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PUBLIC & MEDIA ENGAGEMENT WITH REGENERATIVE MEDICINE

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Regenerative medicine is an emerging field of medical biotechnology that aims to regenerate tissues and restore biological function lost through disease, trauma, aging or congenital abnormalities. It is of particular interest to scientists, policy makers and the public because it touches not only on innovations in molecular and cellular biology, but also on a range of ethically controversial issues related to the origins of stem cells and the translation of scientific research from 'bench to bedside'. One objective of this field is the production of cell-based patient-matched therapies, with much being made of their potential to treat the degenerative diseases associated with aging Western populations. The cell therapy industry is beginning to enjoy commercial success, with sales in excess of \$1 billion a year [1], and clinical trials of adult, fetal and human embryonic stem cell treatments are now underway in the US and the UK. However, the therapeutic promise of stem cell research has yet to translate into the wide range of novel treatments often predicted, and a number

of health risks [2] and practical barriers to the clinical uptake of such products are still to be addressed [3]. Consequently, the political and commercial legitimacy of regenerative medicine continues to rely on the speculative value of stem cells, and the hopeful anticipation that surrounds practices such as egg donation and umbilical cord blood banking [4, 5].

Public attitudes and expectations

As the relevance of scientific and medical knowledge for everyday social life has increased, traditional boundaries between specialist expertise and the knowledge of non-expert publics have begun to blur. The erosion of public trust in experts in the wake of scientific controversies suggests that public perceptions of science, in relation to wider political, economic and regulatory concerns, are becoming increasingly sophisticated [6]. Similarly, 'expert patient' and 'health consumer' initiatives have attempted to improve treatment outcomes and reduce costs by encouraging chronically ill patients and the general public to seek out medical information, engage in cooperative partnerships with medical professionals, and self-manage their own care [7, 8]. Some have argued that the quality and depth of non-expert understandings have been overstated, and that they do not equip people with the insights necessary to make informed diagnostic or treatment decisions, evaluate new technologies, or validate the decisions of scientists and doctors [9, 10]. Others contend that an understanding of public perceptions and cultural attitudes can help experts to engage with the public and respond more effectively to their concerns and anxieties [11, 12].

The expectations that surround new areas of science and technology emerge from unstable fields of language and practice in which different groups of stakeholders vie to secure competing visions of the future [13]. When expressed in public, such expectations are often 'performative' rather than merely predictive because they help to enroll support, mobilize resources, legitimate actions, and guide interactions in the present [14]. Expectations can also inscribe social meanings and narrative 'scripts' for future technological development in relevant artifacts, such as stem cells or the human genome, so they provide a focal point for actions and ideas and come to embody one vision of the future but exclude others [15, 16]. Expectations can therefore help expert stakeholders to maintain their own authority by offering publics and policy makers a strategy for the management of uncertainty [17]. Growing competition for funding and social and political legitimacy also encourages scientists to contribute to over-optimistic expectations by downplaying the risks and exaggerating the short-term benefits of their own particular field [18, 19]. Although 'hype' of this sort can be helpful in securing initial funding and recognition, it might ultimately harm future research by contributing to an atmosphere of disillusionment, blame and mistrust that undermines public support [20].

Public attitudes and expectations and their framing in the mass media have proven to be an important factor in the legitimization, social acceptance and implementation of a wide range of biomedical technologies, and the same is likely to hold true for regenerative

medicine. The political lobbying of health advocacy and religious groups has already helped shape legislation on stem cell research. Now the continued investment of businesspeople, regulators, research subjects and patients is required to maintain existing trajectories of research and clinical translation [14, 18, 21].

Regenerative medicine in the media

In recent years, media coverage of regenerative medicine has been dominated by hyperbolic expectations that highlight the extraordinary medical 'potential' of stem cells and the 'revolutionary' nature of projected therapeutic products. Perhaps in an effort to respond to moral doubts and ethical challenges, scientists and journalists have encouraged the aggressive pursuit of novel therapies by amplifying excitement and ignoring or actively erasing continuities with existing technologies and with setbacks, such as the Hwang cloning fraud [19]. Furthermore, close similarities between news stories and scientific press releases and the frequent repetition of direct quotes from a limited pool of scientists and clinicians suggest that journalists often simply regurgitate the subjective views of particular experts with minimal contextualization or

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critique, effectively allowing them to set news agendas. Such views frequently provide a misleading portrayal of scientific research (as a linear series of 'breakthroughs') and fail to articulate the uncertainty, caution, ambivalence and sensitivity toward patient autonomy that many stem cell scientists express elsewhere [22].

