



Northwest IRB Fresh Sheet Supplement, spring 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.

Responsible Conduct of Research

Chris Witwer, compliance manager at the **Institute for Systems Biology (ISB)** has begun planning a Responsible Conduct of Research (RCR) training course which meets **National Institute of General Medical Sciences (NIGMS)** training grant requirements for post-docs. The program will involve a lecture series covering 7 of the 9 RCR topics (excluding animal and human subjects training, as these are handled separately at ISB) with weekly discussion groups on the ISB campus in the Fremont neighborhood of Seattle. Chris would like to assess interest in institutional collaboration and/or participation by your researchers, and is also looking for recommendations for speakers. Please contact her at 206/732-1406 or cwitwer@systemsbiology.org by Friday, May 1st if you have an interest in this program.

Regional News Round-Up

The Hastings Center has issued a call for manuscripts to *IRB: Ethics & Human Research*, a peer-reviewed journal devoted to ethical issues in research with human participants. Submissions are typically 3500 words including all text, references, tables and figures though longer and shorter pieces are welcomed. The manuscript may be placed in one of the following categories: "Insight" emphasizing theoretical and conceptual concerns, "In the Field" which identifies and assesses institutional, national and international policy issues, "Case Study" analyses specific studies, ethical issues, and IRB policies and deliberation, and "The Participant" offers personal reflections about the human research enterprise. Full submission guidelines can be accessed at <http://www.thehastingscenter.org/Publications/IRB/Guidelines.aspx>.

The **Institute of Translational Health Sciences (ITHS)** has two upcoming seminars to be held at the University of Washington's South Campus Center in rooms 348/350. Contact Jason Malone at 206-598-4734 or jmmalone@u.washington.edu for more information or to be added to the distribution list.

- Tuesday, May 5 at 12 pm - How to Write and Use a Protocol by Carol Wallace, MD; Professor, Pediatric Rheumatology, Seattle Children's
- Tuesday, June 2 at 12 pm – The IND/IDE Development Process by Lynne Rose, PhD; Associate Professor, Pediatrics and Director, Clinical Operations, Cystic Fibrosis TDN Coordinating Center, Seattle Children's

Western Institutional Review Board is accepting registrations for two courses on human subject protection. The first, targeting clinical investigators, is scheduled for May 7, 2009 and will focus on the regulations, ethics and investigator responsibilities when conducting clinical trials. 'Site Operations and SOPs', scheduled for May 8, 2009, is designed to give investigators and site coordinators practical instruction related to feasibility studies, general operations and project management, and the effective development and implementation of standard operating procedures. Both courses will be held in Olympia, Washington and offer continuing education credits. For more information visit http://www.wirb.com/content/wirb_training.aspx or contact Angela Regensburg at 360-252-2478.

The Regulators

The **Office for Human Research Protections (OHRP)** has issued a request for information and comments regarding a 'notice of proposed rulemaking (NPRM), which would hold institutional review boards (IRB) and their operational organization directly accountable for meeting regulatory requirements for the protection of human subjects under 45 CFR part 46. Deadline for electronic and written submission is **June 3, 2009**. Access detailed information at <http://edocket.access.gpo.gov/2009/E9-4628.htm>.

The **Office for Human Research Protections (OHRP)** issued guidance on the Genetic Information Nondiscrimination Act (GINA) for investigators and institutional review boards. The document focuses on the criteria for IRB approval and informed consent as well as addressing implications of GINA for investigators. Also included are definitions of what is and is not considered a genetic test. Read the guidance at <http://www.hhs.gov/ohrp/humansubjects/guidance/gina.html>.

