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ROCHE FRAMEWORK FOR DISCUSSING AND RESOLVING ETHICAL ISSUES IN HUMAN SUBJECT RESEARCH

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Introduction

Roche has established a systematic framework for discussing and resolving potential ethical issues that may arise during the course of everyday work in drug development. The framework incorporates a central point of contact for Roche staff and an escalation process to facilitate review of alternative perspectives when appropriate.

Roche's culture places a high value on ethics. Therefore, finding the proper, transparent resolution of ethical issues that may arise during the normal course of business is considered a high priority within the organization. This philosophy is shared throughout all areas of the company.

This process was formalized within Pharma Development in July 2003. By taking this action, Roche has assumed a leadership role among pharmaceutical companies by recognizing the importance of proper handling of ethical issues that may arise during drug development.

Good governance requires having systems and processes in place to deal effectively with issues within an organization. A robust process such as the one Roche Pharma Development has established helps the company to identify and manage concerns proactively. Perhaps more importantly, this process also plays an important role in supporting employees who may just need an independent point of view or a sounding board.

Why is this process needed?

The development of new drugs often opens areas of science for which the interface with social values and norms has not yet been established. Ethics and integrity are central to the way in which Roche employees work. However, there are times when employees can face grey areas, where the "right" decision is not always clear cut. The process Roche has put in place allows ethical issues to be raised early and resolved as quickly and efficiently as possible. This helps foster a culture where questions and issues are routinely aired, discussed and worked through in a transparent manner that facilitates everyone taking joint ownership of the final outcome. It also provides a support mechanism for Roche employees, so they know that they need not face difficult issues alone, and can obtain independent advice. This enables staff to do their jobs effectively, unhindered by questions to which they don't have the answers.

How and when might the process be used?

Employees are always encouraged to discuss issues within their team and departments and resolve them as far as possible within the normal team decision-making processes. However, there are times when teams themselves may be divided along differences of opinion on a topic, or when individuals within a team might feel uncomfortable. Under such circumstances, use of the process helps to promote an environment in which individuals feel their voice has been heard and their opinion considered, and helps create "buy-in" for the final decision from all team members.

How does the process work? A three step approach

I. Consult with Global Ethics Liaison

When ethical challenges cannot be resolved locally, individuals or teams can approach the Global Ethics Liaison, who is independent from the clinical development teams or departments. The Global Ethics Liaison is a central source for advice on issues involving ethics in clinical research, and can be contacted confidentially by any staff member. Through a process of fact-finding and consultation with peers and appropriate subject-matter experts, as needed, the Global Ethics Liaison will facilitate the team to come to a decision that is acceptable to all team members.

II. Escalate to internal committee of experts

In some cases, the complexity of an issue may be such that even after the initial consultation and discussion, the team remains divided or one or more individuals still feel uncomfortable. This is a clear indication that further discussion is warranted.

The issue can then be taken, in confidence, to an internal committee of experts. This committee will include the Head of Pharma Development, the Head of the Clinical Quality Department, and other experts from within Roche. The exact composition of the committee is dependent on the actual issue under discussion. For example, if the query involves a particular therapeutic area such as oncology, experts from that field will be included in the committee. The committee will hear the points of view of all parties concerned

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and voice an opinion, which will be communicated back to the team by the Global Ethics Liaison.

III. Seek advice from external advisory group

If there is still discomfort, or more discussion is desired, the internal committee may seek advice from an external advisory group, the Clinical Research Ethics Advisory Group (CREAG) to gain an outside perspective. The internal committee will consider the advice of the CREAG and come to a final position. This will then become the official Roche position on the issue, which will be communicated back to the team by the Global Ethics Liaison.

Clinical Research Ethics Advisory Group (CREAG)

The CREAG supports ethics in clinical research by addressing ethical issues in human subject research across all of Roche's activities in this area when called upon to do so. This committee includes outside experts in bioethics and sociology from academia or the hospital environment, but also non-specialists, such as representatives of patient advocacy groups. Global membership ensures that the advice provided is as comprehensive and relevant as possible.

The CREAG also keeps Roche updated on ethical issues from the wider health arena, and acts as a sounding board by regularly participating in periodic ethics discussions with Roche. In addition, the CREAG can provide input in specific instances when a particular ethical issue debated in Roche would benefit from the opinion of an independent third party.

