency of and media interest in bioethical issues, the media have been poorly equipped to report these issues, especially in cities outside Beijing and Shanghai. Journalists should not be blamed for the insufficiency, as bioethics issues are related to both complicated life science research and difficult ethical issues, such as in the case of how to judge whether certain research could cause harms.<sup>2</sup>*

Issues such as therapeutic cloning, human-animal hybrids and genetic testing have entered into national and local media reporting. Nevertheless, one has not seen the kind of systematised effort to involve the public through public consultations, town hall meetings or other forms of citizen participation, a fact perhaps not so surprising when considering an absence of such vocal civil society actors as Europe's many churches. Moreover, these particular issues do not necessarily reflect the concerns of all citizens living in different socio-economic and political contexts.

As concluded by participants at BIONET's Shanghai workshop on stem cell research, it is up to each country to find the right mix of biology, metaphysics and culture to fit their country's narratives. Finding this mix requires some kind of organised deliberation and the

<sup>2</sup> SciDev.Net (2008) *Reporting Bioethics, Final Report*, Institute of Science and Technology Journalism and Communication, Hunan University, Changsha, China, 31 March-1 April 2008

Spaces and arenas for ethical deliberation may not result in consensus, but they nevertheless allow for ongoing discussion and debate around which more concrete legislative frameworks are developed in each country

spaces for and ways in which this is carried out will be different from country to country. Global consensus has proved difficult as illustrated by the UN declaration on human cloning, yet national consensus can prove equally elusive. More practically, dealing with existing codes and infrastructures provides a basis to start with in efforts to establish ethical governance of Sino-European research collaborations. Spaces and

arenas for ethical deliberation may not result in consensus, but they nevertheless allow for ongoing discussion and debate around which more concrete legislative frameworks and administrative procedures are developed in each country. In accordance with BIONET's agenda, such deliberations should be brought to the level of Sino-European research collaboration.



Peking University Third Hospital, Beijing



**Throughout the many workshops and conferences organised by BIONET, regulation was a key topic of discussion.** The Declaration of Helsinki remains a landmark and in both China and Europe it can be seen to function as a general rule which ensures that considerations related to the well-being of the individual in principle should take precedence over the interests of science and society. As already noted, since the Helsinki Declaration, a number of international guidelines and conventions related to biomedical human subjects research have been formulated and adopted. Yet, as became clear through workshop discussions, guidelines and regulations are not sufficient in themselves for a number of reasons.

## Gaps between regulation and implementation

In both Europe and China, a number of regulations concerning biomedical research on human subjects have been promulgated and passed. However, while there might be broad agreement about the principles laid out in such documents – eg, informed consent or mandatory ethical review of life sciences research projects – there is a long way from regulation to implementation, a pathway that can be filled with obstacles in the form of a lack of capacity or ambiguous or vague formulations. As put by one Chinese scientist working in the field of reproductive medicine, regulations and guidelines do not always provide answers to individual cases on a day-to-day basis in the clinic or laboratory.

The most common example cited by European and Chinese researchers was the process of informed consent: how was one able to ensure that sufficient time and appropriate care was taken in very busy and often stressful working environments to make sure that patients were given the time necessary to understand risks and benefits, and to avoid a situation where informed consent is just a formality? How to ensure that informed consent is organized as a process and not just a signature? Answers to such questions could not be found in guidelines and regulations. As a result there was often a diversity of practices with some best practice institutions in China having developed strong systems for ensuring informed consent and others still working to build capacity. Indeed, some participants suggested that best practice institutions play a role in helping to raise capacity in smaller research institutions and hospitals.

## 'Hard' and 'soft' regulation

Most regulations in advanced biological and biomedical research fall under the category of 'soft law', ie, they are not legally enforceable. In Europe, there are often many different instruments used to ensure ethical supervision of research. There are national laws and regulations, the regulations of professional associations, recommendations from national ethics councils or commissions, statements of ethical review committees in research institutions or hospitals, ethical

requirements of public or private funding bodies as well as ethical requirements of scientific journals. In workshop discussions, some participants suggested that it was in particular the funders of research and international science journals who played a key role in ensuring ethical compliance as researchers would always make sure that they lived up to their requirements, otherwise they would risk losing their income or career opportunities. In particular, funding agency (eg, research councils) ethical guidelines are seen to have 'teeth'.

In China, some workshop participants spoke of a 'legislative boom' in

China over the past few decades corresponding to the policy of opening and transforming China, not least by employing standardisation measures as an instrument to foster China's international role as a global player, also in life sciences research. For example, it was noted that almost every bioethical aspect regarding biomedical manipulations, including those involving human embryonic stem cells, has been covered through regulations in order to protect the rights of human subjects and public morality, however most regulations do not enforce legal liabilities (civil or criminal) and damages.

### China's growing bioethical regulatory framework

In China, over the last ten years or so there has been a 'legislative boom' related to biological and biomedical research. The Chinese legal system consists of a range of different regulatory instruments. Laws (*fǎ* 法) are passed by the People's Congress or its standing committee and are fully enforceable by the responsible institution specified in the law. Regulations (*tiáo lì* 条例) are approved by the State Council and are also enforceable. Technical norms or standards (*jì shù guī fàn* 技术规范) which are intended to ensure safety and effectiveness, and ethical principles (*lún lǐ yuán zé* 伦理原则) which are intended to maintain social order, on the other hand are only enforceable if they are specifically authorized in the text of a law or regulation. Finally, there are also administrative measures (*guǎn lǐ bàn fǎ* 管理辦法) which are directed at the administration and management of certain research and therapeutic practices and which are binding for those institutions, which are licensed to carry out these practices.

