



Northwest IRB Fresh Sheet Supplement, summer 2009

Published as necessary by the Northwest Association for Biomedical Research (NWABR), the Northwest IRB Fresh Sheet supplement is your communication tool to reach other human subjects programs throughout the region with news and information. Posting announcements and subscriptions are free to members of NWABR. Contact Laurie Hassell at 206-465-4691 or hassell@nwabr.org for newsletter and membership questions.

News Round-Up

Save the Date – February 4, 2010 for “**Protecting Research Participants: Ethical Challenges within a Regulatory Framework**” a Research Community Forum presented by the **Office for Human Research Protections** and the **Northwest Association for Biomedical Research (NWABR)**. Dr. Jerry Menikoff, Director of OHRP, will be the plenary speaker. The Forum features basic and advanced IRB sessions, biomedical and social/behavioral/educational research topics, and a track for research teams. Agenda development and conference site selection (in Western Washington) are underway. Please forward this announcement to investigators and compliance professionals at your institution, and contact Laurie Hassell at 206-465-4691 or hassell@nwabr.org if you have any questions.

Oregon Health & Science University is accepting applications until July 22nd for enrollment in the Human Investigations Program (HIP). This program is designed to meet the need for highly skilled clinical and translational investigators including medical or dental research fellows, postdoctoral fellows, faculty members from OHSU's medical, dental or nursing schools, clinicians and community practitioners. Program participants can select a non-degree Certificate in Human Investigations track allowing enrollment in individual courses or a Master of Clinical Research curriculum. <http://www.ohsu.edu/xd/education/schools/school-of-medicine/academic-programs/hip/about/index.cfm>

The **Truman Katz Center for Pediatric Bioethics** at **Seattle Children's** will present “No Longer a Child, Not Yet an Adult: Ethical Issues in Adolescent Health Care”, scheduled for July 24-25. A live webcast of the conference will be available from 8:30 am to 3:30 pm on July 24th and 8 am to 3 pm on July 25th. http://bioethics.seattlechildrens.org/events/pediatric_bioethics_conference/pediatric_bioethics_conference.asp

University of Washington Professional & Continuing Education announces several certificate courses in clinical trials, healthcare regulatory compliance, biomedical regulatory affairs and biotech project management. See below for details.

Certificate in Clinical Trials (Seattle)

Learn the essential elements in designing successful clinical trials and understand the management skills necessary to effectively oversee their implementation in this 9-month program taught by leaders in the field. Information meeting: 8/4, 6-7 p.m. (UW campus, Health Sciences). Learn more at http://www.extension.washington.edu/ext/certificates/cli/cli_gen.asp or call 206-685-8936.

Certificate in Healthcare Regulatory Compliance (Online & Classroom Combined, Seattle)

Acquire the critical knowledge and resources to understand and apply current compliance regulations in this program that meets with a combination of online and Saturday classes in a convenient format. Information meetings online or in-person: 7/22, 6-7 p.m. (Health Sciences Building, UW Campus), 8/12 and 9/9 6-7 p.m. (UW Tower). Learn more at http://www.extension.washington.edu/ext/certificates/hcc/hcc_mtg.asp or call 206-685-8936.

Certificate in Biomedical Regulatory Affairs (Bellevue)

Understand the role of a medical products regulatory affairs specialist and the dynamic nature of the regulatory field. Information meeting: 7/28, 6-7 p.m. (Bellevue). Learn more at http://www.extension.washington.edu/ext/certificates/bio/bio_gen.asp or call 206-685-8936.

Certificate in Biotech Project Management (Online)

Discover how to ensure project progression within the scientific community and explore the unique project management challenges in the research, biotech, or biomedical industry in this online program. Information meetings: 7/28, 12-1 p.m. and 8/4, 6:30-7:30 p.m. (Bellevue), 8/5, 12-1 p.m. (Renton), and 8/7, 12-1 p.m. (Downtown Seattle). Learn more at http://www.extension.washington.edu/ext/certificates/bpm/bpm_gen.asp or call 206-685-8936.