In the future, the CREAG will also monitor Roche's posting of trials on www.Roche-Trials.com to ensure that information on this public website always accurately reflects the Roche Policy on Transparency in Clinical Trials. This policy governs Roche's Clinical Trial Protocol Registry and Clinical Trial Results Database, launched on April 15, 2005.[1] This global, public database was established because Roche believes it has an ethical obligation to communicate information about clinical trials, including both positive and negative results, to ensure that a balanced view is readily available to the medical community. Thus, the registry and the results database both contain information on all Roche-sponsored clinical trials, Phase II to IV worldwide, for marketed products**.**

Raising awareness

To promote awareness of the process, and to reinforce the company's corporate values and ethical standards, ethics education is offered to employees. During training sessions the benefit of open dialogue regarding potential ethical issues is stressed, and the concept of ethics and what it means to Roche employees in their daily work is explored.

In all the Roche educational efforts, the Vision of "Leadership In Ethics Through Personal Responsibility" is endorsed, and individuals are encouraged to remember the two goals of the program in all of their daily work: 1) To support the Pharma Development Mission by assisting teams and individuals asked to decide on potential ethical issues; and 2) To foster a culture in Roche Pharma Development so that open and transparent discussion of ethics and resolution of ethical issues within teams and other work groups is the accepted norm. Thus, it becomes straightforward for all team members to take joint ownership of the outcome once the process has concluded.

1 Roche to Publicize Trial Results, R&D Directions, March, 2005, Page 68.

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Letters to the Editor: The editors welcome comments from our readers. We reserve the right to edit and abridge letter as space permits. Please address all correspondence to the deputy editor.

IN THE NEWS

UK GOVERNMENT CONSULTS PUBLIC ON HUMAN EMBRYO LAW

On August 16, the British government's Department of Health launched a major public consultation on laws governing the technology and techniques used in assisted human reproduction and embryo research.[1]

The consultation document and an accompanying interactive discussion forum,[2] seek informal public and professional views on a range of highly controversial and fundamental ethical issues – from the rules governing pre-implantation genetic diagnosis of diseases (PGD), to the regulation of IVF and currently unlicensed fertility treatments, to the status of the embryo in legislation.

This exercise, which will continue until November 25, follows a government commitment made last year to consult with the public prior to reviewing the provisions of the Human Fertilisation and Embryology Act of 1990, something which is likely to occur within the next three years.

"The HFE Act was a landmark piece of legislation… [and] has stood the test of time well," said Public Health Minister Caroline Flint. "However, it was never expected that the Act would remain forever unchanged in this area of fast-moving science."

In addition to the consultation, the Department of Health also published a response[3] to a March 2004 report from the House of Commons Science & Technology Committee,[4] which had made recommendations on many of the issues that the consultation will encompass

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based upon a year-long investigation.

The government's largely-positive response concurs with the majority of the report's 104 conclusions and recommendations, including the controversial suggestion that future legislation should resist the temptation to redefine the legal definition of an embryo, instead limiting itself to describing which forms of embryo can be implanted and under what circumstances. Another suggestion, that a ban on altering the genetic structures of the cells of an embryo be changed in the case of research into mitochondrial disease, also met with approval in the report.

Member of Parliament Evan Harris, a member of the Science & Technology Committee, stated that the government's broad acceptance of its recommendations, "...will allow the law to catch up with science and allow patients the opportunity to benefit from new insights and treatments of diseases." *RJE

1Review of the Human Fertilisation and Embryology Act: A public consultation, http://www.dh.gov.uk/Consultations/LiveConsultations/LiveConsultationsArticle/fs/en?CONTENT_ID=4117820&chk=vchu%2B9

2 http://progress.mywowbb.com/

3 Government Response to the Report from the House of Commons Science and Technology Committee, http://www.dh.gov.uk/assetRoot/04/11/78/74/04117874.pdf

4 House of Commons Science and Technology Committee: Human Reproductive Technologies and the Law, http://www.publications.parliament.uk/pa/cm200405/cmselect/cmsctech/7/7i.pdf and http://www.publications.parliament.uk/pa/cm200405/cmselect/cmsctech/7/7ii.pdf

RESEARCHER AND COMPANY REACH COMPROMISE OVER SUBPOENA FOR DATA

Epidemiologist Kim Dietrich has been subpoenaed by Sherwin-Williams, a paint manufacturer, to turn over the raw data from his studies on lead-paint hazards. A professor of environmental health at the University of Cincinnati, Dietrich has been studying the harmful effects of lead paint on children for more than 25 years. His research shows a link between lead exposure and tendency toward criminal and antisocial behavior.

The state of Rhode Island filed a lawsuit against Sherwin-Williams in 1999 for selling lead filled paint while being aware of its risks. When the case went to trial in 2002, Dietrich served as an expert witness. Before that trial, the judge denied the company's request for raw data from Dietrich and two other expert witnesses. The case ended with a hung jury. Dietrich will not be a witness during the re-trial, but others will testify based on his studies.