Oregon Senate Bill 316, which would require health insurance companies to provide coverage for routine costs of care in clinical trials, was approved by a legislative committee on April 7, 2009 and now moves to the full Senate. Read the full text of the bill at

<http://www.leg.state.or.us/09reg/measpdf/sb0300.dir/sb0316.intro.pdf> and a related article in the **Statesman Journal** (Salem, OR) at <http://www.statesmanjournal.com/article/20090408/LEGISLATURE/904080447/1042/polk>. An unrelated article in the **San Francisco Chronicle**, which describes the experience of a police officer with a rare disease working through the California Health Board system to ensure her insurance provider will pay for an experimental stem cell procedure, can be accessed at <http://www.sfgate.com/cgi-bin/article.cgi?f=/c/a/2009/04/07/BU3N16LKTS.DTL&type=business>. The caveat with this story is the stem cell procedure itself is not experimental but the application to this particular disease, chronic inflammatory demyelinating polyneuropathy (CIPD), is new.

The **Pittsburgh Tribune Review** reported on April 1, 2009 that the **Food and Drug Administration** has cited Washington County Hospital for violations including approving protocols without a board quorum, voting by mail, and failing to hold annual meetings. According to hospital administration, very few research studies are conducted at the site, most of which are part of larger national or regional studies. Read the article at http://www.pittsburghlive.com/x/pittsburghtrib/s_618647.html.

Senators Kennedy and Hutchinson introduced the "21st Century Cancer ALERT Act" on March 26, 2009. Among other provisions, the bill seeks to remove barriers to clinical research participation and expand access to research studies. If passed, the bill calls for the **Office of Human Research Protections (OHRP)** to utilize a centralized institutional review board, which is expected to improve privacy standards and clarify privacy rules to external investigators. Press release from Senator Kennedy's office can be read at http://kenedy.senate.gov/newsroom/press_release.cfm?id=619520a7-5556-4c3e-ab40-1a2dcb07e989.

The **Wall Street Journal** published a report on March 6, 2009 which indicates that lobbying efforts not empirical evidence are the reason a new device to treat knee injuries was approved by the Food & Drug Administration (FDA). The device, Menaflex by ReGen Biologics, Inc. was approved under fast track procedures, which have been called into question by the Government Accountability Office. The original article can be read at <http://online.wsj.com/article/SB123629954783946701.html> with related 'paper trail' resources at the following sites: emails from FDA lawyer - http://online.wsj.com/public/resources/documents/WSJ_regenLetter_090303.pdf, memo from FDA review team leader opposing approval - http://online.wsj.com/public/resources/documents/WSJ_510K_090303.pdf, and a letter from ReGen Biologics' CEO following congressional support for fast track status - http://online.wsj.com/public/resources/documents/WSJ_regenLetter2_090303.pdf.

Information for Researchers and Investigators

American Medical News reports on March 4, 2009 a dwindling supply of venture capital funds for clinical trials and cautions investigators in the US that more of these trials will be conducted overseas. Biotechnology companies are also cutting back the number of trials running concurrently. Read the article at <http://www.ama-assn.org/amednews/2009/03/02/bisf0304.htm>.

The **Institute of Translational Health Sciences (ITHS)** offers interdisciplinary clinical training programs for post-doctorate (<http://www.iths.org/Education/KL2.aspx>), pre-doctoral students (<http://www.iths.org/Education/TL1.aspx>), physicians and health care providers (<http://www.iths.org/Education/Fellows.aspx>) seeking targeted instruction in clinical investigation. Clinical and Translational Research Boot Camp, a collection of several "mini-courses" on topics such as biostatistical concepts, ethical issues in research on human subjects, randomized clinical trials and grantsmanship, is offered in the fall (<http://www.iths.org/Education/CTRBootcamp.aspx>). General information about the ITHS is available at <http://www.iths.org/>.