As concerns life sciences research these have been some of the key regulatory stipulations concerning biological sample collection, manipulation of human biological materials and testing of biological therapies on humans:

1998: Interim Procedures for Human Genetic Resources Administration (State Council, Ministry of Science and Technology and Ministry of Health)

led to the establishment of the Chinese Human Genetic Resources Administration Office. These procedures were strengthened in 2003 and they specify rules for exporting and importing genetic materials.

2003: Regulations on Standards and Norms for Clinical Drug Research Quality Control (State Food and Drug Administration) established Good Clinical Practice guidelines including protection of research participants.

2003: Ethical Guiding Principles for Research on Human Embryonic Stem Cells (Ministry of Science and Technology and the Ministry of Health) set out guidelines for what kinds of research and manipulation would be acceptable.

2004: Administrative Measures on Biosafety in Laboratories with Pathogenic Microorganisms (State Council, Ministry of Science and Technology).

2007: Regulations on Misconduct in Scientific Research (Ministry of Science and Technology), led to the establishment of a science ethics committee and a supervision office to stem academic fraud and plagiarism.

2007: Regulations on Ethical Review of Biomedical Research Involving Human Subjects (Ministry of Health).

2009: Administrative Measures on Clinical Applications of Medical Technologies (Ministry of Health), prohibits clinical use of embryonic stem cells and introduces new approval procedures for autologous stem cell therapies.

Notwithstanding this expanding regulatory framework for biological and biomedical research questions remain as to whether enforceable legal liabilities (civil or criminal) have resulted.

### Fast science, slow regulation

Another shortcoming of regulation relates to the process of formulating them. When compared to the fast pace of scientific discovery and research, regulation will inevitably always be trying to catch up. Chinese speakers at the BIONET Shanghai workshop noted that it had become an increasingly laborious and slow process to prepare legislation related to life sciences research involving human subjects since it overlapped

the areas of different Ministries and also since formulating laws and regulations involved consultations with numerous experts from the legal, bioethical, social and medical fields. For example, even during the duration of the BIONET project (2006-2009) developments in induced pluripotent stem cell research had raised the question of whether scientific progress itself will make current ethical concerns (focused on human embryos) redundant while introducing

When compared to the fast pace of scientific discovery and research, regulation will inevitably always be trying to catch up

a new set of concerns – not how stem cells are derived, but what we should do with them. In genomics research, thanks to new sequencing technologies, new findings were being published on a regular basis with possible consequences for biobank projects and research participant follow-up requirements.

### International harmonisation

Finally, in the context of global science, a number of regulatory gaps appear as different nations adopt different approaches to regulating areas of life science research. That is to say, national regulations cannot in themselves prevent or restrict any kind of research in global context of regulatory diversity. For example, some countries are considered to have permissive regulation and others restrictive regulation when it comes to stem cell research by classifying them according to whether or not they:

- 1) prohibit research involving destruction of human embryos and/or production of 'spare' embryos
- 2) allow creation and research on 'spare' embryos donated by couples in IVF clinics
- 3) allow the creation of embryos for research through Somatic Cell Nuclear Transfer (SCNT)

4) allow research only on imported hESC colonies

5) allow the creation of human-animal hybrids for research purposes.

Moreover, global regulatory uncertainty has also fuelled 'stem cell tourism' as patients travel to various parts of the world to receive experimental treatments not available in their own countries. The point being that global science makes it impossible for single nations to prohibit any kind of research on their own.

This diversity raises numerous questions: To what extent is moral consensus necessary and achievable? How to find policies under circumstances of moral diversity in fundamental questions? Does it make sense to harmonize laws in a globalizing world?



Explaining research to a patient, Reproductive and Genetic Hospital, Changsha

# Ethical oversight – building ethical review capacity



**One of the most important instrumental aspects of ethical governance systems is oversight and adherence.** For it is the principle objective of all ethical governance systems to protect the rights, safety and well-being of human subjects who participate in biological or biomedical research and this implies some kind of oversight of the research process – from recruitment of research subjects, carrying out of research, publication of research to follow up of research participants; and to encourage researchers to pro-actively collaborate in this endeavour.

One key lesson emerging from the case of Hwang Woo Suk in South Korea, is that a separation of science from ethics is no longer (if it ever was) tenable. Once the primary hallmark for ensuring good quality science in biological and biomedical research, peer review has today been joined by ethical review as an equally relevant guarantor of good science. In human subjects research, ‘tainted data’ is not only that which has been fraudulently fabricated or manipulated, it is also that which has been unethically procured. Peer review and ethical review have become inseparable as ‘good science’ is upheld against standards of both rigour and ethical conduct. In particular when it comes to biomedical human subjects research, good science is not only efficient, rigorous, accurate and evidence-based, it is also ethically responsible and protective of human rights and dignity.

Peer review systems that aim to ensure scientific integrity have been developed over many decades, although they have not prevented all cases of scientific misconduct in China or Europe. Nevertheless, there remains plenty of scope for capacity building when it comes to peer review although the particular issue of scientific integrity has not been central to BIONET’s work. Ethical review, on the other hand, has been.

It is only in relatively recent years that ethical review systems have come to be organised at a national level. In Europe, ethical review boards were established locally on an *ad hoc* basis from around the 1960s, often as a result of public debates about cases of misconduct, scandals or disputed practice. It was not until the 1990s that European governments began taking steps to recognise, consolidate and coordinate their work regionally and nationally. The ways in which the work of ethics review committees is organised varies greatly from country to country, with some emphasising institutional levels and others centralising the task of ethically reviewing scientific research. In China, there has also been an initial focus on establishing institutional review boards but the government has stipulated that administrative departments of health at the provincial level all set up consultation organizations on ethical review to ‘guide and supervise the ethical review by institutional review boards (IRBs) under their jurisdiction’. The entire IRB system is currently being developed.