Representatives of Sherwin-Williams said that data requests are routine and that in order to defend themselves they must see the data. Initially, Dietrich refused to cooperate, stating that it would take at least six months and $125,000 to prepare the data. But a few days before Dietrich was to appear in court to explain his refusal, he reached an agreement with Sherwin-Williams. As a compromise, Dietrich will turn over a fraction of his data that were already prepared for another purpose. Many states have taken interest in this trial because a Rhode Island victory could prompt other cities and states to seek compensation for cleaning up lead paint. The trial is scheduled to begin in September. *JP

BRITISH SCIENTISTS DECLARE SUPPORT FOR ANIMAL TESTING

Fifteen years after a declaration stating the importance of animal testing in medical research was released by the British Association for the Advancement of Science,[1] a revised edition of the same document has been signed by over 500 of the nation's leading doctors and scientists.

Released on August 24 by the Research Defense Society (RDS), an organization that represents medical researchers in the debate on animal testing in medical research, the 'Declaration on Animals in Medical Research'[2] reaffirms the medical and scientific benefits of animal research in addition to scientists' commitment to safeguarding animal welfare and ensuring minimal suffering and distress among animal subjects. The declaration reinforces statements on the importance of animal testing in research made by the Royal Society in 2004 and the House of Lords Select Committee on Animals in Scientific Procedures in 2002, which form the basis of the British government's strict controls on animal research. The declaration also states that, wherever possible, animal testing must be replaced by non-animal methods and the number of animals used as test subjects reduced. The declaration also recommends increased openness and transparency over animal testing, which it admits can be difficult "in the face of animal rights extremism."

RDS executive director stated that he was delighted to have received the 500 signatures, which include those of three Nobel Prize winners and 190 fellows of the Royal Society, in less than one month. "It shows the strength and depth of support for humane animal research in this country," he said. *RJE

[1] Animals and the Advancement of Science (1990), BA

[2] http://www.rds-online.org.uk/upload/docs/Declaration%202005.pdf

NSABB HOLDS INAUGURAL MEETING

The National Science Advisory Board for Biosecurity met for the first time June 30th-July 1st in Bethesda, MD. According to its charter, the NSABB will "advise on and recommend specific strategies for the efficient and effective oversight of federally conducted or supported dual-use biological research, taking into consideration both national security concerns and the needs of the research community." Dual-use research is research "conducted for legitimate scientific purpose," that yields results or technologies that may be misused to threaten public health and/or national security." The charge of the NSABB is to advise on national policies concerning dual use research, which includes creating criteria for its identification as well as developing guidelines for its oversight. As part of these efforts, NSABB will also develop guidelines for Institutional Biosafety Committees (IBCs).

NSABB has 24 voting members and 18 non-voting ex-officio's. The

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voting members represent leaders in academia and industry while the ex-officio's represent various federal departments. The first day of the meeting included sessions on the development of criteria for identifying dual use research and the communication of dual use research. The second day continued with presentations on codes of conduct, international perspectives of dual use research, and the growing field of chemical synthesis of bacterial and viral genomes.

Three themes emerged from the meeting. The first was the need to find the right balance between scientific freedom and national security. While a biological threat is very real, the free flow of information is important for continued scientific progress and for keeping America's vital scientific edge. The second was that biosecurity measures must be international in scope in order to be effective. Several members and ex-officio's called for a "culture of responsibility" among the scientific community and talked of the creation of a "code of conduct" for scientists. Finally, there was a plea from members of NSABB not to forget the importance that plants, animals, agriculture and natural ecosystems play in the nation's economy and health.

Five working groups have been established; they will include members of NSABB, ex-officio's, and outside experts. The five groups will focus on the following areas: dual use research and technology, international collaboration, synthetic genomics, communication, and codes of conduct. These groups will meet as needed between NSABB meetings, which will be held quarterly. *JP and BK

STEM CELLS: A WORLD-WIDE DEBATE

The status of stem cell research policy is in considerable flux. In May, the U.S. House of Representatives voted 238 to 194 to ease restrictions President Bush placed on federal funding of stem cell research in August 2001. Bush's stem cell restrictions limit federal funding to about 22 embryonic cell lines developed prior to his 2001 announcement. U.S. scientists complain that many of these lines are inadequate for research as well as being contaminated by mouse proteins, which may make them unusable in humans. The House legislation would allow federally funded stem cell research on new stem cell lines developed from discarded IVF embryos. The co-sponsors of H.R. 810, Mike Castle (R-DE) and Diana DeGette (D-CO) maintain that it would make use only of unused embryos created for the purposes of in vitro fertilization. The House also passed a bill introduced by Christopher H. Smith (R-NJ) that would create a network of blood banks for umbilical cord research and use. Umbilical cords are thought by some to be an alternative source of stem cells, and sponsors of the bill hoped it would draw away voters from the Castle-DeGette bill.