In conjunction with expert views, the dramatic narratives of patients invest media stories on regenerative therapies with emotive weight, but risk further exaggerating their power, simplicity and immediate availability, just as media stories on the Human Genome Project have exaggerated the impact of genomics [23]. The medical progress of patients involved in trials of regenerative medicine products are already the subject of intense media coverage and, despite Geron's recent termination of the first ever human trial of an embryonic stem cell therapy, this coverage is only likely to increase. Depending on the news source and the story one chooses, this field may be portrayed as either risky or revolutionary, a step forward for patients or a step backward for ethics. Regenerative medicine is perhaps all of these things, and it is concerning that the majority of coverage fails to recognize this and reflect on the wide range and complexity of issues involved. While this is perhaps also true of media science more generally, it is particularly concerning given that some scientists and journalists have hailed recent news coverage of this field as a step forward for science communication [24].

Regenerative medicine in public discourse

As most publics do not have access to sources of specialist scientific information, media coverage of regenerative medicine can have a significant influence on perceptions and expectations of the field. As a result, public attitudes are often inextricably bound up with news stories, political debates, popular entertainment, and even the cult of celebrities such as Christopher

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

Reeve. This sometimes limits the expression of more nuanced perspectives, which emerge only through detailed discussion and debate. Accordingly, many people simply reiterate scientific and journalistic perspectives on regenerative medicine: focusing on the revolutionary therapeutic potential of stem cells, the role of cell therapies as 'natural' or 'organic' alternatives to current treatments and their relevance as both an economic commodity and a source of patient empowerment. Expectations created in the media also seem to inspire confidence, not only in the realization and implementation of regenerative therapies but also in the institutions and practices required to bring this about.

Despite public reliance on news coverage, many people also recognize the limitations of the media, treating it with caution and skepticism. Accordingly, media frames are often challenged by those who express a wider range of uncertainties, anxieties and ethical concerns about where research might lead and the potential risks and side effects of treatments. In addition, public discourse often includes contextual references to existing techniques and technologies (such as IVF or bone marrow transplantation) that put the potential risks and rewards of regenerative medicine into perspective. As a result, public perceptions of regenerative medicine routinely go beyond the limitations of news stories by weaving together a broader range of social and cultural concerns, such as experiences of illness, spirituality, health economics and health equity. Such concerns must also be interpreted within the changing contexts of patient identity and public health. It is incorrect to suggest that public attitudes are simply unchanging 'filters' or 'predispositions' that represent the aggregate of personal beliefs and values and either undermine or overrule scientific expertise [25, 26]. Rather, publics develop situated understandings of cell therapies that take account of experiences from their own medical and social lives, which develop as new technical information and cultural contextualization is acquired.

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Though many publics lack detailed knowledge of stem cell science and the likely mechanics of regenerative medicine, some express keen insights into relevant practical, ethical and economic issues shaped by their personal perspectives, such as the creation of a market for human tissue or the screening of cell therapies for disease. Public discourses also hint at nuanced understandings of science as process of trial and error that requires optimism in order to generate research funding. That is why some suggest that they would feel let down if regenerative medicine did not live up to the hype surrounding it, whereas others do not [27].

The future of public engagement

The process of scientific research is often complex and conditional, while the numerous scientific, ethical and political perspectives from which it is considered may differ or even compete with each other. Media coverage and other forms of engagement would benefit from acknowledging and exploring this subtext rather than presenting successive scientific developments as unique or isolated incidents. Openly emphasizing that ambiguity and inconsistency are legitimate components of science will not detract from the value of scientific expertise and could help to produce better science and better policy [11, 28]. Institutional reform of scientific culture will be necessary if public engagement is to become a useful component of scientific research and development. For scientific communities this might involve a greater number of engagement activities that build on each other to promote a sustained two-way dialogue between scientists and publics [29]. However, on a more subtle level it will involve changing everyday practices to facilitate reflexive discussion of cultural perspectives and science's own principles of knowledge creation, as well as improvements in scientists' public and media engagement so they incorporate the same deliberate humility about the limits of scientific knowledge that scientists rely on when communicating with each other [30].

The future of regenerative medicine

While an increasing number of cell therapies are likely to reach the clinic

within the next 5-10 years, the 'regenerative medicine revolution' predicted in media coverage is unlikely to be realized within this time frame [1, 31]. To limit public disillusionment, it is crucial for stakeholders to demarcate the research and development process as intrinsically complex and uncertain, and publicly highlight the same reservations and uncertainties they invoke in private [22].

