

# Human Research Protections Newsletter

## Guest speaker to discuss internet research

On Sept. 14, 2009, Dr. Joseph A. Konstan, University of Minnesota, Dept. of Computer Science and Engineering will present *'Internet Research from Surveys to Social Computing: Ethical Issues and Practical Advice'*. This interactive discussion is open to all NDSU faculty, staff and students. Watch for upcoming announcements soon.



## FDA inspection of NDSU IRB

In a first-time visit to the NDSU IRB, a representative of the Food and Drug Administration (FDA) recently inspected IRB records, including protocols, procedures, meeting minutes and membership rosters. A preliminary determination revealed no deficiencies or problems related to FDA regulations; a final report is expected at a later date.

## August 2009



## Protocol changes

**Reminder:** Changes to an approved protocol require prior IRB approval, with few exceptions. This would include, but is not limited to, changes in: investigators or research team, research site, data collection, subject recruitment or compensation. For more information see: [SOP 7.5 Protocol Amendments](#).

## Your questions:

### What type of review will my project require?

Because research projects will vary significantly in the level and types of risk, involvement of vulnerable groups or type of interventions, the level of IRB review required also varies. The categories of review are set by federal regulations and include: exemption determinations, expedited review, or full board review. Sometimes there will be uncertainty regarding appropriate level of review. In those situations, the IRB will assign a higher level of review to ensure compliance with federal regulations and protection of the rights and welfare of research participants. For more information, see [SOP Section 7, IRB Review Process](#).



## Recent article:

Nine years after the widely publicized death of [Jesse Gelsinger](#), a research participant in his study, Dr. Wilson shares his reflections on the gene therapy trial. The article is available through [ScienceDirect.com](#).

**'Lessons learned from the gene therapy trial for ornithine transcarbamylase deficiency', J. Wilson, Molecular Genetics and Metabolism 96 (2009) 151-157**