Since the passage of H.R. 810, Senator Arlen Specter (R-PA) and Senator Tom Harkin (D-IA) called for immediate voting on an unaltered bill, S.471, in the Senate, even in the face of a promised veto by President Bush. As in the House, bills proposing alternative sources of stem cells are being introduced in the Senate. Alternative sources of stem cells may include de-differentiation of adult cells; "altered nuclear transfer," or non-viable genetically altered embryos; "blastomere biopsy," or developing stem cell lines from a single cell taken from a live embryo without destroying the embryo; and deriving stem cells from embryos that have stopped developing. Critics of these alternatives argue that they are speculative and would delay the progress of research. While Specter and Harkin support these bills, they stress that they be seen as additional, not alternative bills. Embryonic stem cell research gained key support at the end of July 2005 when Senator Bill Frist announced his break from Bush's policy. Although Frist now supports expanded stem cell research, he sees downsides in the Specter-Harkin bill, citing among other things, a lack of built-in ethical oversight. It is yet to be determined how the Senate will vote on what are as many as six stem cell related bills that have been introduced.

Meanwhile, states and other countries are forging ahead with stem cell initiatives. California is the state that has committed the most to stem cell research with the passage of "Proposition 71," approved by voters in November 2004, which commits $3 billion in state funds to the creation of a stem cell institute, the California Institute for Regenerative Medicine. New Jersey Governor Richard Codey committed to invest $150 million dollars to build a stem cell research center and plans to raise $230 million to finance stem cell research grants. Illinois Governor Rod Blagajevich recently announced $10 million to support the proposed Illinois Regenerative Medicine Institute. Connecticut passed a bill that will devote $100 million over ten years to stem cell research.

California, Connecticut, Massachusetts, New Jersey and Rhode Island have banned reproductive cloning while allowing therapeutic cloning, or cloning of human embryos for research purposes. Missouri allows therapeutic cloning and bans the use of state funds for reproductive cloning. Other states have taken a more restrictive stance towards stem cell research. Arkansas, Indiana, Iowa, Michigan and North and South Dakota have all banned therapeutic cloning as well as reproductive cloning. Arizona has banned the use of state monies for therapeutic cloning. For a list of state policies on human cloning and embryonic and fetal research go to www.ncsl.org/programs/health/genetics.htm.

Around the world, South Korea has captured headlines as the first country to clone human embryos for stem cells, the site of a large proposed stem cell bank, and the first country to produce embryos genetically matched to patients. The UK, Belgium, Sweden, Israel, Japan, South Africa, Singapore, South Korea, India and China allow therapeutic cloning, but have either banned or issued statements condemning reproductive cloning.

Countries with restrictions on embryonic stem cell research include Canada, Brazil, Denmark, Finland, France, Greece, Spain, the Netherlands, Taiwan and Australia, which ban research on cloned human embryos but allow research on donated IVF embryos. Germany and Italy, although allowing the importation of stem cell lines from elsewhere, have passed laws against extracting stem cells from embryos. Iran, Saudi Arabia and Malaysia conduct non-embryonic stem cell research. Austria, Ireland, Poland and Lithuania have

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outlawed embryonic stem cell research. For a world map outlining national stem cell policies go to www.mbbnet.umn.edu/scmap.html. *BK

RESEARCHERS' SALE OF DRUG DATA LEADS TO INVESTIGATION

Medical researchers engaged in clinical drug trials at universities across the United States are often paid between $300 and $500 an hour to offer their assessment of drug testing in which they are involved to Wall Street investors looking to make quick profits through insider trading, an investigation by *The Seattle Times* has revealed.

On August 7, 2005, the newspaper reported finding at least 26 cases in which doctors at universities had disclosed critical details of ongoing research to financial firms such as Citigroup Smith Barney, UBS and Wachovia Securities. The U.S. Food and Drug Administration (FDA), which regulates clinical trials, does not have authority over investment transactions, although it has taken steps in the past year to increase information sharing with the U.S. Securities and Exchange Commission (SEC).