As regenerative medicine continues to draw scientific, public and media attention, it is important for researchers to continue exploring cultural understandings of this field. Future research might well investigate the perceptions of those who are highly invested in the field, such as patients undergoing clinical trials of novel cell therapies, those who have campaigned as part of 'pro-cures' movements, or people in the state of California who voted on Proposition 71 (the California Stem Cell Research and Cures Act). As continued sources of funding are sought for stem cell programs like those at the California Institute for Regenerative Medicine, it might be useful to understand how people such as these reflect on regenerative medicine and on how their expectations are being fulfilled or disappointed.

References

- [1] Martin, P., R. Hawksley, and A. Turner, *The Commercial Development of Cell Therapy - Lessons for the future?*, 2009, Institute for Science and Society: Nottingham.
- [2] Amariglio, N., et al., *Donor-Derived Brain Tumor Following Neural Stem Cell Transplantation in an Ataxia Telangiectasia Patient*. PLoS Med, 2009. **6**(2): e1000029.
- [3] Plagnol, A.C., et al., *Industry perceptions of barriers to commercialization of regenerative medicine products in the UK*. Regenerative Medicine, 2009. **4**(4): 549-559.
- [4] Martin, P., N. Brown, and A. Turner, *Capitalizing hope: the commercial development of umbilical cord blood stem cell banking*. New Genetics and Society, 2008. **27**(2): 127 - 143.
- [5] Brown, N., A. Kraft, and P. Martin, *The Promissory Past of Blood Stem Cells*. BioSocieties, 2006. **1**(03): 329-348.

- [6] Leshner, A.I. *Public Engagement with Science*. Science, 2003. **299**(5609): 977.
- [7] Lindsay, S. and H.J.M. Vrijhoef, *Introduction-A sociological focus on 'expert patients'*. Health Sociology Review, 2009. **18**(2): 139-144.
- [8] Ward, K., M. Davis, and P. Flowers, *Patient Expertise and Innovative Health Technologies*, in *Technologies in Health Care: Challenge, change and innovation*, A. Webster, Editor 2006, Palgrave Macmillan: London.
- [9] Prior, L., *Belief, knowledge and expertise: the emergence of the lay expert in medical sociology*. Sociology of Health & Illness, 2003. **25**(3): 41-57.
- [10] Collins, H.M. and R. Evans, *The third wave of science studies: studies of expertise and experience*. Social Studies of Science, 2002. **32**(2): 235-296.
- [11] Irwin, A. and B. Wynne, eds. *Misunderstanding Science?: The Public Reconstruction of Science and Technology*. 1996, Cambridge University Press: Cambridge.
- [12] Wynne, B., *Public Engagement as a Means of Restoring Public Trust in Science—Hitting the Notes, but Missing the Music?* Community Genet, 2006. **9**(3): 211-20.
- [13] Brown, N., *Hope against hype: accountability in biopasts, presents and futures*. Science Studies, 2003. **16**(2): 3-21.
- [14] Brown, N. and M. Michael, *A Sociology of Expectations: Retrospecting Prospects and Prospecting Retrospects*. Technology Analysis and Strategic Management, 2003. **15**(1): 3-18.
- [15] Borup, M., et al., *The sociology of expectations in science and technology*. Technology Analysis and Strategic Management, 2006. **18**(3-4): 285-298.
- [16] de Laat, B., *Future scripts.*, in *Contested futures: A sociology of prospective techno-science*, N. Brown, B. Rappert, and A. Webster, Editors. 2000, Ashgate: Aldershot.
- [17] Zehr, S., *Scientists' Representations of Uncertainty*, in *Communicating Uncertainty: Media Coverage of New and Controversial Science*, S. Friedman, S. Dunwoody, and C. Rogers, Editors. 1999, Erlbaum: Mahwah, NJ. pp. 3-21.
- [18] Horst, M., *Public Expectations of Gene Therapy*. Science, Technology & Human Values, 2007. **32**(2): 150-171.
- [19] Kitzinger, J., *Questioning hype*,

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(Elliott continued from page 3)

rescuing hope? the Hwang stem cell scandal and the reassertion of hopeful horizons. *Science as Culture*, 2008. **17**(4): 417-434.

[20] Nelkin, D., *Promotional metaphors and their popular appeal.* *Public Understanding of Science*, 1994. **3**(1): 25-31.

[21] Irwin, A. and M. Michael, *Science, social theory and public knowledge* 2003, Maidenhead, UK: Open University Press.

