



PROTECTING HUMAN SUBJECTS

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OFFICE OF BIOLOGICAL AND ENVIRONMENTAL RESEARCH — ISSUE NO. 19, Winter 2009

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Research ethics and human subjects

This edition of *Protecting Human Subjects* focuses on the specific application of protecting human subjects and improving the day-to-day operations of Institutional Review Boards (IRBs) and other oversight agencies.

The front-page article for this issue encourages contingency planning for those times when IRBs have to replace administrators and members, either temporarily or permanently. An article on page 8 discusses the implications of a recent Government Accounting Office study, which concluded that the IRB system is vulnerable to unethical manipulation. An article on page 4 says that IRBs are facing unusual dilemmas in considering social science research proposals that study social networks such as Facebook.

Protecting Human Subjects newsletter to be Web only

Future issues of the *Protecting Human Subjects* newsletter will be published only on the Web. We will no longer print paper issues. To sign up for e-mail notification of future issues, see p. 12.

Succession Planning for the HRPP and IRB

Protect your organization from periods of confusion or paralysis by thinking in advance

Most of us don't plan too far ahead. We never think anything will happen to us, and we certainly don't want to plan for a future that looks different than right now.

*by Katherine Ertell,
Human Research Protection
Program, Pacific Northwest
National Laboratory*

But life has a funny way of just happening, and one day you wake up and find out that retirement is right around the corner . . . and you aren't ready!

Or that a new baby is coming . . . and you aren't ready! Or that you have cancer . . . and you sure aren't ready for that.

For senior business executives, planning ahead for those expected, and unexpected, life events is part of the job. Executives are expected to move up and out of their organization, so companies pick promising staff members to groom for future promotions. It often takes several years to prepare candidates for a senior management position, so planning starts early.

For a long time, succession planning was reserved for top management. But in the last few years, the concept has caught on with government, small business, and professional firms.

Workforce is graying

The government workforce is graying, and the knowledge and culture of government needs to be passed on to younger staff. Small businesses, especially family-owned businesses, want to be sure the business stays in the family after the founders retire.

In addition, professional firms are finding it harder to recruit good employees and realize they need to plan ahead to provide service continuity for their clients.

So what does this have to do with Human Research Protection Programs (HRPP) and IRBs? Think about



Katherine Ertell

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Succession Planning for the HRPP and IRB

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what would happen if your IRB administrator or chair had to take a sudden medical leave or was offered a great retirement buy-out and decided to retire in a month. Would your program be able to weather the storm? Does anyone in your organization know what the administrator or chair does? Could your management figure out how to keep the HRPP running?

Does anyone in your organization know what the administrator or chair does?

Most of us haven't thought much about this, and probably none of us have a succession plan in place for ourselves. After all, we aren't top management. But most of us would not want our programs to fall apart if we left, either. So, from a practical standpoint, what can we do to ensure a smooth transition when the time comes?

Types of succession

Start by thinking about the two types of succession you are likely to face: temporary, or emergency successions, for short-term events such as medical leaves; and permanent successions, for job changes and retirements. You need a slightly different strategy for each: with a temporary succession, you just want to survive. With a permanent succession, you want to thrive. But you can use similar tools for planning each type of succession. Your human resources department may be able to help you. Here are the basic things you need to do:

- Define the skills and attributes needed for each position.
- Identify the talent pool and any possible successors.
- Train and mentor successors.
- Promote or hire when the time comes.

An easy tool to start your planning is a job description for each position. If you don't have one, write one—and make it accurate and descriptive, not generic. Describe responsibilities and tasks. Ideally, you would have a job description for the IRB administrator, IRB chair, and IRB member.

Procedure manuals and instructions

A desk manual or procedure manual for each position, but especially for the IRB administrator, can save the day for a sudden absence. A desk manual should define the tasks required to keep the program running. You may need instructions on how to do certain tasks, or where to find the resources to complete a task.

It's helpful to figure out which tasks are critical or time-sensitive, versus which ones are nice but not necessary or can be delayed with no repercussions.