In 24 of the 26 cases, the firms passed on the leaked information to select clients, advising them whether to buy or sell a particular drug stock. The report gives three examples where the premature release of trial information resulted in unusually rapid buying and selling of stock in the biotech companies Isis Pharmaceuticals, Eyetech and Encysive Pharmaceuticals.

The researchers in most clinical trials are "blinded" so that they don't know which patients get the drug and which receive a placebo. When details are disclosed to investors prematurely, information can filter back to researchers who may then be tempted to modify the study, increasing the likelihood of bias being introduced. In addition, since the viability of small biotech firms often hinges on the prospects of individual drug properties, bad news that leaks prematurely can undermine investor confidence and may prove financially catastrophic. Consequently, researchers who reveal ongoing clinical trial data are capable not only of tainting their results, but also of undermining such trials before they are completed.

Responding to the *Times'* article, on August 8 Sen. Charles Grassley (R-IA), chairman of the Senate Committee on Finance, sent a letter to both the U.S. Attorney General and the chairman of the SEC urging them to pursue a complete and thorough review of the paper's findings. "Selling drug secrets violates a trust that is fundamental to the integrity of both scientific research and our financial markets," the letter stated.

Until now, the buying and selling of research data has been hidden from securities regulators and the public, but this practice is actually widespread according to biotech and Wall Street insiders questioned by the paper. The *Times'* also reported that the practice is driven largely by hedge funds – unregulated investment pools for wealthy private and institutional investors that use aggressive high-risk strategies not available to mutual funds. Inside information on clinical drug trials has now become so valuable to investors that they will pay up to $1 million a year to special firms that pair them with doctors involved in ongoing research. Gerson Lehrman Group is the largest of these so-called 'match-makers' and claims to have 60,000 doctors available to speak with investors. *RJE

EPA CRITICISED OVER PESTICIDE STUDIES INVOLVING HUMAN SUBJECTS

Four Democratic Members of the House Science Committee have questioned the legality of two-dozen industry pesticide studies that intentionally exposed human subjects to harmful toxins, yet which have been chosen for consideration by the Environmental Protection Agency (EPA) to help regulate safety standards.

In a letter to the EPA administrator, dated July 18, 2005,[1] Representatives Bart Gordon (D-TN), Mark Udall (D-CO), Eddie Bernice Johnson (D-TX) and Brian Baird (D-WA) described the EPA's current procedures for critically evaluating dosage studies involving human test subjects as "seriously deficient." They criticized the Agency for failing to address recommendations and fundamental ethical issues raised in a report it commissioned from the National Academy of Sciences (NAS)[2] and in a joint review it commissioned from the Science Advisory Board (SAB) and the Federal Fungicide and Rodenticide Act (FIFRA) Scientific Advisory Panel (SAP)[3].

The letter was stimulated by a report released on June 16, 2005 by two California Democrats, Sen. Barbara Boxer and Rep. Henry Waxman,[4] which analyzed 22 of the 24 controversial studies involving human subjects and concluded that nearly one-third of them were "specifically designed to cause harm to the human test subjects or to put them at risk of harm." In addition, the Boxer-Waxman report suggests that most - if not all - of the studies violated the terms of FIFRA, either by making use of registered pesticides in a manner inconsistent with their labeling or by failing to provide evidence of informed consent from the 'volunteers' who participated.

Data from the controversial studies were submitted to the EPA by third-party organizations seeking pesticide permits and were considered in accordance with the Agency's ad-hoc, case-by-case review process. This process has been in place since November 2004, when Bill Clinton's 1998 moratorium on using such data in regulatory decision-making was lifted by the Bush Administration in light of new procedural guidelines - ironically from the same NAS study which the EPA has now been criticized for failing to take on board.

In May and June of this year, the House and Senate passed identical amendments to a measure determining the EPA's budget for 2006 which would have reinstated the moratorium on considering data from human pesticide studies for one year beginning October 1, 2005. However, an amendment by Sen. Burns (R-MT) that would permit the EPA to consider such tests within specified constraints was also passed by the Senate.

On July 27, U.S. House and Senate conferees approved a compromise between the conflicting amendments to produce a final version of the EPA budget bill, which was then signed into law by President Bush on August 2, 2005. The bill now states that the ban on considering human toxicity studies will remain in effect until the EPA issues a final rule to address the surrounding ethical issues, something which must occur within 180 days of the bill becoming law.