Described mandates are very similar in both China and Europe, namely to provide public assurance by giving an informed opinion on:

- the scientific research being proposed – scientific merit
- the suitability of the investigators (their qualifications and knowledge of the research topic)
- the adequacy of facilities
- the adequacy of analyses of benefit and harm as well as possible adverse effects
- the methods and documents to be used to inform trial subjects and obtain their informed consent (with special attention to persons without the capacity to consent / minors)
- the arrangements for the recruitment of subjects
- the amounts and arrangements for rewarding or compensating investigators and trial subjects (with special attention to inducement and conflicts of interest)
- the adequacy of insurance arrangements

Membership of ethics review committees is also a key issue as there has been a move to encourage broad participation so as to ensure independent opinions. China's Regulation on Ethical Review of Biomedical Research Involving Human Subjects specifies membership as follows:

*Institutions implementing biomedical research involving human subjects and application of relevant technologies... shall set up Institutional Review Boards. IRBs shall mainly undertake ethical review and carry out ethical review and supervision over biomedical research involving human subjects and application of relevant technologies... Members of IRBs shall be elected by those departments or institutions setting them up, and shall be chosen from among experts in such fields as biomedicine, management, ethics, law and sociology after extensively soliciting opinions. The members of each IRB shall not be less than 5 and shall include both male and female. IRBs in ethnic minority regions shall consider including ethnic minority members.*

### **IVF patients, pregnant mothers and stem cell donors**

In China's Hunan province, the Central South University's Institute of Reproductive and Stem Cell Engineering is housed in the same building as the Reproductive and Genetic Hospital CITIC-Xiangya in China's Hunan province. Stem cell researchers get their embryos from embryologists at the fertility clinic. And as an unexpected side effect of China's 'one-child' policy, there is no shortage of supply. As a result, the Hospital has over the last years built up a rigorous ethical review system, initially in the clinical context of Assisted Reproductive Technologies and more recently in the context of stem cell research.

The Hospital has therefore established an Ethics Committee Office complete with secretariat and staff which has developed 62 different informed consent forms covering assisted reproductive technologies, genetics technologies and stem cell research. The Ethics Committee consists not just of hospital administrators but also of doctors, nurses and psychologists.

Couples undergoing infertility treatment at the Hospital are asked whether they wish to discard or donate not just so-called 'bad quality' or 'spare' embryos which will not be implanted but also if they wish to discard or donate to research any 'leftover' frozen embryos following a successful birth (some couples choose to freeze any 'good quality' embryos which will not be transferred in the first cycle of treatment in case treatment fails). A random analysis of 414 signed informed consent forms in Changsha had shown that in 62 per cent of the cases patients had indicated that they would donate frozen 'spare embryos' following successful delivery of a healthy baby.

Stem cell scientists also collaborated with local hospitals which provided cord blood samples for stem cell research. In the past, obstetrics departments had charged an administration fee to provide cord blood samples from the 'biological waste' following a birth. Informed consent was not a requirement. However, since the Ministry of Health promulgated new regulations for cord blood banks in 2001 according to which pregnant women must consent to donating cord blood, new informed consent procedures have had to be developed to ensure that pregnant women are in good time informed about what cord blood donations would be used for.

In both cases, doctors and nurses at the Reproductive and Genetic Hospital have underlined that patient trust is the most important factor for consent. The patients must be confident that their biological samples will not be misused.

While a requirement to ethically oversee biomedical research has by now been enshrined in national law throughout Europe and China, putting such oversight into practice is a process with numerous hurdles and challenges

Yet, while a requirement to ethically oversee biological and biomedical research involving human subjects has by now been enshrined in national law throughout Europe and China, putting such oversight into practice is a process with numerous hurdles and challenges – which are again complicated when both regions are connected through research collaboration. In each of the fields covered by BIONET – reproductive medicine, stem cell research, clinical trials and biobanking – a consistent point made by many workshop participants was that with China being such a vast country there is a variability of institutional practices under the same standards. There are good ethical review practices in top hospitals and laboratories but more problems in less-resourced hospitals and laboratories or in differently developed regions. Among the problems highlighted by scientists and clinicians in China were:

- Lack of independence – many ethical review committees were chaired by the heads of hospitals and external members often did not have voting rights
- Conflicts of interest arising from researchers' financial interests
- Lack of resources to monitor and follow up once research has been approved

- Researchers tend to give yes/no answers with insufficient commentary on issues of researcher qualifications, risk-benefit analyses, informed consent and compensation
- Lack of qualified members for ethical review committees, members may have basic training in Good Clinical Practice but not in ethics
- Lack of resources for ethics committees to train researchers
- There are still large discrepancies in the quality of informed consent, examples range from half-a-page to 4-5 pages – insufficient explanation of randomisation, placebo, other available treatments, risks, adverse effects
- No attention to insurance questions – the most frequent source of dispute comes from disagreement about compensation if adverse or harmful effects result from participating in a clinical trial

Two constructive proposals were aired and debated at meetings in Changsha and Xi'an: firstly, so-called 'centres of excellence' could play an important role in promoting and sharing their best practices with other less-resourced laboratories and hospitals. This would amount to a provisional two-layer development zone model, in which the more advanced institutions would establish more rigorous regimes of ethical review and the developing zones

would gradually be capacitated to catch up. Secondly, smaller hospitals and laboratories could pool their resources and, for example, form joint ethical review committees. Building ethical review capacity has become a priority for the Ministry of Health and the bioethics community in China is actively supporting such initiatives by providing training for ERC and IRB members.

