

OBA News

News from the NIH Office of Biotechnology Activities

October 31, 2008

^^

OBA Launches Annual Reporting Tool for Human Gene Transfer Trials - The National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) has updated the Genetic Modification Clinical Research Information System (GeMCRIS) — a web-accessible database of human gene transfer clinical trials.

A new feature has been added that allows investigators and sponsors conducting human gene transfer trials to create and submit annual reports via a secure electronic interface within GeMCRIS. With this tool, reports can be submitted instantaneously to NIH OBA. The annual reporting module allows for safety information to be uploaded directly into GeMCRIS using an excel spreadsheet template. The entire annual report can then be submitted electronically through GeMCRIS, or additional information can be submitted separately to NIH OBA. Investigators and sponsors can save their NIH OBA submission on their own computer and send a copy to the FDA in accordance with 21 CFR 312.33.

The electronic reporting tool is key to efforts by both NIH and FDA to improve oversight and facilitate investigator reporting for human gene transfer trials

The public GeMCRIS site is available at: <http://www.gemcris.od.nih.gov/>.

Investigators and sponsors who wish to use the system to submit annual reports and/or adverse events occurring on human gene transfer trials registered with NIH OBA should send a written request on institutional letterhead by U.S. mail or fax to: GeMCRIS Systems Administrator, NIH Office of Biotechnology Activities, 6705 Rockledge Drive, Suite 750, Bethesda, Maryland 20892; Fax: 301-496-9839.