[22] Ehrlich, K., et al., *Embryo futures and stem cell research: the management of informed uncertainty*, in *Sociology of Health & Illness* 2011. doi: 10.1111/j.1467-9566.2011.01367.x.

[23] Webster, A., *Social science and a post-genomic future: alternative readings of genomic agency.* *New Genetics & Society*, 2005. **24**(2): 227-238.

[24] Elliott, R. *The Medialization of Regenerative Medicine: Frames and Metaphors in UK News Stories.* In: S. Rödder, M. Frantzen and P. Weingart (Eds.) *The Sciences' Media Connection - Public Communication and its Repercussions.* *Sociology of the Sciences Yearbook 28*, in press. Dordrecht: Springer.

[25] Ho, S.S., D. Brossard, and D.A. Scheufele, *Effects of value predispositions, mass media use, and knowledge on public attitudes toward embryonic stem cell research.* *International Journal of Public Opinion Research*, 2008. **20**(2): 171-192.

[26] Brossard, D., et al., *Religiosity as a perceptual filter: examining processes of opinion formation about nanotechnology.* *Public Understanding of Science*, 2009. **18**(5): 546.

[27] Elliott, R. *The Public Perception and Cultural Framing of Regenerative Medicine*, 2011. PhD Thesis, University of Nottingham.

[28] Hulme, M. and J. Ravetz. 'Show Your Working': What 'ClimateGate' means. 2009 1 December 2009 August 2011]; Available from: <http://news.bbc.co.uk/1/hi/8388485.stm>.

[29] Stilgoe, J., *The (co-) production of public uncertainty: UK scientific advice on mobile phone health risks.* *Public Understanding of Science*, 2007. **16**(1): 45-61.

[30] Jasanoff, S. *Technologies of Humility*, *Nature*, 2007. **450**(7166):33.

[31] Lysaght, M., A. Jaklenec, and E. Deweerd, *Great Expectations: Private Sector Activity in Tissue Engineering, Regenerative Medicine, and Stem Cell Therapeutics.* *Tissue Engineering Part A*, 2008. **14**(2): 305-315.

In the News

NEW TOPICS SOLICITED FOR RESEARCH ON RESEARCH INTEGRITY FUNDING

The Office of Research Integrity and the National Institute of Environmental Health Sciences are seeking input from the research community to help identify potential topics for consideration in future solicitations for the Research on Research Integrity (RRI) Program. To date, research integrity research has been primarily descriptive. ORI and NIEHS plan to move the science on research integrity into an experimental model with testable hypotheses. The overall goal of the RRI program is to transform the efficacy and effectiveness of RCR education in promoting research integrity, and cost efficiency of behavior change interventions when research misconduct is found. ORI and NIEHS invite researchers and other interested parties to suggest topics specifically related to research integrity issues in which there is little published data, as well as specific questions related to broader topics. Recent topics include Research Integrity (RI) and the Public Trust; RI and Bias; RI and Community-Based Participatory Research; and RI and Factors Affecting Researcher's Behavior. The official Request for Information is posted at <http://grants.nih.gov/grants/guide/notice-files/NOT-ES-12-004.html>. Comments will be accepted through February 1, 2012.

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EXECUTIVE EXTENDS CHARTER FOR PRESIDENTIAL COMMISSION FOR THE STUDY OF BIOETHICAL ISSUES

On November 23, 2011 the White House Office of the Press Secretary announced

the continuance of certain Federal committees until September 30, 2013 [1]. Among those is the Presidential Commission for the Study of Bioethical issues. The Commission, which was established on November 24, 2009 by President Obama, is tasked with advising the President on bioethical issues that "emerge as a consequence of advances in biomedicine and related areas of science and technology [2]."

[1] <http://www.whitehouse.gov/the-press-office/2011/11/23/executive-order-continuance-certain-federal-advisory-committees>

[2] <http://bioethics.gov/cms/sites/default/files/Executive-Order-Establishing-the-Bioethics-Commission-11.24.09.pdf>

To read more about the Commission, see: <http://bioethics.gov/>

*RC

MINNESOTA SUPREME COURT RESTRICTS STATE'S STORAGE AND USE OF NEWBORN BLOOD SAMPLES

On November 16, 2011, the Minnesota Supreme Court ruled that the state's Department of Health cannot store blood samples of newborns, collected as part of a genetic disorders screening, for use in additional research without written parental consent.