Whereas capacity building in ethical oversight of clinical research is well underway, an extra effort is required in connection with research proposals which rely on donations of biological samples

Another key point to make concerning ethical review is that, to date, much of the work around ethical review committees and institutional review boards has focused on clinical trials and clinical research. Yet, with the rising tide of 'biobanking', collection of biological samples (whether from patients or healthy volunteers) has become an equally important component of advanced life sciences research. This means that any capacity building efforts should also be directed at laboratories and hospitals which collect biological samples for research purposes. It is only in recent years that the use of formerly

so-called 'biological waste' (eg, following births, surgical procedures or diagnostic tests) has become subject to the informed consent of those from whom it originates, whether in Europe or China. Some of our workshop participants described resistance on the part of their colleagues who had perhaps for years been taking an extra vial of blood during diagnostic tests for research purposes without necessarily informing patients. Also discussed were examples from both a Chinese and a European biobanking project in which informed consent forms stated that 'There are no known risks involved with this study. The collection of blood may cause a small amount of pain' and 'Your participation in the study does not involve any particular risk. The blood test corresponds only to the taking of standard blood test.'

As a result, whereas capacity building in ethical oversight of clinical research is well underway, an extra effort is required in connection with research proposals which rely on donations of biological samples (gametes, embryos, blood, saliva, urine, etc) as well as biographical information from research subjects.

# Ethical interaction – grounding research in local contexts



**Once biological and biomedical research proposals have been prepared, ethically reviewed and funding secured, the mundane, everyday work of scientists**

**begins.** Patients or donors have to be recruited, informed consent sessions have to be organised, (if appropriate) reimbursement arrangements have to be administratively formalised, (where applicable) schemes for benefit-sharing have to be developed and follow-up procedures with research participants have to be arranged. Traditionally, informed consent procedures and forms have been seen as the most important tool for ensuring that interaction between researchers and patients is ethical and legal. Signed consent forms are considered the most important component of ethical audit trails which, should research subjects suffer from unintended consequences or disagreements arise, researchers must be able to produce to document that they have acted ethically by communicating due information.

In by far most cases, ethical oversight of scientific research ends once a research proposal has been ethically reviewed and approved. There is little follow up or quality control of informed consent processes, not least because of a lack of resources. Yet it is exactly at this stage that research integrity is most under pressure from multiple directions. A university might be pressuring senior researchers who in turn might be putting pressure on junior researchers to 'get some

results', conflicts of interest can arise if researchers have financial interests in the research at hand, community research projects can have unintended consequences on community cohesion if certain members of the community are excluded while others are included in research projects, patients may feel that saying no to participation will affect their access to medical treatment, etc. Moreover, the pressures of limited resources and time mean that informed consent processes can quickly become routinised and bureaucratic, a matter of signing a form with minimal interaction around and explanation of intended research.

In workshop discussions concerning informed consent procedures and forms, most agreed that these were not sufficient in themselves to protect and safeguard research participants (whether in the context of reproductive medicine, clinical research or biobanking). Yet they were nevertheless described as a necessary sign of respect shown by researchers towards research subjects – they serve as a point of departure for a relationship between scientist and a potential participant in a research project. Moreover, widely debated distinctions between so-called 'Western' notions of autonomy and rational choice which focus on the individual on the one hand, and 'Eastern' notions of harmony and the collective (family, village, Nation) on the other, are difficult to maintain empirically, as both regions appear

to be sharing the same basic ethical intuitions in this regard. In both China and Europe, family and close friends are most often consulted before important decisions are made, especially if these are seen to have some kind of financial consequences. And also, in both China and Europe similar concerns are shared about the potential exploitation, for example of women for procuring oocytes or of desperate patients willing to try anything. The more important point to be made is that informed consent processes must be embedded into local contexts with due understanding and recognition of cultural norms and social practices, wherever research takes place.

There is an extensive literature on informed consent as concerns clinical research. With BIONET's focus on advanced life sciences research, we have identified four particular areas of concern related to ethical interaction between researchers and potential/ actual research subjects.

### Concern 1: Vulnerability – contexts of inducement and coercion

The assumption behind informed consent is that most individuals are capable of and should be responsible for making decisions about whether or not to participate in biological or biomedical research. By providing individuals with sufficient good quality and appropriate information and without putting undue pressure

upon them, they will be able to decide whether they would want to take part in a particular research project. Yet, there are three important ways in which this assumption has been challenged, especially through empirical social science research which has focused on how research subjects experience their participation in biomedical or biological research. First, it is very often the case that potential participants are either not given the time or do not take the time to read informed consent forms. Moreover, scientific research objectives can be complicated and risk-benefit information complex. Second, it is not often that an individual will make decisions about participating in medical research on their own. They may ask their doctor (who might be recruiting them) 'what would you do?', they may seek out information on the internet or they may discuss matters with friends and close family. Even if it is an individual who signs an informed consent form, this does not mean that a decision has been 'autonomous' raising the question of when influence is 'undue'. Thirdly, and perhaps most importantly, there are very often factors other than enlightenment which can influence a decision to participate in biomedical or biological research.

Vulnerability is a concept used to describe situations where certain individuals are in need of special protection because of their circumstances.

Traditionally, informed consent procedures and forms have been seen as the most important tool for ensuring that interaction between researchers and patients is ethical and legal

**Capacity to consent** – much of ongoing debate concerning vulnerability in human subjects research has been about so-called ‘capacity to consent’. The less individuals are considered to be capable of autonomously consenting the more vulnerable they are considered to be, eg, mentally impaired or minors. Individuals deemed incapable of consenting should usually not be included in clinical research, and if they are special protections must be afforded them and consent must be sought from legal guardians.