Keep a list of your most valuable contacts within the organization: think about who are your "go-to" people in finance, legal, medical, research, corporate, and human resources. Who are the people you trust to offer advice on the culture or tribal history of your program?

Short-term absences

Once you have a manual in place, think about how you might identify a potential successor. For short-term absences, you will likely need to tap someone in the organization.

Keep a list of your most valuable contacts in the organization—your go-to people in finance, legal, medical, research, corporate, and human resources.

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Web sites

"Alternative" treatments and research ethics

http://scienceblogs.com/ethicsand-science/2009/03/conventional_medicine_alternat.php

Global bioethics

<http://globalbioethics.blogspot.com/>

Ethics and emerging technologies

<http://www.ieef.org/>

Is there someone who assists you occasionally, or someone you know who seems to have the ability and interest? Could they learn those crucial tasks now, then practice filling in for you when you are on

vacation? Even training someone to check your mail and know which messages are important enough to forward on can be helpful. Are there retired staff members who could come back to work for a few weeks?

Are there retired staff members who could come back to work for a few weeks?

For long-term succession, think about whether you are likely to find a good candidate either internally or externally in your local area. If you are in a major metropolitan area where there are other IRBs and HRPPs,

there may be plenty of qualified people interested, and if that's the case, you may not need to do much long-term succession planning except to keep your desk manual up-to-date.

If it will be hard for you to recruit an experienced person, your replacement may have to learn on the job. In that case, it's important that you not be the only person in your company to hold all the knowledge—because you may be gone by the time your replacement arrives.

Succession for the chair or board member

Succession planning for the IRB chair or member is a little different than for the IRB administrator, since chair is not a full-time job. Nevertheless, when the chair leaves, someone will need to fill the slot quickly, so always keep potential candidates in mind. Ask the chair whom he or she would recommend. If there is a term limit on the chair position, you have a mandate to plan ahead.

Some institutions have vice-chairs or co-chairs who can step in immediately in the chair's absence and who are the planned successors. If your preferred candidate for a new chair is not already on the IRB, a period of time as a member and as chair-in-training is valuable for the transition; otherwise, there could be an intense learning period.

Having an IRB member leave the board does not normally cause a large problem, since most IRBs have more members than required by law, and consultants can always be retained on a short-term basis to fill a technical expertise gap. You might

consider whether you even need to replace certain members. Is your IRB large enough already, and do you have an adequate mix of skills represented by the remaining members? If you have research that requires specialized reviewer expertise that is hard to find, start thinking early about who could replace that specialized member, and ask your board for a recommendation.

Retirement age

If many members of your IRB are close to retirement age or already retired, it may be time to start thinking of potential candidates for succession. There is nothing wrong with asking IRB members how long they want to serve. Keeping a list of people who have expressed interest in being an IRB member, or who have the right skills and attitude to serve, can come in handy when you need to add a member.

At Pacific Northwest National Laboratory, the HRPP has a plan that includes having a vice-chair who can fill in for the chair when needed but does not automatically ascend to chair. This provides stability and support during transition times. When the chair's remaining term is about a year, a chair-in-training is appointed to begin the transition process.

Challenges

The administrative team (administrator, chair, vice-chair, chair-in-training) stays in close contact and shares knowledge. The IRB secretary develops a desk manual prior to her retirement.

We also cross-train the secretarial staff to help provide administrative backup when needed. Even so, there are always challenges when staff or board members leave.

Planning for the future is never easy, whether at home or at work, and none of us in the human research field will ever have as sophisticated a succession plan as senior managers will. But if you can find a little time to do some planning, even if you don't develop a formal plan, it can make your life easier and keep your program running more smoothly when those inevitable changes come along.Δ

We also cross-train the secretarial staff to help provide administrative backup when needed.

Facebook and human subjects research

Investigators using social networks find challenges for ethics review boards



Nancy Walton

If you want to study people between the ages of about 15–40, Facebook (FB) and other social networks are arguably a good way to reach people and a rich source of demographic and contextual data about those people, according to Nancy Walton.

