

Science Transforming Life®

# IRB Update

#### **APRIL 2013**

#### THIS ISSUE

News from the Clinical Translational
Research Center (CTRC) 1
Monitor Access to Electronic
Medical Records1
Guidance about "Practicability" 2
Man Jumps from Building to Escape
a Clinical Trial

submission. SARC will inform you of any scientific suggestions or stipulations. Once successfully addressed, you may submit your protocol to the IRB for review and approval. Final SARC approval is granted after all IRB requirements have been fulfilled. The CTRC program administrator is available assist you with the SARC submission process and can be contacted below.

All CTRC protocols are reviewed by the Scientific Advisory Review Committee (SARC) prior to IRB submission. A brief 4-5 page form, your protocol, and a CTRC specific budget are required for the initial SARC

**News from the Clinical Translational Research** 

Donald Leung, MD, PhD, Lisa Maier, MD, and Fred Wamboldt, MD

New protocols that are funded by the NIH, foundation-initiated and/or investigator initiated (with any form of funding) pilot studies or cooperative group-funded studies (i.e., Program Project Grants), may be eligible for CTRC support. This includes space to consent subjects, administer questionnaires and conduct study visits. A variety of services are available (including nursing, Behavioral Medicine Core Lab,

Inflammation/Immunology Core Lab and biostatistics) at a discounted rate

Center (CTRC)

for CCTSI members.

Ronnie Calzada, CTRC Program Administrator

For more information, contact: Ronnie Calzada calzadar@njhealth.org 303-398-1717

#### **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

### **Monitor Access to Electronic Medical Records**

Steve Leibold, MSHA, Corporate Compliance Manager and Privacy Officer Kathy Flesher, Manager, Health Information Management

When a monitor from an external organization, such as a commercial sponsor or consortium, requests access to the EMR, it is important to respond that you are not permitted to grant access. Once monitors are given access, there is no way to stop them from looking at "unauthorized" patient records. You can sit with the monitor one-on-one while they look at each patient record to make sure the monitor only looks at the specific report/record. As an alternate option, Kathy Flesher in Health Information Management can print records for specific subjects. Send her an email with a list of subject names, information needed, and date desired.

# **Guidance about "Practicability"**

Wendy Charles, MS, CIP, CCRP, Director, Research Regulatory Affairs

When requesting waivers of informed consent and authorization, researchers must justify that "the research could not <u>practicably</u> be carried out without the requested wavier or alteration" [45 CFR 46.116(d)(3) and 45 CFR 164.512(i)].

#### What does "practicably" mean?

Federal regulations do not define the word, "practicably." <u>Black's Law Dictionary</u>, on which courts sometimes rely in interpreting legislative or administrative agency intent, defines the term as: "reasonably capable of being accomplished; feasible."

# What is the IRB looking for when justifying practicability?

There isn't a single "magic" answer because each study involves slightly different circumstances. In order to demonstrate that it would be impracticable to obtain written informed consent/authorization, the Investigator must present a compelling case as to why the research cannot practicably be carried out if required to obtain consent/authorization from each individual.

The focus should be on what is best for prospective subjects (and protecting subjects' rights), not what is best for the Investigator. Answers that focus on how it would be "inconvenient" or "time-consuming" for the Investigator will not be accepted.

The IRB is looking for researchers to present a compelling combination of several factors. Consider the following:

- The size of the population being researched;
- The nature (disease state or culture) of the population being researched;
- How recently patient/subjects were last contacted and how soon there might be contact in the future for any purpose;
- The limits of contacting individuals directly when there is no existing or continuing treatment relationship between the researchers and the individuals:
- The proportion of individuals likely to have relocated or died since the time the

- personal information was originally collected:
- The risk of introducing potential bias into the research, thereby affecting the generalizability and validity of results;
- The risk of creating additional threats to privacy in order to contact individuals to seek their consent/authorization;
- The risk of inflicting psychological, social or other harm by contacting individuals or families with particular conditions or under certain circumstances; and
- The difficulty of contacting individuals indirectly through public means, such as advertisements and notices;

Again, a compelling justification will include consideration of multiple applicable reasons.

#### Example for a chart review study:

Waivers of informed consent and authorization are most frequently requested for chart review studies. Below is an example for a hypothetical chart review study of an acceptable justification as to why it would be impracticable to obtain informed consent/authorization for this study.

"The research could not be practicably carried out without the waiver. Identifying and contacting the thousands of potential subjects, although not impossible, would not be feasible for a review of their medical records for information that would not change the care they would already have received. The Investigator does not have a treatment relationship with most subjects, and subjects are not expecting to be contacted. Further, after two years, many subjects will have changed their telephone numbers or moved without providing forwarding addresses."

#### For more information, contact:

Wendy Charles charlesw@njhealth.org 303-398-1855

## Man Jumps from Building to Escape a Clinical Trial

**Wendy Charles** 

The concept of voluntary participation is the cornerstone of ethical research. When a research subject prefers not to participate or to discontinue participation, there must not be any perception of coercion to be in the study or remain in the study.

There was a recent story published about a particularly poignant case about research coercion. As reported in <a href="The Times of India">The Times of India</a>, a 32-year-old painter, Chandrasekhar from Chandanagar, reported that staff conducting research for a drug maker in Miyapur, India, tried to force him to participate in a clinical trial. He had participated in previous trials and went to the company's office to learn about the new trial. Worried that he might experience health problems, Chandrasekhar declined to participate, but the trial administrators would not let him leave.

"So with no other option to escape, I jumped from the second floor of the company's building and suffered injuries on my right leg," Chandrasekhar said.

#### The Times of India:

http://articles.timesofindia.indiatimes.com/2013-03-22/hyderabad/37935974\_1\_clinical-trials-manjumps-chandrasekhar

As a reminder, when a subject in a research study decides not to participate in a study or to drop out, any subsequent discussion must be done without any attempt at coercing a change of mind, either perceived or actual. "No" should be considered to mean "no."

For regulatory information about subject drop outs, review:

http://www.hhs.gov/ohrp/policy/subjectwithdrawal.ht ml.