The Regulators

Genetic Engineering & Biotechnology News published a series of articles spotlighting regulatory affairs at the FDA. Page 2 of 3 contains a piece by Dr. Terrence Chew about the perils of ignoring the basic requirements of clinical trials compliance. Failure to submit an Investigational New Drug application, adequate record keeping, adherence to the protocol and other topics are referenced. <http://www.genengnews.com/articles/chitem.aspx?aid=2949&pn=2>

Genetic Engineering & Biotechnology News addresses the FDA's guidance when utilizing 'leftover human specimens' in an article published June 15, 2009. Criteria for permitting the use of these samples include the following: specimens must be left over from routine care or analysis and subject to disposal, identification of the sample source must not be possible for the sponsor or investigator (coded samples are okay), clinical data from the samples do not permit source identification, 'de-identification' is irreversible, and reports to the subject's health care provider are prohibited. <http://www.genengnews.com/articles/chitem.aspx?aid=2947>

Office for Human Research Protections and the **Food and Drug Administration** remind human subject research program personnel that regulations requiring the registration of IRBs with the Department of Health and Human Services go into effect on July 14, 2009. Required elements include contact information person submitting registration, approximate numbers of all active protocols and those studies conducted or supported by HHS, and the approximate number of full time equivalent positions devoted to IRB administrative activities. All IRBs reviewing FDA-regulated research must register between July 14 and September 14, 2009. Visit <http://ohrp.cit.nih.gov/efile/> to complete the process.

Oregon Senate Bill 316, which requires insurance companies to provide coverage for routine care for participants in clinical trials, was signed by Governor Kulongoski on June 16, 2009. Text of the bill can be found at <http://www.leg.state.or.us/09reg/measures/sb0300.dir/sb0316.en.html> with related media coverage from **Salem News** at http://www.salem-news.com/articles/june182009/patient_access_6-18-09.php.

House of Representatives Bill HR 2866 – Improving Access to Clinical Trials Act, which seeks to increase participation in clinical trials, was introduced on June 15, 2009. The bill, if passed, will allow the Supplemental Security Income Program to disregard the first \$2,000 received by an individual for participation in clinical trials for the treatment of rare diseases as defined by the Orphan Drug Act. Provisions for the review and approval by institutional review board and adherence to standards for human subjects protection are included. Read the full text at <http://www.gpo.gov/fdsys/pkg/BILLS-111hr2866IH/pdf/BILLS-111hr2866IH.pdf>.

Kudos

The **Institute for Systems Biology** (ranked #7), the **Fred Hutchinson Cancer Research Center** (ranked #14) and **Oregon Health & Science University** (ranked 27th) are listed in the top 40 places to work for postdocs as determined by The Scientist Magazine. The survey collected responses related to infrastructure and institutional facilities but also included elements important to foreign postdocs such as immigration law navigation, foreign language training and cultural adjustments. Read the article at <http://www.the-scientist.com/2009/03/1/47/1/> (subscription). Congratulations!

Leroy Hood, President of the **Institute for Systems Biology**, was chosen by Rolling Stone Magazine as one of 100 People who are Changing America (ranked #63). http://www.rollingstone.com/news/story/26754176/the_rs_100_agents_of_change/5. Dr. Hood, along with luminaries such as Secretary of State Hillary Rodham Clinton, was awarded an honorary degree citation by Yale University. <http://opa.yale.edu/news/article.aspx?id=6709>.

Classified

Quorum Review is taking applications for a **Regulatory Attorney** position with 3-5 years of proven success in the application of health law and/or related regulatory issues. Primary responsibilities include providing clarity and guidance to IRB members and staff, analysis and recommendations regarding regulations interpretation, pre-review of negotiations with sites and sponsors, address issues associated with audit results and reviews, and legal review of contracts, service agreements, etc. Submit letter of interest and resume to Human Resources at www.quorumreview.com.

Quorum Review is taking applications for a **Study Manager**, which serves as the point of contact with clients. Responsibilities include providing customer service related to the management of study activities, detailed and time-sensitive information to clients and process information being reviewed throughout the study. The ideal candidate will have proven 3-5 years of experience providing customer service, excellent communication skills and strong analytical skills in evaluating service delivery gaps. An associate's degree or equivalent is required. Submit letter of interest and resume to Human Resources at www.quorumreview.com.

Human Subjects Media Coverage

Channel 7 News (Denver, CO) published an article entitled "Are Clinical Trial Results Compromised by Money?" in which issues such as selective publication of study results, use of medical journals as marketing instruments, financial disclosure and scientific misconduct were discussed. <http://www.thedenverchannel.com/education/20052956/detail.html>

Life Science Leader published an article entitled “The Key Considerations of Clinical Trials”, which provides a description of the clinical trials process for the lay audience and questions clinical trials are designed to answer. Access the article online at http://www.lifescienceleader.com/index.php?option=com_jambozine&layout=article&view=page&aid=3819.

