

NOVEMBER 2011

THIS ISSUE

Engaging Librarians in the Responsible Conduct of Research	1
Recruiting Using Advertising – Use and Potential Re-use of IRB Approved Language	2
Please Remember	3
Get to Know the IRB Staff - Halloween	3

Engaging Librarians in the Responsible Conduct of Research

Shandra Protzko, MS, AHIP. Director, Library and Knowledge Services

In June 2001, a healthy 24-year-old woman died after participating in a research protocol at the Johns Hopkins Asthma and Allergy Center. The clinical trial involved the administration of hexamethonium bromide by inhalation and methacholine challenge. The day after being given the hexamethonium, this woman (a volunteer lab technician) experienced a cough and dyspnea followed by flu-like symptoms, fever, reduced FEV1, pulmonary infiltrates, adult respiratory distress syndrome with progressive hypotension and multiple organ failure. The Johns Hopkins investigators subsequently found several reports regarding pulmonary toxicity published between 1953 and 1962, including a 1955 article in CMAJ and a review article published in 1972; these reports were not included in the protocol submitted to the review board prior to the trial.

While the literature uncovered by the investigation of this tragic event may not have stopped the trial, the value of expert, comprehensive literature reviews to inform human research and minimize risk is clearly illustrated. Literature searches can help researchers discover changes in a drug's risk/benefit profile, or find prior studies that are applicable to study treatment or that validate procedures.

National Jewish Health medical librarians can perform literature searches before a protocol is reviewed to supplement the work of principal investigators. We can help you find full text articles owned by the library or request interlibrary loans for titles we don't own.

Additionally, our Current Awareness Service or Auto Alert (also known as SDI or Selective Dissemination of Information) allows you to keep up to date on the latest published research on a topic, author or journal. This free, personalized service delivers the latest results of your customized search directly to your email inbox each week. Consult with a medical information specialist for free expert searching in Medline, Embase, Cochrane, and other databases.

CONTACT US

National Jewish Health
Institutional Review Board
1400 Jackson Street
Room M211
Denver, CO 80206-2761

Phone: 303.398.1477
Fax: 303.270.2292

nationaljewishIRB@njhealth.org

For more information, contact:
Library and Knowledge Services
library@njhealth.org
303-398-1482

Recruiting Using Advertising – Use and Potential Re-use of IRB Approved Language

Diana Pruitt, RTT and Deb Clayton, MA

We have heard from several IRB Contacts, and it seems there may be some confusion in the human subjects research community concerning the use (and possible re-use) of IRB approved language for recruitment purposes. For those of you who have been recruiting for research studies at NJH, some of what you learn from this article may come as a surprise. It used to be that once advertising copy for recruitment purposes was approved that it was used over and over in various formats.

After an assessment of some of our practices, the NJH IRB staff is implementing some changes. The purpose of these changes is to verify that not only approved copy is used, but that the context of the advertising is appropriate for our potential research subjects.

Advertising copy can be submitted either with the initial submission or any time after the study has been approved. The copy will then be reviewed (this may be an iterative process until the copy is approvable) and approved by the IRB and returned to the site.

[So now you have approved copy. What's next?](#)

The rest of this article focuses on the types of recruitment advertising most frequently submitted to the NJH IRB for review and approval. The instructions below assume that the copy being used for the advertising has already received IRB approval

Flyers:

The IRB Contact/or designated study staff inserts the IRB approved text into the formatted flyer on the flyer (with the pictures and/or tear off tabs) and submits the document (s) for IRB approval. The purpose of this submission is so that the IRB can review and approve the finished advertisement. The purpose of this IRB review is to see the advertisement that the potential subject will see.

Once the IRB determination has been made, the site will be notified of the approval. Advertising cannot be used until the IRB approves it.

Radio ads:

These instructions assume that radio script copy that has already been IRB approved. The IRB Contact or designated study staff submits the recording to the NJH IRB for review and approval. The basis for this review is to ensure that the finished advertising contains the same wording that was previously approved by the IRB. A copy of the recording will be kept in the IRB study file.

Valpak and Newspaper ads:

These instructions assume that the ad copy has already been IRB approved. The IRB Contact or designated study staff submits the final layout to the NJH IRB for review and approval. The basis for this review is to ensure that the finished advertising contains the same wording that was previously approved by the IRB and that the ad layout is appropriate for the potential subject population. A copy of the advertising will be kept in the IRB study file.

Mass email through NJH and Colorado University:

This assumes that the ad copy has already been approved. In addition to the IRB approved text, the IRB Contact or designated study staff submits the email text AND subject line for IRB review and approval. This email recruiting information does not have to be submitted and approved by COMIRB if NJH IRB approves the email.

For more information, contact:

Deb Clayton
claytond@njhealth.org
303-398-1393

Please Remember ...

Assistance with COMIRB Submissions:

When performing research involving UCD and NJH, please remember that Astrid Eder, PhD, is a valuable resource for assistance at COMIRB.

When National Jewish Health serves as the IRB of record, Astrid will assist with the Facilitated (Secondary) Review process conducted by COMIRB. Likewise, she is particularly helpful when COMIRB serves as the IRB of record for research that will have a portion performed at NJH.

Astrid can be reached at:
COMIRB, Mail Stop F490
13001 E. 17th Place, Room N3214
Aurora, CO 80045
303-724-1034, fax 303-724-0990
astrid.eder@ucdenver.edu

Conducting Research at HealthONE Facilities:

When planning to perform research at HealthONE facilities, please remember that the investigator must pursue a contract with each facility where research will be conducted. The PI should contact

the appropriate Ethics & Compliance Officer (ECO) prior to submitting for NJH IRB review to avoid delays in starting the project. For more information, visit the [HealthONE website](#).

After NJH approval, the investigator must complete the HealthONE IRB Registration Form using HealthONE's online submission system. For detailed instructions, review the [June 2011 IRB newsletter](#).

CITI Training

October 1, 2011 marked the three year anniversary of National Jewish Health's affiliation with the CITI program for online human subjects protection training.

Because human subjects protection education expires after three years, please remember that many researchers will soon be required to renew their human subjects protection education.

A study cannot be approved/renewed if current (within three years) human subjects protection education is not on file for all members of the research team.



Get to Know the IRB Staff - Halloween



L-R: Diana Pruitt, Michele Gaffigan, Emily Hoch, Deb Clayton, Wendy Charles