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After much delay, the Agency is currently preparing new regulations that would extend the principles of the Common Rule (federal policy for the protection of human research subjects) to third party studies and is expected to issue a proposal in September. According to the new budget legislation, the EPA Administrator must then allow 90 days for public comment on the proposal before issuing a final rule. The rule must also forbid the use of pregnant women, infants and children as test subjects, be consistent with the principles of the 2004 NAS report, and establish an independent Human Subjects Review Board. All of these elements were key omissions from a highly-criticized draft copy of the EPA proposal, made public on June 28 by Sen. Boxer and Rep. Hilda Solis (D-CA). *RJE

1 Online at: http://www.house.gov/science_democrats/releases/epa_dems_pesticides_18jul05.pdf

2 National Academy of Sciences. 2004. *Intentional Human Dosing Studies for EPA Regulatory Purposes: Scientific and Ethical Issues*. National Academy Press, Washington, DC. 208pp (online at: http://books.nap.edu/catalog/10927.html)

3 Science Advisory Board and FIFRA Scientific Advisory Panel. 2000. Comments on the Use of Data from the Testing of Human Subjects. EPA-SAB-EC-00-017. (online at: http://www.epa.cov/sab/pdf/ec0017.pdf)

4 Minority Staff of the House Government Reform Committee and the Office of Senator Barbara Boxer. June 2005. *Human Pesticide Experiments*. (online at: http://www.democrats.reform.house.gov/story.asp?ID=869)

CALL FOR NON-IVF EMBRYO DONATION STIRS DEBATE

The man who created the cloned sheep Dolly is once again in the news. Professor Ian Wilmut is asking Britain's Human Fertilization and Embryology Authority (HFEA) for permission to ask women to donate eggs explicitly for stem cell experiments. This is the first such request in the UK, where the eggs used in embryonic stem cell research are usually unneeded IVF embryos that would otherwise be discarded. Wilmut argues that women should be allowed to donate eggs solely for research. In fact, some women may rather donate eggs for research than for fertility treatments because of the potential to help a greater number of people. Proponents of such direct to research egg donation say that there are not enough quality embryos leftover from IVF treatments to do stem cell research as quickly or efficiently as needed. They point to South Korea, where women are actively recruited to donate their eggs, which is the only country to have created stem cell lines specifically matched to patients.

Opponents of allowing women to donate their eggs explicitly for research argue that this turns both eggs and women into "commodities." Others are worried that potential donators do not know exactly what they are getting into. Informed consent would be critical to ensure that women knew about the risks of egg removal and what would then happen to the egg. Compensation or other incentives to donate make the ethical issues even more complicated. HFEA is currently conducting a review of donation ethics for sperm, embryo and egg in Britain, where no compensation may be received for embryo donation unless by direction from the HFEA. Their general rule is to allow for compensation for the expense of the procedure, but not to allow for a profit on embryo donation. The European Union has a similar directive. In the U.S., different states have different approaches to the issue. While some states that encourage stem cell research, including New Jersey, have not addressed the issue at all, others, including California, Connecticut and Illinois, have provisions prohibiting the sale of embryos and other human tissue for research. Massachusetts specifically prohibits the creation of fertilized embryos solely for research purposes. The National Academies of Science recommend that no compensation be received for egg donation. Others stress that consent forms for egg donation should be approved by Institutional Review Boards to ensure that donors are adequately warned of possible risks, including infertility, and are aware of how the embryo will be used. Still others point out that the demand for egg donors in the U.S. for fertility reasons alone is already great. The fear is that increased demand for eggs will lead to repeat donors, resulting in the possibility of women paid as "egg producers." Fittingly, the solution to the shortage of embryos that may circumvent the problem of egg donation may be in the works in Britain. British researchers recently announced that it may be possible in the future to develop eggs and sperm from stem cells themselves, thus decreasing the demand for egg donors.[1] The research, however, is in its very early stages, and raises its own set of ethical issues. *BK

[1] Roberts, Michelle. "Stem cell finding offers IVF hope." *BBC News*. June 20, 2005.

MEETING OF EXPERTS FOCUSES ON CODES OF CONDUCT

The Meeting of Experts from State Parties met for the third time in Geneva from June 13-24. The Meeting of Experts is part of a three-year program mandated by the Fifth Review Conference of the Biological and Toxin Weapons Convention (BTWC), which concluded in 2002. The BTWC prohibits the development, production, and stockpiling of biological and toxin weapons. The purpose of the Meeting of Experts is "to discuss, and promote common understanding and effective action on" specific topics as directed by the BTWC. This meeting focused on the development and implementation of "codes of conduct."