The **National Cancer Institute Bulletin** published an article illustrating the increasing complexity of the clinical research process and offering suggestions from NCI’s Clinical Trials Working Group. Improving operational effectiveness by integrating strategies used by companies such as Toyota and Southwest Airlines will streamline operations and speed up decision-making. The Working Group plans to reduce the activation time for clinical trials to less than 90 days. Read the article at <http://www.cancer.gov/ncicancerbulletin/061609/page6>.

Nature published an article calling for a more streamlined system in Europe for approving clinical trials taking place in different countries. A single multinational study clinical trial authorization process would, according to researchers, eliminate duplicative processes which result in approvals in one country but not in another. The European Union’s Clinical Trials Directive has been implicated in the current problems while others claim that relatively minor alterations in the policy will achieve necessary oversight. <http://www.nature.com/news/2009/090710/full/news.2009.662.html>

The **New York Times** published several articles associated with a suspected case of medical research fraud in which a clinical researcher at Walter Reed Army Medical Center reported that a study of a bioengineered bone growth product produced by Medtronic outperformed traditional bone grafting techniques. The product was later found not to be more effective than traditional therapies and the author failed to notify co-authors of the study before publication, and received substantial payments from the product’s maker while in the Army. Related articles (in order of publication) can be accessed at <http://www.nytimes.com/2009/05/13/business/13surgeon.html?fta=y>, <http://www.nytimes.com/2009/06/06/business/06surgeon.html?pagewanted=1&fta=y>, <http://www.nytimes.com/2009/06/13/business/13device.html?fta=y>, <http://www.nytimes.com/2009/06/18/business/18surgeon.html?fta=y>, <http://www.nytimes.com/2009/06/23/business/23army.html?fta=y>,

Star Tribune (Minneapolis, MN), http://www.startribune.com/business/50493352.html?elr=KArks7PYDiaK7DUdcOy_nc:DKUiD3aPc:Yyc:aUU and <http://www.nytimes.com/2009/06/24/business/24device.html?ref=health>. A related **Wall Street Journal** article reports that the institutional review board at Washington University did not receive any financial disclosure information when the studies were reviewed. <http://online.wsj.com/article/SB124760292798141001.html>

The **New York Times** announced the approval by the Empire State Stem Cell Board of payments up to \$10,000 to women who donate their eggs to research. Payments will be approved by institutional review boards but opponents claim undue financial inducement will encourage donors to disregard health risks associated with the procedure. <http://www.nytimes.com/2009/06/26/nyregion/26stemcell.html?ref=health> A related opinion piece can be read at <http://www.nytimes.com/2009/07/11/opinion/11sat4.html?th&emc=th>

ScienceDaily reported on a new toolkit available for researchers and institutional review boards designed to simplify the language of consent forms and other communications with patients and research participants. In the toolkit, called PRISM (Project to Review and Improve Study Materials), investigators and IRBs can find tools to determine reading level, consent and HIPAA related information, alternative wording suggestions and numerous resources. Read the article at <http://www.sciencedaily.com/releases/2009/07/090708153242.htm>. Access the toolkit from the Group Health Center for Health Studies at http://www.centerforhealthstudies.org/capabilities/readability/ghchs_readability_toolkit.pdf.

The **St. Petersburg Times** printed an article reporting on the arrest of Vladimir Martin for failure to practice medicine without a license. Seventeen clinical trials were conducted by Mr. Martin, who attended medical school in the former Soviet Union before moving to Florida in 2003. In one study reviewed by Sterling Institutional Review Board in Atlanta, a research participant filed a complaint with the oversight committee months before going public. Read the article at <http://www.tampabay.com/news/business/article1012526.ece>.