Walton, who is the author of *The Research Ethics Blog*, discussed the challenges of conducting research using FB during the annual meeting of the Canadian Society for Bioethics. She also reported on it for her blog (<http://www.researchethics.ca/blog/2009/06/FB-and-research.html>).

Her discussion is excerpted here:

In many disciplines, social networks are used as both a source of recruitment and a source of data. Between the three ethics boards that I'm involved with, we've reviewed a significant number of research protocols that involve social media networks, and the numbers are increasing.

Here's an example: those who conduct research on children who are chronically ill are looking at ways of engaging participants using the social media networks that make up much of the daily life of sick or

hospitalized kids. Many kids with chronic illnesses such as cystic fibrosis or childhood leukemia are often very physically isolated, yet they are able to maintain an active social life through the internet and networks such as FB, Second Life or Twitter. These active social networks represent an opportunity that researchers are realizing and starting to access. This kind of research is not going away but likely only going to become more common, and ethics review boards need to be aware of some of the unique issues that arise in this context.

There's lots to talk about here, but for this entry, I'll focus on a couple of issues that arise out of the recruitment of potential participants using social media networks, specifically FB.

Breast cancer survivors

Social media networks are often used for recruitment of potential participants. A researcher can easily access FB groups created to provide a place for those with common interests or common problems to congregate and connect. For example, there are, as of today, 137 FB groups for breast cancer survivors, 8 FB groups for survivors of childhood abuse and 22 FB groups for persons living with AIDS. For

(Continued on next page)

News notes

■ Research studies are increasing in India along with focus on ethics

The number of clinical trials being conducted in India has doubled from 170 in 2006 to 350 at the end of 2008, and the numbers are continuing to rise, according to a posting in *The Research Ethics Blog*.

See <http://www.researchethics.ca/blog/2009/07/india-ramping-up-for-clinical-trials.html>

The report by Chris MacDonald tracked a variety of articles in the India media, some of which discussed the country's effort toward "ramping up its system and infrastructure to bring more transparency and ethics into clinical trials."

The Hindu Business Line reported, "Apart from making it compulsory for all Clinical Research Organisations to register themselves and the trials being undertaken on behalf of any pharmaceutical company, a system is also being set up to track the volunteers who participate in these trials.

"The regulator is putting in place a finger printing technology for the volunteers, which will make sure that the same persons are not involved in two different trials at the same time"

many researchers, these are a goldmine of opportunity to recruit research participants, by posting a recruitment notice on the FB group page or targeting all the group members with a FB e-mail message inviting them to consider participating in a study.

Disclosure is the norm, a FB community value

Is this different from posting an information notice on the bulletin board of a community center or cold-calling people? I think it is. FB is a community. That's why people like it there. It is a virtual community in which people have friends and sustainable connections, sometimes with FB "friends" who they have never met in real life. Disclosure is the norm, a community value. It may even be more than a norm—there may be subtle or more obvious social pressures to disclose information about oneself.

Post a profile without a profile picture? You'll risk being inundated with messages from FB friends urging you to post a flattering picture of yourself. Post a profile without much information? Again, you'll find your profile stark and even uninteresting, compared to those peoples' profiles who post their relationship status; age; birthday; work; favorite movies, books and tv shows; and photos of their life events. The temptation is very strong to adhere to the norm of disclosing plenty of personal information to your network of friends.

So for a researcher to send a recruitment notice to you through FB might mean that researcher already has a significant or even a copious amount of information about a potential participant, as opposed to the researcher stapling a recruitment notice on a bulletin board and waiting to see who might respond.

Various levels of privacy

For those of you who might not be familiar with FB and how much one can or cannot see about others on their profile, you might ask, "How can a researcher see information about that person's permission?"

FB has various gradients or levels of privacy. When you create your profile, you set your privacy settings to control who sees what about you and how much they can see. Some people allow no information to be seen by persons other than those with whom they are FB friends, thus restricting access to their information to persons they know.