Various aspects of codes of conduct were discussed, including the overall benefits of codes and whether there should be a universal code or multiple codes. Many experts stressed that there should be a balance between scientific freedom and protecting people from the deliberate or accidental misuse of science. Experts also called for the need to raise awareness and increase education among the scientific community on biological weapons issues. Some cautioned against limiting the codes to scientists alone, which would exclude decision makers, facility managers, and technicians. Other cautioned against trying to re-invent codes, and suggested working with existing codes and practices.

Experts in attendance included government scientists, representatives

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from international organizations, non-profit organizations, academic institutions, scientific publishers, research funders, and biotechnology and pharmaceutical industry associations.

A final Meeting of Experts will be held from December 5-9, 2005 before the Sixth Review Conference of the BTWC. For more information, visit the BTWC's website at http://www.opbw.org/. *JP

RESOURCES

SYNTHESE

The journal SYNTHESE, volume 145, no. 2, June 2005, includes several original articles on the subject of "Candor in Science." Authors and their topics are:

- LOUIS M. GUENIN / Introduction
- JAAKKO HINTIKKA / Omitting Data-Ethical or Strategic
- Problem?
- LOUIS M. GUENIN / Intellectual Honesty
- SHERRILYN ROUSH / Testability and Candor
- GERALD HOLTON / Candor and Integrity in Science

The journal is online at http://www.springerlink.com

The Encyclopedia of Science, Technology, and Ethics

The Encyclopedia of Science, Technology, and Ethics considers both the professional ethics of science and technology, and the ethical and political issues raised by science and technology in an increasingly complex and global society. This broad coverage supports the numerous courses in applied and professional ethics and policy related to the practice of science and technology in education. Additionally, it provides a practical introduction to useful knowledge and ideas for both professionals and general readers. The Encyclopedia embodies a historically and culturally inclusive approach, with entries on specific religions, linguistic and cultural perspectives, and philosophical positions.

Published/Released: July 2005; ISBN: 0-02-865831-0; 4-set volume; price US $425.00 Also available as an e-book through Gale Virtual Reference Library. For a guided tour of Gale Virtual Reference Library and a list of titles, visit www.gale.com/eBooks.

Encyclopedia of Science, Technology, and Society, Oxford University Press; June 2005; ISBN 0-19-514193-8; price US $150.

A one-volume reference that examines science and technology as social and cultural phenomena. The 136 articles are conceptually organized into three catagories: Science and Society; Technology and Society; and Medicine and Society. Some of the topics covered are abortion, biological terrorism, drugs and society, technology and law, professional responsibilities in research, public understanding of science, and many more. Features include a selected bibliography, cross referencing throughout the volume, a directory of contributors, and a topical index. For additional information, contact Don Myers at Oxford University Press; donald.myers@oup.com.

ANNOUNCEMENTS

Conference: Responsible Conduct of Research: Essentials for Research Success and Integrity, Pocatello, ID; October 20-21, 2005. Sponsored by U.S. Office of Research Integrity, and co-sponsored by Idaho State University, Boise State University, Idaho National Laboratory, Portneuf Medical Center and University of Idaho.

The purposes of the conference are to educate the academic community in the areas of Responsible Conduct of Research (RCR), Research Integrity, and Research Misconduct, and to emphasize the importance of making these areas an integral and ongoing part of a research or administrative career.

The conference seeks to increase participant knowledge and understanding of:

- the standards, challenges, and benefits of RCR;
- research misconduct and human subjects' protection regulations; and
- the importance of a professional commitment to research integrity.

For more information, see: http://www.isu.edu/research/rcr/

Seminar: Scientists and Subjects: An Online Seminar on the Ethics of Research with Human Subjects, January 9-March 19, 2006. An Internet-based seminar open to members of Institutional Review Boards and other administrators, and college and university faculty members who teach future researchers. The seminar is limited to17 members on a first-come, first-served basis. Seminar fee is $200. Continuing Medical Education credits are available for an additional processing fee of $50 (16 credits). Prospective participants must submit a check or purchase order to cover the registration fee and complete an application form, available on the Web at http://poynter.indiana.edu/sas/, no later than Friday, December 9, 2005. For more information, contact Kenneth D. Pimple at Indiana University; pimple@indiana.edu.

Call for Papers: The Journal of Empirical Research on Human Research Ethics (JERHRE) seeks articles on improving ethical decision-making in human research. Visit JERHRE's main web site at www.csueastbay.edu/JERHRE or access the main site via www.JERHRE.org for a full description of JERHRE's aim and focus, distinctive features, manuscript submission instructions, and subscription information.

JERHRE begins quarterly publication March 2006 and is currently accepting manuscripts for its June 2006 issue. To receive a free personal on-line, one year subscription please email joan.sieber@csueastbay.edu.