The Hindu published an opinion piece about the registration of studies in the Clinical Trial Registry in India, which became mandatory on June 15th. The author states that approximately 300 trials are currently registered with another 150 expected by the end of the year. The registry is designed to improve transparency of clinical studies in India, help potential volunteers find a study and improve public confidence in the process by setting ethical requirements for sponsors. The article is available at <http://www.hindu.com/seta/2009/06/18/stories/2009061850121400.htm>. A related article in the **Economic Times of India** can be found at <http://economictimes.indiatimes.com/News/News-By-Industry/No-more-off-the-record-human-clinical-trials/articleshow/4664662.cms>. Access the Clinical Trial Registry at <http://www.ctri.in:8080/Clinicaltrials/index.jsp>.

Time Magazine featured an article about ‘The Second Wave’, referring to a movement to provide better information about how drugs affect women during pregnancy. Physicians, scientists, ethicists and government officials launched this initiative in the spring of 2009. <http://www.time.com/time/magazine/article/0,9171,1901482,00.html>

The **Washington Post** published a report about a policy in Minnesota which stores newborn blood samples long-term and allows researchers to access them without parental consent. Officials in many states said research projects must be approved following scientific and ethical review. Identifying information is stripped in most cases or parents are contacted for consent before releasing the samples to researchers. Opponents worry that state agencies retain the ability to identify each sample and further genetic research can also reveal the identity of the individual. http://www.washingtonpost.com/wp-dyn/content/article/2009/06/29/AR2009062903118_2.html

Research Participant Perspectives

EmpowHer featured a short article by an ovarian cancer survivor who participated in a phase 1 monoclonal antibody study. Her experience was very positive. <http://www.empowher.com/news/herarticle/2009/06/18/ovarian-cancer-and-why-im-fan-clinical-trials>

The **Kingston Whig Standard** (ON, Canada) published an opinion piece from a contributor who took issue with some of the language used when clinical trials are referenced – “x patients failed medication y”. The author stated that “I’m not on trial – the chemicals I take for my disease are.” Her positive experiences associated with clinical trials participation include making a contribution to the latest drug development and better health care. <http://www.thewhig.com/ArticleDisplay.aspx?e=1649961>

The **Springfield News-Sun** (OH) reported on the efforts of a cancer patient who battled until her death for the Access to Cancer Clinical Trials Act, a bill what would require insurance companies to pay for routine care while a patient is enrolled in a clinical trial. Read the article at <http://www.springfieldnewsun.com/lifestyle/womans-insurance-battle-goes-on-after-death-159078.html>.

US News & World Report blog writer Ben Harder has submitted via blog a request for comments from readers who have participated in a clinical trial or those who have considered it. [Editor’s note: LH – The author relates his experience having been turned down for two different clinical trials in which he expressed relief for not having been chosen, “it seems half-crazy to me now that I almost took that risk.”] Read the blog entry and provide comments at <http://www.usnews.com/blogs/thinking-harder/2009/07/10/0710thinkinghardertrials.html>

Information for Researchers and Investigators

The **Atlanta Journal Constitution** published a short report about a study indicating that women are continuing to be underrepresented in clinical trials research. According to the article only 41% of participants are women in studies receiving government funding, only 37% in studies without. The authors suggested that women found study participation overly burdensome when juggling work and family responsibilities and researchers should revise recruiting methods. Access the report at <http://www.ajc.com/health/content/shared-auto/healthnews-brn/627849.html>. A related article in **Medical News** can be found at <http://www.medpagetoday.com/PublicHealthPolicy/ClinicalTrials/14588>.

The **City of Bothell** and other event organizers have made presentation materials and other resources available from the 2009 Washington State Biomedical Device Summit, held on June 23rd. Slides from the presentation on the opportunities and challenges in the sector as well as key findings from the Industry Outlook Survey, conducted by the Biomedical Device Innovation Zone, are available. <http://www.ci.bothell.wa.us/CityServices/EconomicDevelopment/IPZ/09BioSummit.ashx?p=1526>

ScienceDaily reported the publication of a model for medical device development which includes five major phases and four ‘decision gates’. The model considers FDA regulation parameters for both devices and pharmaceuticals in order to account for issues associated with combined drug-device products. Access the article at <http://www.sciencedaily.com/releases/2009/06/090629132210.htm>.

ScienceDaily reported on a meta-analysis of randomized controlled trials and the impacts of study design on clinical outcomes. Results indicate that comparator studies had a higher incidence of response and remission than placebo-controlled trials. [Editors Note – LH: The study relates specifically to the use of antidepressants for the treatment of major depression.] Access the article at <http://www.sciencedaily.com/releases/2009/06/090622064703.htm>.

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