However, some other people leave their profile "wide open", i.e., with all their posted information visible to anyone who might happen upon it. In between these two extremes are various privacy configurations that can allow certain people to see certain things and not other things, etc.

A different understanding of privacy?

Our understanding of privacy outside a social media network is reasonably clear. We close our bedroom curtains when we enter our bedroom to prevent neighbors from seeing in. However when we're relaxing in our backyard, we are fully aware that our neighbors can see us then.

We understand the difference, in many aspects of our daily lives, between what we are putting out there publicly and what we are holding back and keeping private. To use another example, we share information about private things like problems in our personal relationships or our opinions on sensitive issues with our very close friends quite easily but might hold back details about these kinds of private issues with acquaintances or more distant friends.

We're clear on how much we want to share with each category of friends, and over time, people get very practiced at managing that. It's clear in research that some kinds of information are private—things like your medical information and opinions are private, and researchers must have explicit and clear permission before accessing those kinds of data.

However on FB, it's much less obvious what is private and what is public. It may even be confusing—confusing not just for ethics review board members who might have little insight into the community values and norms of social media networks, but also to novice FB users and overly enthusiastic but less computer-savvy FB members who may not even be aware of how "public" their personal information really is.

Ethics review boards and privacy

If this understanding of privacy is unclear to members of the social network, chances are it's just as unclear to researchers (who may be accessing profile information without consent and without thinking that they might need consent) and to members of ethics review boards, who are already mandated with knowing about many kinds of special groups, unique methodologies and special contexts in which research occurs.

Social media networks and ideas about privacy within these networks constitute yet another thing that research ethics board members must start to understand.

(Nancy Walton is chair of the Research Ethics Board and Associate Professor at Ryerson University in Toronto, Canada. She is a member of the National Council on Ethics in Human Research.)Δ

Post-approval monitoring

Brookhaven Lab's monitoring is conducted by both a BNL coordinator and the IRB

Researchers and the IRB share the responsibility for ensuring that the rights and welfare of human subjects are fully protected and that studies comply fully with applicable regulations and institutional policies.

*by Darcy Mallon, Director,
Office of Research Administration,
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The IRB also has the responsibility to determine that

research protocols are being followed as approved. This process is called protocol compliance monitoring or post-approval monitoring.

Describing risks

Each protocol must contain a Data Safety Monitoring Plan (DSMP). It describes the possible risks associated with the protocol and the proposed protections against those risks.

At Brookhaven National Laboratory (BNL), the IRB is located at the State University of New York at Stony Brook (SBU). Compliance monitoring is performed first by the protocol coordinator at BNL and secondly by the Research Subject Advocate (RSA) from SBU.

Each subject chart is reviewed by the protocol coordinator following the subject's visit. The protocol coordinator ensures that all required documentation is contained within the subject chart and that all required signatures and dates are entered.

Random selection

Following this review, compliance monitoring reviews are performed by the RSA. Generally, studies are selected randomly for review. However, some may be selected because

they are considered high risk or because the IRB requested a review of a certain protocol.

The scope of the review will vary according to the safety issues that need to be addressed; however, in

most cases a review of compliance with the DSMP will be performed.

The protocol will be assessed for compliance with the parameters such as safety tests and measures and adverse events. Documents to be reviewed may include any of the following: Case Report Forms (CRFs), subject records, laboratory results, signed consent forms, drug accountability documentation, screening logs, protocol, amendments and all IRB correspondence.



Issues and concerns

Following the review, the RSA discusses with the research team any issues or concerns that are discovered during the review. This allows time for resolution of issues prior to the writing of the report.

A report is written that contains the findings of the review and recommendations. Recommendations could include corrective actions required for major and minor deviations noted in the review and the possible need for follow-up reviews.

The report will be sent to the investigator and the IRB with recommendations for further action as necessary.

In performing a review, the RSA takes all reasonable precautions to maintain the confidentiality of subjects' identities and sponsors' proprietary information, and all reports are kept confidential.