Minnesota's newborn screening program tests for over 50 genetic disorders. Parents have the option to refuse screening or request destruction of blood samples after screening is complete, or children may request destruction of the samples once they are of age. Otherwise, samples are stored for potential use in improving and evaluating the screening tests as well as other genetic research after being de-identified.

The initial lawsuit against the state was filed in 2009 by nine families who alleged this storage and use of the samples is a violation of the Genetic Privacy Act, which prohibits the storage, use, or dissemination of genetic information without written consent of the individual. The district court

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determined that the blood samples were not “genetic information” as defined by the Genetic Privacy Act, and the Act did not apply.

On appeal, it was determined that the blood samples are genetic information, but there was not enough support for the claim that these samples were used improperly.

The Minnesota Supreme Court concluded that the blood samples are genetic information and therefore not exempt from the requirement of written consent, except when stored for follow-up on those samples found to have positive test results, and that the newborn screening statutes do not expressly allow indefinite storage. Whether or not the blood samples in question were subject to a violation, with the families entitled to any remedies, was left to the district court to determine.

The dissenting opinion disagreed that blood samples are genetic information, but instead considered them “specimens,” and therefore exempt from the requirement for written consent. As of December 2008, the Minnesota Department of Health had over 800,000 samples stored and over 50,000 have been used in studies by the state and outside research institutions such as Mayo Medical Laboratories.

<http://www.lawlibrary.state.mn.us/archives/supct/1111/OPA100101-1116.pdf>

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DoD ISSUES POLICY REVISIONS FOR PROTECTION OF HUMAN SUBJECTS IN RESEARCH

On November 8, 2011, the US Department of Defense (DoD) issued a renewal of Directive 3216.02 - instructions and ethical standards for the use of human subjects in DoD-supported research [1]. The Directive implements current federal regulations for the protection of human subjects in research, otherwise known as the “Common Rule” [2].

The DoD Directive incorporates a number of unique requirements, including a clarification of the standard for evaluating risk, special requirements for recruitment - specifically with regard to military personnel, exceptions for the requirement of informed consent, required coverage of participant’s medical expenses and compensation for participation, and special directions for classified research.

Because of the atypically hazardous nature of the work of some DoD personnel, the Directive narrows the Common Rule standard for evaluating risk. The current federal regulatory definition for evaluating risk is that it is “encountered in daily life or during the performance of routine physical or physiological examinations or tests.” The DoD regulations add, “the risks imposed...on a special population should not be evaluated against the inherent risks encountered in their work environment (e.g. emergency responder, pilot, soldier in a combat zone).” Other distinctive requirements within the Directive include:

Recruitment of Human Subjects and Special Populations

- Additional regulations are in place for the protection of vulnerable research participants such as women who are pregnant, prisoners, and children. Of note, all active duty Service and Reserve members are considered to be adults, but the Directive cautions those who would recruit members under the age of 18 to seriously consider the necessity of their participation in research. The use of detainees as research subjects is strictly prohibited.
- The Directive also establishes guidelines for the recruitment and participation of military personnel and DoD civilians in research. Military personnel and civilians must obtain authorization from a commanding officer in order to participate in research. Superior officers and supervisors are prohibited from influencing the decision of their subordinates to/not to participate in research, and superiors may not be present during the recruitment process.

Research Monitor

- Recruitment of military personnel for research that involves more than minimal risk requires the presence of an ombudsman. For research involving the participation of DoD civilians, it is up to the IRB whether or not to appoint a research monitor.

Waiver of Informed Consent

- Informed consent may be waived in certain instances of human research, specifically when there is “an intervention or interaction with a living individual for the primary purpose of obtaining data regarding the effect of the intervention or interaction.” Informed consent may be waived if: 1) the research is necessary to advance development of a medical product for the Military; 2) the research may directly benefit the experimental subject; and 3) the research complies with all other applicable laws and regulations.

Coverage of Medical Expenses and Compensation for Participation

- Although not required by the Common Rule, the Directive requires that in circumstances where DoD has primary involvement in research, it will cover the cost of any medical expenses that directly result from participation in non-exempt human subjects research.
- Federal and non-Federal personnel may be compensated up to \$50 per blood draw for participating in research, provided the research meets the established requirements. Compensation to off-duty personnel, however, cannot be made from a Federal source.

Classified Research

- The Directive provides additional guidance for research that is classified or that involves classified information. Approval from the Secretary of Defense is required for all non-exempt research involving human subjects that is classified. In lieu of waivers of informed consent, which are banned under these circumstances, research subjects must be notified that the DoD is the supporting research institution and

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subjects must receive a statement explaining that the research is classified. For the purposes of IRB review, an expedited review process is prohibited. If any member of an IRB disagrees with the majority approval of the research, he or she may appeal the decision directly to the Secretary of Defense.