**Authority to consent** – in some cultural contexts distinctions between community consent, family consent and individual consent suggest that there can be differences in opinion as to who has ‘authority to consent’. The assumption that if an individual is capable of consenting then it will always be him or her who has the autonomous authority to consent is challenged in certain contexts. Indeed, research projects which enter into certain communities can disrupt forms of social organisation by bypassing established forms of consultation and decision-making and insisting on individual consent. For example, medical care in China has become increasingly commercialised over the last two decades meaning that health care decisions will often have financial consequences and must therefore be agreed by families. And since participating in medical research will

often impact health care, individuals may not be considered to have the ‘authority to consent’ autonomously.

**Poverty and lack of health care** – when research is carried out in resource-poor settings, socio-economic circumstances can be another vulnerability factor. Indeed, for some, participation in medical research means access to basic healthcare which might otherwise be difficult or expensive to obtain. In such cases, it is difficult to avoid some form of inducement as there are clear advantages from participating as opposed to not participating. Some argue that the more poor and uneducated individuals are the less possible it is to ensure free and informed consent. In such models, non-coerced informed consent is not possible unless an individual’s education and socio-economic status has reached a certain level. Others argue that this builds on outdated, patronising and ‘Eurocentric’ ideas about civilisation and rationality, and that free informed consent is possible in any socio-economic circumstances as long as informed consent procedures and forms are adapted to local circumstances. The debate about whether or not informed consent is possible in all socio-economic contexts also runs the risk of reducing informed consent to a legal-technical formality and the act of communication itself to a mere response to the form instead of to the matter at stake.

One model of vulnerability according to education and socio-economic status discussed at BIONET <sup>3</sup>	
<b>A</b>	Educated and economically sound sections where the conditions for individual informed consent are not socio-economically constrained.
<b>B</b>	Educated though economically less well-off sections, living under extended family set-ups where decision-making process is a collective exercise, often with dominant participation of father or husband and the individual's choice is subordinated to family perspectives or even to extraneous considerations.
<b>C</b>	Less educated, economically underdeveloped groups/populations where a community head has a say in matters relating to individual's private life.
<b>D</b>	The very poor whose main concern is to safeguard his/her survival. Conditions for individual informed consent are virtually nonexistent.

Doctor-patient relationships – relationships between healthcare providers/researchers and patients can lead patients to say yes to participating in research for fear of damaging their relationship with a doctor. Insufficient studies among research participants have been carried out to date in China, but some initial pilot studies presented at BIONET workshops have suggested that a major reason that patients participate in research is to get therapeutic benefit or to cure their disease. Some patients also suggest that they agree to participate in research in order to ensure a better relationship with their doctors. The inherently unequal relationship between doctors and patients means that direct or structural

coercion is an ever present possibility, especially if conflicts of interest occur. For example, the links between reproductive medicine and stem cell research have been intimate since embryonic stem cell research has hitherto relied on a steady supply of 'spare' eggs and embryos and as a result, in many cases, stem cell laboratories have been established in close proximity to and in partnerships with IVF clinics. This proximity can create conflicts of interest, as there may be undue pressure on clinicians to stimulate 'extra' eggs or to create 'extra' embryos for research rather than reproductive purposes. In recent years, doctor-patient relations are seen to have deteriorated considerably in China due to increasing commercialisation of health

<sup>3</sup> Source: Adapted from R R Kishore (2008) 'Clinical Trials: The Indian Perspectives', presented at BIONET Xi'an workshop, 9-12 September 2008

care combined with high expectations of modern medicine.

**Patient desperation** – finally, as already noted, with advanced biological research promising stem cell and gene therapies for hitherto untreatable conditions desperately ill patients might be easily convinced to participate in medical research. In these situations, the less treatment options an individual has, the more vulnerable they are seen to be.

If the point of departure of interactions between researchers and research subjects is some kind of informed consent procedure which marks a sign of respect shown by researcher to research subject, then ethical interaction between them must take into account every factor which might lead to undue influence, coercion or inducement. Research subject vulnerability is multi-faceted and directly correlated to risks of coercion, inducement and exploitation. What BIONET workshops have shown is that there is no ready-made answer as to which situations will automatically lead to unethical interaction, but a willingness to acknowledge and analyse potential pitfalls before, during and after research can help ensure that measures are taken to counteract these. A great deal of collaborative social scientific research and conceptual reflection will be necessary in order to work out the multi-faceted realities to which ethical governance needs to respond on the ground.

## Concern 2: Experimental therapies

As already noted, advanced life sciences are surrounded by narratives of hope, promise and even hype. There are hopes that regenerative medicine and gene therapies will provide solutions to some of the most debilitating conditions in the world, from neurodegenerative diseases to cardiovascular disorders and spinal cord traumas. And although most scientists working in these fields will point out that stem cell therapy is still a long way off, as any random internet search will show many forms of stem cell therapy are currently to those who can afford it. Indeed, stem cell tourism has become a growth business, even in the absence of mature and approved therapies.

Many of the most important medical advances in history have required 'experimentation' on human health and lives with casualties but also with significant benefits for future patients. Arguably, 'too much' caution can slow down innovation and medical advances. Yet on the other hand, good science is based on thorough, sceptical and time-consuming scrutiny. As put by one stem cell scientist, if 'we don't understand the biology enough' at this stage, should patients be subject to experimental treatment? How should caution, a 'pre-clinical' requirement to know biological modes of action, patient safety and clinical experimentation be balanced?

### **'Tomorrow's medicine today!' – global stem cell tourism**

Medical tourism is nothing particularly new. It flows in all directions from North to South, West to East and vice versa. Affluent westerners travel to top-class medical facilities in Asia or the Caribbean for routine medical operations at lower cost and shorter waiting times, fertility tourists from all over Europe travel to Spain in search of oocyte donors and so-called 'National Health Service tourists' travel to the United Kingdom, France and other countries to benefit from universal healthcare services. In more recent years stem cell tourism has emerged as a new form of medical tourism whereby patients travel to different countries to get access to experimental therapies which might not otherwise be available in their countries of origin.