Human Subjects Media Coverage

BBC News reported on March 12, 2009 that 'red tape' is impeding clinical research in the UK and published a warning from researchers that the process is inadvertently 'killing people'. According to researchers, a European Union directive introduced in 2004 and National Health Service bureaucracy requires well-known treatments such as aspirin to proceed through the same regulatory mechanisms as new compounds in spite of well-understood risks. Read the article at <http://news.bbc.co.uk/2/hi/health/7939606.stm>. Additional coverage in the **Financial Times** can be accessed at http://www.ft.com/cms/s/0/a8a8f1c4-0f1d-11de-ba10-0000779fd2ac.html?nclink_check=1

BioWorld Today published an article by Carolyne Hathaway et al regarding the considerations for taking clinical trials overseas. Issues discussed include the decision to proceed under an Investigational New Drug Application (IND), contractor experience, and cultural and regulatory differences. Read the article at http://www.bioworld.com/servlet/com.accumedia.web.Dispatcher?next=bioworldHeadlines_article&forceid=50315.

The **Boston Globe** reported on February 3, 2009 that Harvard Medical School will follow other premier medical schools to adopt stricter conflict of interest (COI) rules for researchers and physicians. This move follows recent congressional investigations into COI oversight and calls from students at Harvard Medical School demanding stricter rules. Read the article at http://www.boston.com/news/education/higher/articles/2009/02/03/harvard_will_stiffen_rules_for_staff_at_med_school/. Final approval by Massachusetts officials limiting gifts from drug and device companies to physicians and researchers and requiring disclosure was announced on March 12, 2009. Regulations take effect on July 1, 2009. Read the article at http://www.boston.com/news/local/massachusetts/articles/2009/03/12/state_bans_drug_firm_gifts_to_doctors/.

EurekaAlert published a press release from Georgia State University which discusses inherent conflict of interest issues associated with finder's fees paid to researchers and related institutional review board (IRB) policies. Online IRB documents for 117 medical schools receiving National Institutes of Health were examined by the investigator who found that less than half of the IRB policies addressed finder's fees or bonus payments as conflicts of interest. Read the press release and access study contact information at http://www.eurekaalert.org/pub_releases/2009-03/gsu-coi031809.php. Related News Blog comments in the Chronicle of Higher

Education are available at <http://chronicle.com/news/article/6157/universities-face-conflict-of-interest-questions-over-finder-fees-for-study-participants>.

The **European and Developing Countries Clinical Trials Partnership (EDCTP)** announced the formation of the National Bioethics Committee of Gabon, established to protect African study participants. Nineteen members representing three Gabonese research institutes, hospitals and ministries anticipate protocol review will begin soon. Read the announcement at <http://www.edctp.org/Announcement.403+M57c9a8e620a.0.html>.

Financial Times (London) reported on March 25, 2009 that GlaxoSmithKline (GSK) will make public all of the findings of all clinical trials within 18 months of their completion for approved drugs, including observational studies and "meta analyses". GSK has been under pressure related to risks associated with its drugs Seroxat and Avandia. Read the article at <http://www.ft.com/cms/s/0/1babb50e-18dc-11de-bec8-0000779fd2ac.html>.

Changing concerns at the **Food and Drug Administration** is the topic of an article in **Genetic Engineering News**, which focuses on FDA's oversight of early stage clinical trials held outside of the United States, financial interests of investigators that impact off label product usage, and outsourcing of product manufacturing. Read the article at <http://www.genengnews.com/articles/chitem.aspx?aid=2867>.

Global Atlanta published an article on April 4, 2009 which provides an overview of the contract research industry in France and the creation of a trade association to advance industry initiatives. The infrastructure, including specialty hospitals, regulatory oversight and economic incentives, are highlighted as reasons France has become a significant outsourcing avenue for pharmaceutical companies. Read the article at <http://www.globalatlanta.com/article/17250/>.