This DoD Directive applies to the Office of the Secretary of Defense, the Military Departments, the Office of the Chairman of the Joint Chiefs of Staff, the Combatant Commands, the Office of the Inspector General, The Defense Agencies, and all other entities within the Department of Defense. In any circumstance where the Directive conflicts with other laws or requirements, all DoD components are instructed to follow the regulations that are the *most* protective of human subjects.

[1] DoDI 3216.02

<http://www.dtic.mil/whs/directives/correspdf/321602p.pdf>

[2]<http://www.hhs.gov/ohrp/humansubjects/commonrule/index.html>

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EU COURT EMBRYONIC STEM CELL RULING

On October 18, the European Court of Justice ruled that a process involving the removal of stem cells from a human embryo that results in the embryo's destruction cannot be patented. This decision does not restrict embryonic stem cell research, but has implications for commercial and industrial uses of embryonic stem cells in Europe.

The judgment is a clarification of the concept of a human embryo from a 1998 Directive by the European Parliament on the legal protection of biotechnological inventions, which prohibits the patenting of "inventions" using human embryos for commercial and industrial purposes as "contrary to ordre public or morality" [1].

Since 2004, Greenpeace has challenged a patent held by Dr. Oliver Brüstle of the University of Bonn on a process for converting stem cells to neural precursor

cells in the potential treatment of neurological diseases such as Parkinson's disease. The environmental organization has stated that it is not opposed to the research [2], but is opposed to the commercialization of the human body, and therefore sought a definition of a human embryo to clarify what can and cannot be patented in Europe under the 1998 Directive [3].

The Federal Court of Justice in Germany found the patent invalid, and Brüstle appealed, leading the Federal Court to refer questions about the definition of an embryo and commercial use to the Court of Justice [4].

In the October 18 decision, the Court of Justice classified a "human embryo" as a fertilized human ovum that has the capability to begin development, but also an unfertilized ovum that has undergone parthenogenesis or has had a mature human cell nucleus transplanted and can potentially begin development. Whether or not the cells involved in Brüstle's patent are covered by this definition has been left to the German Federal Court to decide [5].

The Court of Justice also determined that a patent implies commercial or industrial use. Therefore, research using human embryos also cannot be patented, except when beneficial to the embryo itself, such as with therapeutic or diagnostic processes.

Researchers in Europe are concerned that the prohibition on patenting the results of embryonic stem cell research will discourage investments in this type of work in Europe since there will be no incentive if profits from discoveries cannot be protected. Not only is there concern that this decision will hinder future discoveries and treatments for a range of neurological and other disorders, but some are concerned that European-based research will now be available to be used, patented, and profited from in other parts of the world, with the resulting products then sold back to Europe.

Some researchers are less concerned because embryonic stem cell research makes up only a small part of all stem cell research, patents can still be held

outside of Europe, and techniques and technology related to embryonic stem cell research can still be patented. Others have applauded the definition of a human embryo to include a fertilized human ovum, although the Court has stated that it has "not [been] called upon to broach questions of a medical or ethical nature, but must restrict itself to a legal interpretation" [5].

[1] Directive 98/44/EC, Article 6 of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions; http://eur-lex.europa.eu/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=en&numdoc=31998L0044&model=guicheet

[2] Greenpeace challenges patent, 20 October 2004; <http://classic.the-scientist.com/news/20041020/01/>

[3] Greenpeace International Press Release, 18 October 2011; <http://www.greenpeace.org/international/en/press/releases/Greenpeace-welcomes-European-Court-of-Justice-ruling-on-stem-cells-patents/>

[4] Report on German Court referral to European Court of Justice; http://www.eplawpatentblog.com/PDF_December09/Biotech%20ECJ%20DE.pdf

[5] Court of Justice of the European Union Press Release, 18 October 2011; <http://curia.europa.eu/jcms/upload/docs/application/pdf/2011-10/cp110112en.pdf>

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2011 WORLD SCIENCE FORUM ADOPTS A DECLARATION

On November 16 -19, the Fifth World Science Forum convened in Budapest, Hungary, on the theme of "Changing the Landscape of Science: Challenges and Opportunities." The meeting brought together many of the world's leading scientists and science administrators, who gathered to foster an international dialogue focused on the consequences of science and technology and the relationship between science and society.