Call for Essays: Essays are solicited for a new volume on the ethics of embryo adoption. We welcome philosophical, theological and interdisciplinary examinations that seriously engage Christian, but especially Catholic arguments and resources. This volume would be the first collection to focus on the ethics of embryo adoption from the Catholic tradition.

(**Announcements** continued on page 8)

(**Announcements** continued from page 7)

Possible topics include but are not limited to: embryo adoption in relation to other forms of reproductive technology; embryo adoption and the law; feminist perspectives on embryo adoption; embryo adoption and respect for life; ethical issues that arise after embryo adoption. Essays should be approximately 7500 words in length and are due March 1, 2006. Please address all queries and submissions to Sarah-Vaughan Brakman (sarah.vaughan.brakman @villanova.edu) or Darlene F. Weaver (darlene.weaver@villanova.edu).

Call for Papers: Papers invited on ethics in conjunction with the academy, graphic images, scholarly communication, or biometrics for possible publication in the Journal of Information Ethics. Deadline: Open. Contact: Robert Hauptman, Journal of Information Ethics, St. Cloud State University, St. Cloud, Minn. 56301 E-mail: hauptman@stcloudstate.edu

Fellowship: Department of Clinical Bioethics Fellowships at the National Institutes of Health. Two-year postdoctoral fellowship begins September 2006. Fellows will conduct mentored theoretical and empirical research in the ethics of health policy, international research ethics, and human subject research. Fellows will also participate in ethics consultations, review of research protocols, bioethics seminars, and manyother educational opportunities available at the national institutes of health. No bioethics experience expected or required. Stipend based on prior experience and current US government schedule.

Applications to include CV, 1000-word statement of interest, writing sample(s) not to exceed 30 pages, official graduate and undergraduate transcripts, and three letters of reference. Deadline: received by December 30, 2005.
For further information: www.bioethics.nih.gov; bchen@cc.nih.gov; 301-496-2429. EO/ AAE

Call for Papers: The Journal of Business Ethics invites submissions for a Special Issue on ethical issues in biotechnology. The Special Issue will be dedicated to the exploration of ethical issues faced within companies in the biotech sector, as well as ethical issues faced by companies seeking to implement the products of biotechnological research.
Guest Editor: Chris MacDonald
Deadline: December 1, 2005

Examples of possible topics include, but are not limited to:

- Corporate-sponsored stem cell research;
- Ethical issues in the commercialization of university-based research;
- Genetic testing in the workplace;
- Commercial genetic databases;
- Direct-to-consumer marketing of genetic technologies (e.g., genetic tests);
- The commodification of organisms, tissues, cells, etc.;
- Agribusiness and agricultural biotechnology;
- Human subjects research and safety concerns;
- The role of biotechnology in sustainable development;
- Corporate bioprospecting or "biopiracy."

Papers should be submitted by e-mail (in either MS Word or PDF format) to: chris.macdonald@smu.ca Submissions should be roughly 2500-5000 words, and should generally adhere to the Journal's style requirements.
Enquiries should be directed to:
Chris MacDonald, Ph.D.
Department of Philosophy
Saint Mary's University
phone: 902-420-5820
chris.macdonald@smu.ca

Fellowship: The University Center for Human Values at Princeton invites applications from all disciplines for Laurance S. Rockefeller Visiting Fellowships. These fellowships will be awarded for the academic year 2006-07 to outstanding scholars and teachers interested in devoting a year in residence at Princeton writing about ethics and human values. A central activity for the Fellows is participation with University Center faculty members in a Fellows Seminar to discuss work in progress. Fellows are also invited to participate in other activities, including seminars, colloquia, and public lectures. Applicants typically have a doctorate or a professional postgraduate degree and cannot be in the process of writing a dissertation.

Fellows normally receive stipends of up to one-half their academic year salaries (not exceeding a maximum stipend set each fall) for the fellowship period, which extends from September 1 to July 1. The Fellows' home institutions are expected to provide at least half of their salaries in addition to all benefits.

All materials, including letters of reference, must be RECEIVED by November 1, 2005. The Selection Committee begins reviewing applications immediately, and incomplete applications may be at a disadvantage.

Recipients of the Laurance S. Rockefeller Visiting Fellowships for 2006-07 will be announced by February 1, 2006. For additional information, including how to apply, please go to the website at: http://www.princeton.edu/~uchv/LSR_Fellowships.html

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American Anthropological Association
American Association of University Professors
American Political Science Association
American Psychological Association
American Psychological Society
American Society for Engineering Education
American Sociological Association
Botanical Society of America