Private clinics throughout the world are taking advantage of the ambiguous status of experimental therapies in many countries. Extravagant claims are made about the purported curative properties of stem cells in the treatment of Alzheimer's, spinal cord injury, multiple sclerosis and many other diseases. Patients are recruited through internet sites (eg, [www.stemcellschina.com](http://www.stemcellschina.com)) and personal networks. Patient blogs, testimonials as well as 'before and after' video clips feature prominently on these sites. Patients are offered 'treatment packages' including accommodation, medical check ups and of course a course of stem cell injections. Patients can pay anywhere between \$10,000 and \$40,000 for a single treatment which usually consists of 2-3 injections of stem cells. Little or no information is provided about the quality and/or origin of stem cell lines used in treatment.

In Europe, stem cell therapies fall under the recently adopted Regulation on Advanced Therapies and in China, as of 1 May 2009 a new set of Administrative Measures on Clinical Applications of Medical Technologies came into force requiring that stem cell therapies be subject to rigorous safety and efficacy trials. These regulations notwithstanding, stem cell 'therapies' continue to be available to those patients willing to pay in both Europe and China.

One of the key ethical challenges for current clinical testing of stem cell therapies is how to proceed when not much is known about the biological mode of action of stem cells as they are used to treat degenerative diseases or brain trauma. For interaction between researchers and research

subjects, as a minimum, experimental therapies should be subject to strict application of existing clinical protocols, ethical review and informed consent procedures and where safety of the patient is the priority; ideally embedded in a comprehensive system of ethical and social checks and balances. In

Europe, cell and gene therapies, in addition to several national codes, fall under the Regulation on Advanced Therapies (2007) which sets out a system of scientific evaluation (safety, quality and efficacy of advanced therapies), a traceability system for monitoring starting materials (cell lines), products and patients and a central approach to marketing authorisation of products across the EU. In China, a set of central national Administrative Measures on Clinical Applications of Medical Technologies came into force in 2009 which designate all forms of stem cell therapy and gene therapy as Category 3, ie, those that are ethically problematic, high risk or still in need of clinical verification. The Ministry of Health is now responsible for regulating

Category 3 therapies in order to ensure safety, quality and efficacy.

This, however, is in stark contrast to the kinds of stem cell therapy patients can pay for in different parts of the world today including China and Europe. In many cases, there is no way for patients to know whether the stem cell injections they are receiving are of clinical grade, or what they can expect to get out of the treatments. Legal loopholes remain, allowing companies to continue providing experimental therapies to those patients willing to pay for them. This makes it even more important to encourage the scientists themselves to pro-actively adhere to the highest standards.



Collection of blood samples for genomic research, Kunming

### Key elements of China's stem cell ethical governance network

#### *Ministry of Science & Technology*

973 & 863 research funding programmes

#### *Ministry of Education*

211 & 985 projects provide funding for stem cell research

#### *Ministry of Health*

National and Provincial Ethics Committees, Institutional Review Board

Ethical principles on stem cell research

Administrative Measures on Clinical Applications of Medical Technologies

#### *Chinese Academy of Science*

National Natural Science Foundation

#### *Key stem cell scientists and laboratories*

<b>Deng Hongkui</b>	Peking University College of Life Sciences
<b>Li Lingsong</b>	Peking University Stem Cell Research Center
<b>Pei Xuetao</b>	Chinese Academy of Military Medical Sciences
<b>Pei Gang</b>	Tongji University, Shanghai
<b>Zhang Yu</b>	Beijing Capital Medical University, Xuanwu Hospital
<b>Zhao Chunhua</b>	Center for Tissue Engineering, Chinese Academy of Medical Science and Peking Union Medical College
<b>Ouyang Hongwei</b>	Beijing Institute of Zoology, CAS and Tianjin SCRMC
<b>Zhou Qi</b>	Center for Developmental Biology, SJTUSM
<b>Sheng Huizhen</b>	Fudan University
<b>Tang Qiqun</b>	CAS KLSCB and IBCB, SIBS/CAS
<b>Wang Xin</b>	Institute of Hematology, SJTUSM and CAS
<b>Chen Zhu</b>	Stem Cell Center, Shanghai Jiaotong University
<b>Han Wei</b>	CAS KLSCB and IHS, SIBS/CAS; SJTUSM
<b>Jin Ying</b>	CAS KLSCB and IBCB, SIBS/CAS
<b>Jing Naihe</b>	Huashan Hospital, Fudan University Medical School
<b>Zhu Jianhong</b>	Tianjin Institute of Hematology, Chinese Academy of Medical Sciences
<b>Cheng Tao</b>	Stem Cell Program, Biomedical Institute, Xiamen University
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***University and private hospitals***

Regenerative medicine, stem cell therapies, eg, [www.stemcellschina.com/](http://www.stemcellschina.com/)

***Biotechnology companies and venture funds***

China National Center for Biotechnology Development  
20 biotech parks, 500 biotech enterprises  
Beike technologies

***Chinese and international scientific journals***

Publication of stem cell research findings

***Media***

Reporting on issues such as stem cell therapy IVF and donation of embryos for research.