KFSN-TV in Fresno, California profiled on March 13, 2009 a family who chose two different clinical trials to save their son with 'bubble boy' disease. Watch the video or read the transcript at http://abclocal.go.com/kfsn/story?section=news/health/health_watch&id=6709288. **KVUE** (Austin, TX) published a similar story focusing on study participants who choose trials to access care they can otherwise not afford. http://www.kvue.com/news/top/stories/033109kvue_clinical_trials-cb.8d50a33b.html

The **Los Angeles Times** published a report on March 14, 2009, which examines the delay in clinical trials when enrollment is slow. According to a cited CenterWatch report, more than 70% of clinical trials are delayed for this reason. Researchers who fail to explain the nature of clinical trials and/or consent issues contribute to misperceptions by patients who believe participation in a trial will 'take away from' their standard treatment. Read the article at http://www.latimes.com/news/nationworld/nation/la-sci-clinical-trails14-2009mar14_0_5126834.story. An unrelated article in the **Catholic Courier** calls for increased minority participation in trials and cites many of the same factors. <http://www.catholiccourier.com/tmp1.cfm?nid=78&articleid=106535>

Medical News Today discusses Investigator Driven Clinical Trials (IDCT) following a report by the Medicines and Healthcare Products Regulatory Agency (UK), which highlights the main obstacles hindering these trials in Europe. Issues discussed in the report include regulatory elements and infrastructure requirements. Read the article at <http://www.medicalnewstoday.com/articles/142260.php>. Access the full report at http://www.esf.org/fileadmin/links/EMRC/FL_IDCT.pdf.

My Fox New York profiles two research participants in a video report first aired on March 24, 2009. Issues raised include compensation, availability of diagnostic tests, unknown outcomes, and placebos. Access the video at http://www.myfoxny.com/dpp/good_day_ny/medical_headlines/090324_Clinical_Trials.

The **New York Times** published an article on April 7, 2009 about the creation and implementation of public policy that essentially enrolls all individuals within the specific jurisdiction in a research study without consent or protocol review. The issue under discussion is the recent announcement in New York City to pressure the food industry and restaurant chains to cut salt intake. The article describes several reasons why this may be counter productive with regard to the health of citizens. Access the article at <http://www.nytimes.com/2009/04/07/science/07tier.html?ref=health>.

The **Times of India** profiled Sukanya Ahmedabad, a 'slum dweller', who relies on clinical trials as a major source of income. Ms. Ahmedabad states that agents comb slums looking for research subjects. Monetary inducement for participation overrides caution according to a community development worker. Read the article at <http://timesofindia.indiatimes.com/Cities/When-humans-become-guinea-pigs/articleshow/4269231.cms>.

Twitip (blog) offers suggestions for clinical trial recruiters to use Twitter as a tool to reach potential research participants and create a community of interested individuals. Developing prototype Twitter pages and 'Tweets' (messages that go to your network), creating key words to make communication about specific topics, using Twitter applications to monitor success of marketing strategies, and tracking individuals who have successfully 'reTweeted' study information to build awareness are discussed within the blog. All tips can be accessed at <http://www.twitip.com/whispering-tweets-into-a-patient%E2%80%99s-ear-top-ten-suggestions-for-clinical-trial-recruiters/>.

The **Wall Street Journal** reported on April 16, 2009 that the Clinical Trials Registry-India (CTRI) will begin requiring all clinical trials (drug, device, procedural, etc) conducted in India to be registered starting in June of this year. The Drug Controller General of India will provide preregistration approvals following a review of basic trial information, after which the trial sponsor will be required to submit funding sources, oversight committee and the nature of the trial before subjects are enrolled. Read the article at <http://www.livemint.com/2009/04/16234404/Mandatory-registration-of-huma.html>.

WBIR (Knoxville, TN) reported on March 16, 2009 an increase in clinical trial participation among healthy volunteers as the economic recession continues. The president of NOCCR, a local company specializing in clinical trials, states that individuals aged 18-35 are contacting the organization in hopes of taking part in a study unrelated to specific health issues. Access the video or the transcript at <http://www.wbir.com/news/health/story.aspx?storyid=81409&catid=3>.

The **Wichita Eagle** printed an article on April 12, 2009 about the benefits of participating in clinical trials. Compensation, routine medical care, and concern for others are among the elements discussed. The article also includes an interview with a "professional lab rat". Read the article at <http://www.kansas.com/news/story/770145.html>.