Meeting participants endorsed a Declaration on a New Era of Global Science [1]. The Declaration contains five major elements. The first element

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focuses on developing a new universal code of conduct. The main purpose of establishing a scientific code of conduct is to promote high standards of moral conduct and minimize social concerns associated with new scientific advancements. In the code of conduct, the scientific rights, freedoms and responsibilities of researchers will be clearly established and universal rules of scientific research should be shared among the scientific communities around the world. Scientists feel it is vitally important to discourage short-term economic interests or political interests when selecting or developing industrialized research projects.

The second element of the Declaration is that scientists must place a higher priority on educating people about new scientific developments. Scientists in all nations will contribute resources and do their part to educate the populace about new scientific developments. More educated societies will empower science by enabling a greater number of people to become familiar with scientific developments, thus creating a more open and trusting relationship with science. Trust that scientists are operating with high moral and social standards will enable scientific developments to gain traction in both democratic and non-democratic societies.

The third element of the Declaration is that scientist must become more effective in sharing scientific information. One way for all scientists to support the efforts of their colleagues is to establish better international collaboration and information sharing for scientific research. International cooperation is essential to promote shared knowledge, and sharing scientific knowledge is necessary to avoid costly research repetition.

The Declaration's fourth element states that scientists should overcome knowledge divides through increased amounts of global collaboration. The cost of scientific developments has created a gap between the sciences in developing nations compared to developed nations. The Declaration calls upon all scientists

to work together for the continued growth of science and scientific knowledge.

The final element of the Declaration focuses on discovering new ways to increase investments into science and scientific developments in all nations. There is a strong socio-economic link between nations who have a high standard of living with significant national investments in the sciences. Creating programs to encourage the participation of women in science is another way countries can invest in the sciences. There is a pressing need for new effective science policies that will enable nations to increase global scientific research and achieve better university education in the sciences.

[1] http://www.sciforum.hu/cms/upload/docs/programme/WSF_2011_Declaration_adopted.pdf

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Resources

The U.S. Office of Human Research Protections (OHRP) has announced the availability of the 2012 edition of "The International Compilation of Human Research Standards." The volume is a listing of over 1,000 laws, regulations, and guidelines on human subjects protections in over 100 countries and from several international organizations. The 2012 edition updates and expands the human research standards in many other countries based on information provided by in-country experts.

<http://www.hhs.gov/ohrp/international/intlcompilation/intlcompilation.html>

GLOBAL HEALTH REVIEWERS

Global Health Reviewers is a free, open-access website and forum for ethics reviewers, as well as others interested in medical research ethics, to promote exchange of ideas and information between ethics committee reviewers, researchers, and others. Its goal is to provide resources, support, and opportunities for discussion to ethics committee members and scientists, particularly those in resource-poor areas.

The website offers three main sections: a large collection of resources, a forum for discussions, and an area for members' blogs on clinical research.

The "Resources" section provides a general ethics review FAQ for committee members, including some in-depth answers and links to further reading; a glossary of terms reviewers may encounter; links to documents, guidelines, and regulations from over 1000 national, international, and institutional bodies; and links to free courses and learning modules on international research ethics.

Within the "Community Activity" section are member-submitted information, such as event information and links to international ethics committee websites, and a forum for Discussion Groups. Discussion groups are created by members and can be anything from a public forum for general ethics review discussion that is open to anyone interested, to invite-only private forums for discussions of sensitive cases and subjects not visible to non-members.

Global Health Reviewers is free to join, and access to resources outside of events information and certain discussion groups are available without a membership. It is sister-site to Global Health Trials, which provides resources and information sharing for clinical trials in "resource-limited" areas, and Global Health Bioethics, which provides resources and information sharing for people conducting bioethics research. Global Health Reviewers is operated by the University of Oxford and funded by the Bill and Melinda Gates Foundation.

<http://ghr.globalhealthhub.org/>

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Announcements

Call for Papers – The Society for the Study of Artificial Intelligence and the Simulation of Behaviour (AISB) and the International Association of Computing

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and Philosophy (IACAP) invite submissions for the planned Symposium on a Framework for Responsible Research and Innovation in Artificial Intelligence. The symposium will be part of the joint meeting to be held July 2-6, 2012 in Birmingham, UK. Abstract submissions are invited on topics such as: the responsibilities of the individual researcher and/or developer in AI, how to define and enforce collective responsibility in AI, ways to address unforeseen consequences and side effects in AI, the limitations of responsibility in AI, and the legal framework for responsibility, liability and accountability in AI. Extended abstracts, up to 1500 words, may be submitted. All submissions should be sent by email to bstahl@dmu.ac.uk, by February 1, 2012. For more information, see: www.responsible-innovation.org.uk