Additionally, the RSA provides training to principal investigators and research team members on good clinical practices and basic clinical research coordinator training.Δ

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OHRP's guidance on GINA

Genetic Information Nondiscrimination Act has research exceptions



Julie Kaneshiro

The implications of the new Genetic Information Nondiscrimination Act (GINA) are discussed in guidance from the Office for Human Research Protections (OHRP).

by Julie Kaneshiro,
Policy Team Leader, Office for
Human Research Protections -

certain conditions are met, including that there is clear indication that participation is voluntary and that choosing not to participate will have no effect on enrollment status or premium or contribution amounts.

The guidance (<http://www.hhs.gov/ohrp/humansubjects/guidance/gina.pdf>) spells out how the law affects investigators and Institutional Review Boards (IRBs).

GINA, signed into law in May 2008, prohibits discrimination in health coverage and employment based on an individual's genetic information. It is intended to protect people from losing health insurance or jobs based on their genetic information or the genetic information about their family members.

However, GINA provides research exceptions. For example, employers are allowed to disclose genetic information about an employee to an occupational or other health researcher if the research is conducted in compliance with 45 CFR part 46, which requires, in part, that an IRB review and approve proposed research before the research may be initiated, as well as obtain the informed consent of subjects, unless informed consent has been waived by an IRB.

In addition, health insurers and group plans engaged in research are allowed to request (but not require) that an individual undergo a genetic test if

Informed consent and IRB review

Among other requirements, the OHRP guidance points out that the informed consent process must include a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained (unless an IRB has approved an alteration or waiver of these requirements as permitted under 45 CFR 46.116(c) or (d)). The guidance also identifies the criteria required for IRB approval that relate to assessing the risks of research.

OHRP notes that even though the provisions of GINA related to health coverage generally will take effect between May 22, 2009, and May 21, 2010, the protections are pertinent to genetic research that is conducted prior to these effective dates because these protections eventually will extend to genetic information obtained as part of any research study regardless of when the research was conducted.

Therefore, IRBs conducting initial or continuing review of genetic research prior to GINA's stipulated effective dates should take into account the protections to be provided by GINA when considering whether the consent process and document should include language regarding GINA, as well as when assessing the criteria required for IRB approval.Δ

Research ethics books & reports

■ Standard of care in clinical research

"What is the Best Standard for the Standard of Care in Clinical Research?" by Rieke van der Graaf and Johannes van Delden. *The American Journal of Bioethics*, Vol. 9, No. 3, March 2009.

What kind of care should be provided to the control group in clinical research? The authors examine the wide variety of international ethics guidelines and argue that none is universally adequate.

■ The benefits/risks of research

Everyday Practice of Science, by Frederick Grinnell, Oxford University, January 2009.

This book illustrates the dynamics between researchers, pointing out that society cannot have the benefits of research without the risks. It discusses issues related to What research should be done? Who should do it? Who should pay for it? How much? How do you manage the challenge of modern genetics and human research ethics?

GAO undercover operation

IRB system vulnerabilities allowed bogus registration and HHS-approved assurance

In spring of 2009, the Government Accountability Office (GAO) conducted an undercover operation to investigate three key aspects of IRB operation: establishing an IRB, obtaining an HHS-approved assurance, and obtaining IRB approval for human subjects research.

*by Katherine Ertell,
Human Research Protection
Program, Pacific Northwest
National Laboratory*

After the investigation, GAO concluded that the IRB system is vulnerable to unethical manipulation, which increases the risk that human subjects research could be approved without full, appropriate review. This could pose substantial risk to people participating in high-risk clinical studies.

Created fictitious IRB

GAO investigated these aspects of IRBs by creating a fictitious IRB and medical device company, including phony company officials, a phony physician with counterfeit credentials, and a nonexistent medical device.

They succeeded in registering their bogus IRB with HHS; applying for and obtaining an HHS-approved assurance; creating a Web site for the bogus IRB; and advertising their services. One real medical research company actually contacted the fictitious IRB to get approval to add a clinical site for an ongoing trial involving invasive surgery.

