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### **NIH Releases New Guidelines on Stem Cell Research Funding**

On April 17, 2009, the National Institutes of Health ("NIH") released new draft guidelines entitled "National Institutes of Health Guidelines for Human Stem Cell Research" ("Guidelines"). The purpose of the Guidelines is to implement President Obama's Executive Order issued March 9, and to ensure that research with human embryonic stem cells is ethically responsible, scientifically worthy, and legal.

Researchers hope that the study of human embryonic stem cells will lead to a better understanding of human development and possibly the development of cells and tissues useful in treating diseases and conditions such as Parkinson's disease, amyotrophic lateral sclerosis ("ALS"), and spinal cord injury.

The Guidelines prohibit funding for work with embryos created solely for research purposes, but allow extramural NIH funding of research using embryonic stem cells derived from in vitro fertilization ("IVF") for reproductive purposes. The Guidelines also specify information that must be included in the written informed consent for potential donors.

NIH requests public comments on the Guidelines, which must be submitted within thirty (30) days of publication of the Guidance in the Federal Register. NIH expects to publish the Guidelines in the Federal Register by April 24, 2009. The draft Guidelines are available at: <http://stemcells.nih.gov/policy/2009draft>.

### **OHRP Offers Guidance to Investigators and IRBs on the Genetic Information Nondiscrimination Act**

The Office for Human Research Protections ("OHRP") recently issued its first formal guidance on the Genetic Information Nondiscrimination Act ("GINA") for investigators and Institutional Review Boards ("IRBs"). The document applies to non-exempt human subjects research conducted or supported by the Department of Health and Human Services ("HHS").

GINA provides a baseline level of protection against discrimination based on genetic information in health insurance, group health plan, and employment contexts. Because GINA has implications regarding an individual's willingness to participate in genetic research, investigators and IRBs should be aware of its protections and limitations.

OHRP recommends that IRBs consider whether informed consent documents for genetic research should include a description of GINA's protections and their effective dates (November 21, 2009 for employers with fifteen (15) or more employees and May 21, 2010 for health insurance companies and group health plans). In addition, OHRP asks IRBs to

consider warning patients that GINA does not protect research subjects from discrimination by companies offering life insurance, disability insurance, or long-term care insurance, or from discrimination based on an already manifest genetic disorder.

Comments on this proposal are welcome at any time and may be sent to [www.ohrp.hhs.gov](http://www.ohrp.hhs.gov) or via facsimile at 240-453-6909.

*For more information about any of these topics, please contact your local counsel or Jennifer A. Girod at [jgirod@hallrender.com](mailto:jgirod@hallrender.com) in our Indiana office, or Leah Voigt Romano at [lromano@hallrender.com](mailto:lromano@hallrender.com) in our Michigan office.*

Is your organization interested in potential funding opportunities through the American Recovery and Reinvestment Act? Hall Render is monitoring these opportunities, as they are announced by various federal agencies, and we work with health care providers to identify projects and programs that may qualify for funding, particularly in the areas of health information technology and biomedical research. For more information, contact Leah Voigt Romano at [lromano@hallrender.com](mailto:lromano@hallrender.com).

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