Call for Papers - The 5th International Conference on Information Law and Ethics is seeking abstract submissions for its meeting on June 29-30, 2012. The conference invites papers on any field of law and/or ethics related to any aspect of information. Papers on the historical development of information laws and ethical theory are encouraged. Submitted abstracts of 250 words (references excluded) should be sent for review to: botti@otenet.gr. The deadline for submission is March 15, 2012. For more information, go to: <http://conferences.ionio.gr/ici12012>

Conference - The AAAS Science and Human Rights Coalition will hold its 7th meeting on January 23, 2012 at AAAS Headquarters in Washington, DC. The upcoming meeting will focus on Indigenous populations, science and technology, and human rights. To read more about the work of the Coalition, see: <http://srhrl.aaas.org/coalition/index.shtml>. To register for the meeting and to view the agenda, go to: <https://www.signup4.net/public/ap.aspx?EID=AAAS16E&OID=50>

Conference - The U.S. Office of Research Integrity's Quest for Research Excellence 2012 Conference has been rescheduled. The conference, postponed

due to hurricane Irene, will be held in Washington, DC on March 15-16, 2012. It will bring together educators of responsible conduct of research and researchers of research integrity with representatives from professional societies, funding agencies and regulators. To register, go to: <http://www.regonline.com/builder/site/Default.aspx?EventID=972393>

Conference - Educating Scientists in Research Ethics for the 21st Century: A trainer-of-trainers conference will be held in Washington, DC, March 16-19, 2012. Leaders in the field of research ethics and education will provide participants with information, strategies, and extensive curricular resources. A variety of sessions will allow both novice and experienced teachers of research ethics to benefit. Topics include emerging technologies, social responsibility, research misconduct, conflict of interest, and cultural issues in teaching RCR. The conference is relevant to individuals in all research-oriented fields who will be providing training in research ethics to individuals ranging from undergraduates to faculty and staff. The conference is sponsored by AAAS, ORI, Sigma Xi, and the University of Pittsburgh Survival Skills Program. To register, go to: <http://www.skillsandethics.org/2012conference>

Fellowship - The McCoy Family Center for Ethics in Society at Stanford University seeks up to four new postdoctoral fellows for 2012-2013. Applications are encouraged from those with diverse backgrounds including philosophy, the social sciences, and professional schools. The Center is especially interested in candidates with research interests in inequality, human rights, immigration, and environmental justice. Fellows will teach one class, participate in a Political Theory Workshop, interact with undergraduates in the Ethics in Society Honors Program and help in developing an interdisciplinary ethics community across the campus. Applicants must have completed all requirements for their PhD by June 30, 2012. Candidates must also be no more than 3 years from the awarding of their degree. The deadline for application is January 11, 2012. To access the online

application system, go to: <https://academicjobsonline.org/ajo/jobs/1133>. For more information on the Center and the fellowship program, see: <http://ethicsinsociety.stanford.edu/grants-fellowships/postdoctoral-fellowships/>. For inquiries, contact [Joan Berry](mailto:Joan.Berry).

Visiting Scholar - The Jepson School of Leadership Studies at the University of Richmond is accepting applications for the position of Zuzana Simoniova Cmelikova Visiting Scholar in Leadership and Ethics for 2012-2013. The program is designed to give visiting scholars the opportunity to develop courses, to design programs, or to conduct research. Visiting scholars may be new PhD's or experienced scholars who hold a PhD in an academic area related to the study of leadership and ethics. Review of applications will begin on December 1 and continue until the position is filled. Additional information about the Jepson School and the University can be found at: jepson.richmond.edu. Applications should be sent electronically to: <https://www.urjobs.org/>. Inquiries may be directed to Nancy Nock, International and Grant-Funded Programs Coordinator, Jepson School of Leadership Studies, nnock@richmond.edu.

Workshop - The Poynter Center for the Study of Ethics and American Institutions will host the 19th annual Teaching Research Ethics Workshop at Indiana University Bloomington, May 15-18, 2012. Session topics will include an overview of ethical theory, trainee and authorship issues, conflicts of interest, using human subjects in clinical and non-clinical research, and responsible data management. Sessions will feature techniques for teaching and assessing the responsible conduct of research. For more information, contact Glenda Murray, Poynter Center, at: glmurray@indiana.edu. For more information or to register, go to: <http://poynter.indiana.edu/tre>