**Concern 3: Donation of biological materials and/or biographical information**

One of the characteristics of advanced biological and biomedical research today is its reliance on biological samples. Potentially self-renewing stem cells can be sourced from six-day old *in vitro* fertilised human blastocysts, aborted human foetal tissues, umbilical cord blood, bone marrow, brain tissues as well as other somatic sources. That is to say, stem cell lines are derived from biological samples, which are taken from human embryos, aborted foetuses, newborns or adults. Genetic research relies on blood or saliva samples which can be used to sequence DNA information from individuals to be used in single

gene or genome wide association studies. In this latter case, donors of biological samples can also donate biographical, lifestyle and/or family medical history information.

There are in particular two sets of problems related to donation of biological samples and/or personal information. The first concerns how such samples and information are sourced while the second concerns what will happen with the donated samples and personal information once collected and stored – can they be used for research purposes other than those stated in the original research project for which they were collected? Who owns these samples once they have been collected and stored?

Ethical interaction between researchers and research subjects in situations where biological samples are procured requires respect and sensitivity, and donor safety will always be the prime concern

**Sourcing** – there are different risks associated with different kinds of sourcing of biological samples. The procurement of human oocytes for stem cell research involves some of the greatest risks for females as collection of eggs can only take place after hormonal stimulation which can have severe health consequences.

Donating bone marrow samples is also associated with certain health risks and discomfort. Sourcing can also take place in different contexts, for example, during medical procedures, during a birth or following an abortion. For example, at the BIONET Shanghai workshop, a case was discussed where pregnant women were asked to donate cord blood after having gone into

labour. In such contexts, sourcing of a biological sample can be an intrusion. Ethical interaction between researchers and research subjects in situations where biological samples are procured requires respect and sensitivity, and donor safety will always be the prime concern. For example, when egg and embryo donors are recruited from IVF clinics, donation must be strictly voluntary and must not influence fertility treatment in any way. Proper informed consent should be obtained by a third party and not by the treating doctor or researching scientist. Also donation should not be commercialised so as to ensure that no inducements are present. In China, all relevant

regulations expressly forbid any coercion or commercial incentives to achieve the donation of eggs or embryos. And finally, the principles of patient benefit and minimisation of harm must always come first, a point that is all the more important bearing the close connections between fertility treatment and stem cell research. Likewise when biographical, life style or family medical history is obtained from donors through interviews or questionnaires, due social and cultural sensitivity is a requisite. Key ethical questions include: Are there any risks involved in taking a biological sample? In which contexts are individuals being asked to donate?

**'Immortalisation'** – a particular feature of biological sample procurement in advanced life science research is that of immortalisation. A stem cell line derived from an individual's biological samples can be immortalised and end up in a stem cell bank where it may then be sent to other laboratories across the world or perhaps even used in therapeutic treatment of other patients. This raises questions about who 'owns' such immortal lines and just what it is that a donor is consenting to – especially in light of incalculable future developments. Similarly, donors of DNA samples and associated biographical data to biobanks will have their samples and records stored in sample repositories and databases for the remainder of their lives and perhaps even beyond. What happens if persons unrelated to the original research

project get access to this information and what guarantees should donors have about who can have access to biobank databases? In BIONET workshops there were numerous debates about the merits and pitfalls of blanket consent vs. specific consent and whether or not donors should be re-consented every time a new research project using certain biological samples was proposed.

#### Concern 4: Benefit-sharing and trust

Research subjects for advanced life sciences research are recruited in very different situations and contexts. In BIONET workshops, we in particular focused on three contexts: IVF clinics (reproductive and stem cell research), hospitals (clinical research) and communities (biobanking).

On the one hand, it is not in the specific interest of an individual to participate in research since benefits are aimed at the collective as increased knowledge can help improve treatment and lead to new medical breakthroughs. Empirical research among IVF patients has shown how some are willing to donate eggs or embryos for research as a way of 'giving something back' since they feel they have benefited from past scientific research themselves. Some might consider allowing spare embryos to perish as 'wasteful', while others might see the inevitable destruction of spare embryos through embryonic stem cell research as 'wasteful'. In

both Europe and China, BIONET workshop participants stressed that it was necessary to organise a trustful communication culture and in particular to take the time to explain sometimes very complex information about stem cell research.

In hospital-based clinical research, therapeutic misconceptions can be difficult to set straight as many recruited patients consider participation in clinical research as medical treatment which can inevitably lead to false expectations and a breakdown in relationships of trust between doctors, researchers and patients. In BIONET's Xi'an workshop on clinical trials, Chinese participants suggested that patients, physicians, researchers and health care administrators regularly confused clinical trials with medical care and even that some physicians and investigators seem deliberately to treat clinical trials as medical care in order to 'sell' them to potential participants. Again, the need for trustful communication between physicians, researchers and patients is a key part of ethical interaction, and the distinction between research and medical care must be made clear to research participants.

In biobanking it is often a whole community or section of the general public who will be recruited. If a genetic research project expects to recruit research subjects from a small community steps must actively be taken to ensure that trust is

established between scientists and community members. What might seem like administrative technicalities on paper (eg, study inclusion criteria) can have unintended consequences in a community. In BIONET's Shenzhen workshop on biobanks a case was discussed whereby the setting up of a register for the DNA of some rural communities with a view to investigating sickle cell disease was surrounded by fear of information leaks and possible loss of face in the community (eg, what if it became known that a family declined to participate?). In a genetic project among ethnic minorities in China, potential participants were explicitly told 'you will not benefit directly from participating in this study. However, your participation will benefit the general population by increasing knowledge related to genome diversity and its significance in diseases'. The specific benefits that might flow to those ethnic communities who contributed their samples were not discussed.