One IRB approved the protocol

Using their medical device company cover, GAO contacted three private IRBs to review an application for approval of a trial testing a medical device on humans.

The device was a gel called Adhesiabloc, which was to promote postsurgical healing and would be classified by FDA as a significant-risk device. One IRB, Coast IRB, approved the protocol for human testing. The other two IRBs did not approve the

protocol and called the protocol “junk” and “the riskiest thing I’ve ever seen on this Board.”

Considerable publicity resulted from this investigation, and Coast IRB has since ceased operations. In the aftermath of the media storm, IRBs across the country have been asking themselves what they can learn from this investigation and are assessing how vulnerable they are to unethical manipulation.

What prompted the investigation?

GAO reported that the investigation was prompted to better understand the due diligence process used at independent IRBs, following a hearing by the Committee on Energy and Commerce in 2007 that included the Copernicus IRB’s role in FDA approval of the antibiotic Ketek. The antibiotic was linked to dozens of cases of severe liver injury after its introduction to the market in 2004.

IRBs have historically existed at academic centers, which reviewed proposals from their institution. Independent IRBs, however, are being used more and more, and they do not have the institutional ties to researchers that academic or other internal IRBs do.

Process lacks “effective controls”

GAO’s report states that “the process for obtaining HHS approval for an assurance lacks effective controls.” When HHS was briefed on the findings of the investigation, they replied that the assurance process does not offer protection against unethical manipulation.

HHS also indicated that it does not review applications to assess whether the submitted information is factual. This has left many people wondering how meaningful an

assurance is, beyond being a regulatory requirement.

GAO has stated that the failure to check the credentials of investigators to ensure they were qualified to

GAO concluded that the IRB system is vulnerable to unethical manipulation, which increases the risk that human subjects research could be approved without full, appropriate review

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GAO undercover operation

(Continued from page 8)

conduct clinical trials was a key finding. No IRB that reviewed the protocol discovered that the company, investigators, and device were all fraudulent.

GAO was also concerned that the entire review process with all the IRBs was conducted by e-mail and fax, with no personal contact. The technical competency of the IRB that approved the protocol was clearly deemed inadequate.

No IRB discovered that the company, investigators, and device were all fraudulent.

Questions remain
The investigation leaves IRBs with many questions and few answers. Is monetary compensation a significant influence on IRB decision-making processes for independent IRBs? Is it an undue influence for internal IRBs that charge their internal clients (an increasingly common

practice, as overhead budgets in academia and government shrink) for reviews?

Also, do IRBs conduct sufficient credentialing of PIs? Do IRBs rely too much on the federal-wide assurance when accepting reviews done by other institutions? What is the IRB’s liability if it fails to conduct adequate due diligence? What is adequate due diligence? Can IRBs prevent and detect IRB-shopping?

Remember the primary mission

The GAO investigation has caused most IRBs to look long and hard at their practices and to be increasingly careful in looking at investigators and their protocols.

The long-term effect of the GAO investigation is yet to be seen. Coupled with the increasing media reports of ethical issues with clinical trials, many hope that the investigation will lead IRBs to remember and revitalize their primary mission.

That mission is the protection of the health and welfare of human research participants—and how that protection goes far beyond assuring an adequate consent form.Δ

To read the full GAO investigation summary (includes links to a highlights page and the full report), go to <http://www.gao.gov/products/GAO-09-448T>

Other Resources

The March 26, 2009, Hearing Before the Committee on Energy and Commerce (includes links to transcripts, board minutes, marketing instruments, protocol documents, etc.) is at

http://energycommerce.house.gov/index.php?option=com_content&task=view&id=1552&Itemid=95

The FDA Hearing on Ketek, February 13, 2007, is at http://energycommerce.house.gov/index.php?option=com_content&view=article&id=318&catid=31&Itemid=58 .Δ

News notes

■ Research ethics during space travel and the right to opt out of studies

NASA’s chief bioethicist, Paul Root Wolpe, discussed the unique problems for research protocols involving astronauts in space for an August 10, 2009, article in *The New York Times*.

See http://www.nytimes.com/2009/08/11/science/space/11conv.html?_r=1.

He said, “Every astronaut who goes into space is . . . a human research subject.”

While most astronauts want to help by participating in studies, “There have been some who, in some situations, have refused.”

For example, astronauts have refused experiments because they were “concerned that medical information collected on them couldn’t really be private and might interfere with their getting health insurance after retirement.” Nevertheless, like research subjects on earth, astronauts are covered by the Common Rule and can opt out.

News notes

■ Reminder notice for registration of IRBs reviewing FDA-regulated research

The Food and Drug Administration (FDA) on September 14, 2009, issued a notice to clarify confusion in the IRB community regarding IRBs that registered in the OHRP database before July 14, 2009, and that review FDA-regulated research. Following is the FDA notice:

If those IRBs had voluntarily provided information concerning FDA-regulated studies, it will be visible when their information is accessed in the modified database, but that does not mean the IRB is registered with FDA. All previous IRB records were migrated as "OHRP only" into the new registration database, which was activated on July 14, 2009. This designation must be updated to read "OHRP/FDA" (or "FDA only," if that is the case) to register the IRB with FDA. In addition, any existing FDA-specific information should be reviewed to determine if an update is necessary. (FDA-specific information includes an estimate of the number of active FDA-regulated studies and a checklist for choosing the type of FDA-regulated research—drugs, biologics, devices, etc.)

To determine if a recent update accomplished the required change, you can search for your IRB information at

<http://ohrp.cit.nih.gov/search/>.

An IRB search with your IRB number will display basic information including "type" near the far right. If it does not read "OHRP/FDA" or "FDA only," you need to submit a new update (see below).

If you are updating your information to provide or update the FDA-specific information, use the electronic submission system page for updating registrations at <http://ohrp.cit.nih.gov/efile/IrbRnwStart.aspx>. After obtaining a submission number from the system, you will begin the update process.

To enter information for each separate IRB, access the pull-down list of IRB type and select "OHRP/FDA" or "FDA only." If you had already registered, the information previously entered will appear when you "save and continue," along with data-entry fields to enable you to enter or update the FDA-specific information required by the new IRB registration rule.

For further information on FDA's IRB registration requirements, contact Jean Toth-Allen, Ph.D., Office of Good Clinical Practice, Office of the Commissioner, Food and Drug Administration, 5600 Fishers Lane, HF-34, Room 16-85, Rockville, MD 20857, telephone (301) 827-1585,

■ Journal focuses on issues in human research using refugees

The current issue of the *Journal of Empirical Research on Human Research Ethics* focuses on research protection when using refugees as subjects (Vol. 4, No. 3, September 2009). The issue contains articles such as

"All refugee research is not the same," an introduction by Joan E. Sieber.

"Ethical and effective ethnographic research methods: A case study with Afghan refugees in California," by Valerie J. Smith.

"The control of foreigners as researchers in Thailand," by Mary J. Ditton and Leigh Lehane.

In the introduction, editor Joan Sieber says that refugee populations are vulnerable and research involving them is ethically challenging. The difficulty stems from language and cultural differences, fear and distrust of strangers, and concern about safety in the host country.

She says that while such research can be daunting, some investigators have shown that it can be done well and be useful. She cites as an example research to determine the needs of elderly Afghan women refugees whose husbands had been murdered by the Taliban.

Meetings

■ International Conference on Bioethics

July 15–17, 2010.

Chicago, Illinois

For information, see <http://www.cbhd.org/events>

■ 10th World Congress of Bioethics

July 28–31, 2010.

Singapore, China

For information, see <http://www.bioethics-singapore.org/wcb2010/>

■ 2010 Advancing Ethical Research Conference

December 6–8, 2010.

San Diego, California

For information, see <http://www.primr.org>



Protecting Human Subjects

This newsletter is designed to facilitate communication among those involved in emerging bioethical issues and regulatory changes important to both DOE and the human subjects community.

Elizabeth White, MPH, MBA,
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