If human subjects will not necessarily personally benefit from participating in biological and biomedical research (indeed the decision to participate or not may itself cause anxiety and apprehension), and benefits to their specific community are unspecified, how does it make sense to talk about benefit-sharing? First and foremost, if it is the knowledge gained from research which will ultimately benefit the collective, then active steps must

be made to ensure that research projects undertaken in particular communities are relevant to those research subjects being studied (eg, rural populations should not be approached to recruit for clinical drug research destined for affluent urban populations). Moreover, those undertaking the research should always explicitly consider whether research subjects would have access to potential treatments arising from research, especially in the context of clinical research for pharmaceutical products and give clear ethical justification for their decisions if this is not to be the case.

### Ethical capacity building of principal investigators

What these four areas of concern regarding ethical interaction between advanced life science researchers and research subjects – vulnerability, experimentation, donation and benefit-sharing – show is that principal investigators have a large task in identifying and analysing their target populations for study recruitment. Hence, capacity building is not only something that should be directed at ethics review committee members, but it should also be provided for principal investigators of scientific research projects, as they should be trained in how to adhere to the given standards. Ethical review of research projects before they commence is of course important, but perhaps more important is

to set up mechanisms for ethical oversight through the duration of a scientific project (eg, quality control of informed consent procedures, interviews with research subjects and researchers). One of BIONET's strengths as a network has been its interdisciplinary base, and in this particular area social sciences can contribute through in depth,

empirical research among participants in advanced life science research projects. Interdisciplinary collaboration is a key approach to identifying what is needed in terms of capacity and capability building, and how it can be achieved under the conditions of international, cross-cultural collaboration in the life sciences between Europe and China.



Sequencing at the Beijing Genomics Institute

# Conclusions – ethical governance of global life science collaborations



## **The BIONET workshops and conferences were attended by more than 300 Chinese and European scientists, clinicians, lawyers, social scientists, ethicists and others.**

From our presentations, debates, case studies and workshop discussions, it was made clear that ethical governance is not just about how guidelines and regulations are implemented and followed, rather it involves a complex system wherein research practice is guided by respect for the rule of law, transparency, scientific and ethical accountability, human rights and freedom from corruption. It involves collaboration and coordination not just between individual scientists, but increasingly among an entire network of scientists (principal investigators, junior researchers and postgraduate students), university departments, associations of science or medicine, commercial organisations, clinicians, patients, scientific journals, Ministry officials, local government departments and others. Regulation and regulatory frameworks are only one element in much more complex networks of multi-layered governance. There can be many pressures to achieve results – international competition (as nations compete to be at the forefront of the biotech revolution), prestige (for scientists, governments, research councils), financial reward (as biotech companies and governments push to have basic research translated into therapy), patient desperation

(especially those suffering from incurable diseases).

When Sino-European life science research collaborations are initiated, benefits are gained through the pooling of resources, sharing of expertise and perhaps also lowering of costs. Yet, such collaborations also engender their fair share of challenges as outlined in this report. When scientists from Europe and China join forces, they are not only bringing together scientific expertise, they are also bringing together distinct forms of ethical deliberation and communication, different systems of ethical regulation, varied procedures for ethical review as well as different traditions of recruitment and interaction between researchers and research subjects. Moreover, the increasing commercialisation of science on a global scale further complicates attempts to ethically supervise international collaborations.

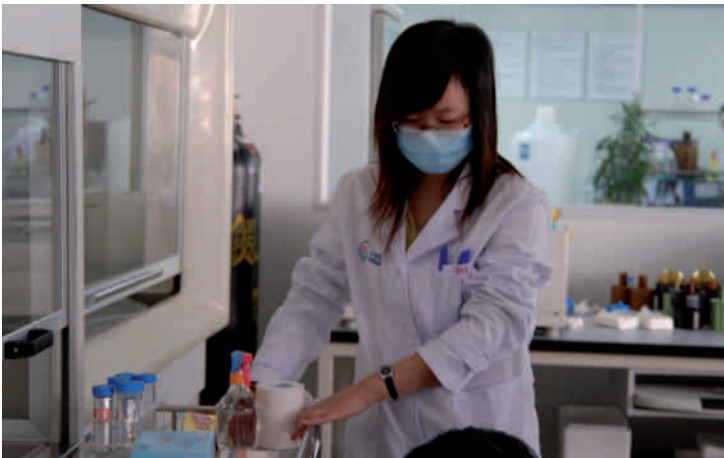
For these reasons attention should be paid to each of the layers or spheres of ethical governance identified in this report. Traditions and forms of **ethical deliberation** and communication at national levels are different from country to country and matters of language and translation must be addressed in order to improve cross-national dialogue on ethical issues raised by life science research. Countries throughout the world are building infrastructures of **ethical regulation** which continues to have an impact on the possibilities for

## Regulation and regulatory frameworks are only one element in much more complex networks of multi-layered governance

life science collaboration. Scientists and ethical review committees must be aware of national regulatory differences before collaborations are initiated. While systems of peer review have been developed over many decades (and still do not prevent all scientific misconduct), systems of ethical review are much more recent. Sino-European research collaborations will have to be reviewed in both regions and for this reason scientists and regulators must be aware of differences in systems of **ethical oversight** to ensure that they adhere to relevant procedures. And finally, researchers who travel to an unfamiliar country to carry out research involving human subjects must be aware of cultural and socio-economic factors which will affect the way in which **ethical interaction** – facilitated by informed consent procedures – between researchers and potential

research participants takes place.

While the BIONET project focused on workshops as a kind of mapping out exercise, what is now needed is much more in depth and empirically rich social scientific research into these different layers of ethical governance in China and Europe. Through such future work, building on the platform established by BIONET, and in conjunction with the standing Sino-European Platform for Biomedical Research Ethics proposed by the BIONET expert group, and together with related initiatives being taken by others, we feel confident about the future for ethically sound research collaborations between European and Chinese researchers in the life sciences and biomedicine that will benefit medical knowledge and the health and well-being of the populations in both regions.





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