THE UNIVERSITY OF IOWA

IRB Connection

HUMAN SUBJECTS OFFICE

Volume 2, Issue 13
October 2014

Human Subjects Research in the News:

A Shave, a Haircut, and a Blood Pressure Test
The Atlantic
September 2, 2014

Mining for Antibiotics, Right Under Our Noses
NYT, September 11, 2014

In a Study, Text Messages Add Up to a Balance Sheet of Everyday Morality
NYT, September 11, 2014

People With This Blood Type are At Greater Risk for Memory Loss in Later Life
Huffington Post,
September 12, 2014

You Can Buy Happiness, If It's An Experience
Maanvi Singh
September 3, 2014

HAWKIRB

Upcoming Training Sessions

How to Complete a New Project Application
October 16, 2014 2-4:30 PM
Hardin Information Commons EAST

After IRB Approval…
October 24, 2014 10-11:30 AM
HP Smith Conference Room (W256 GH)

HSO Office Hours

Wednesdays 2-4PM and Thursdays 10-12PM in 101 Hardin Library

Mondays 2-4 PM in N186 Lindquist Center

No appointment necessary

What is Financial Conflict of Interest in Research?

The term, "conflict of interest" is thrown around a lot, especially on research campuses. Broadly defined, it means, "…a set of circumstances that creates a risk that professional judgment or actions regarding a primary interest will be unduly influenced by a secondary interest," (Lo & Field, 2009). Given this broad definition, the Conflict of Interest in Research Office (COIR) dials in the definition, based on University of Iowa policy and federal regulations, and applies it specifically to research conducted at the University of Iowa. In this context, it means, "…a financial interest that is related to proposed University research (i.e., the interest reasonably appears to be affected by the research or is in an entity whose financial interest reasonably appears to be affected by the research) and that could directly and significantly affect the design, conduct, or reporting of research."

Let's say Dr. Jones, a UI investigator, serves on a scientific advisory committee for Big Pharma Company. For this work, Dr. Jones receives $6,000 a year. Then Dr. Jones submits a sponsored research proposal to the Division of Sponsored Programs for a clinical trial that will be sponsored by Big Pharma Company. Because there is a nexus between the financial interest and the research, Dr. Jones now has a financial conflict of interest related to research.

Does this mean that Dr. Jones is bad researcher? Absolutely not. Does it mean that she cannot conduct the research? That depends. The next step would be for the Conflict of Interest in Research Committee (CIRC) to review the interest, review the research proposal, and make a determination as to whether the interest could be managed.

Typically, the above scenario would be deemed as manageable by the CIRC. The Committee would then recommend a management plan to the Vice President for Research and Economic Development. If the Vice President agrees with the management plan, it would then be sent to Dr. Jones for her signature.

The important thing for Dr. Jones to remember is to keep her disclosure up to date in the *e*COI system. Next issue, we will examine disclosures in *e*COI.

The Site Visit — An Offer You Can't Refuse

The University of Iowa's Human Research Protection Program (HRPP) is in the process of applying for re-accreditation from the Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP), as we mentioned in the April 2014 issue of the IRB Connection. Currently, we are at step 3—the site visit!

AAHRPP will conduct their site visit of the UI on November 19-21. Two to four individuals from other HRPPs, with a wealth of human subjects research experience, will review IRB records and interview a variety of HRPP staff including the Institutional Official, HSO staff, IRB Chairs, and Members and Other Committee Members. AAHRPP will provide us with a list of investigators they wish to interview. If you are notified that you have been selected to meet with the site visitors, please understand this is not optional. It is a required element of our reaccreditation process.

Once achieved, AAHRPP re-accreditation demonstrates each researcher's and HRPP member's part in the University's overall commitment to sound and ethical human subjects research!

NEWS FLASH!

Effective October 1st, Michele Countryman, the current HSO Assistant Director has been named the HSO Interim Director. Dr. Andy Bertolatus will remain with the HSO/IRB as Executive IRB Chair.

Additionally, the HSO is sad to announce two staff departures. Well, officially we're thrilled: it is always exciting to see colleagues continue in their career development! But these are friends as well as colleagues, and will be missed.

Anne Alberhasky has managed the IRB Education and Compliance Program for several years, coordinated our AAHRPP accreditation, and wrote the best-ever IRB Education module referencing Chupacabras. She will be working as a Translational Research Manager in the HCCC.

Kelli Wallace has coordinated and reviewed many types of projects, in WIRB and in HawkIRB. Social and Behavioral Science (IRB 02) reviews will always have a special place in her heart—may she never forget the 6 categories of Exemption. Kelli will be coordinating research studies for the CPH.

Best of luck with future endeavors to Anne & Kelli, and may they never forget: *expedited does not mean fast.*

'Subjects Who Are Lost to Follow-up'

One section of the HawkIRB application that is often confusing is Section VII.E.7, that asks if the research team will attempt to recontact subjects who are lost to follow-up. Quite simply, lost to follow-up means that the researcher is unable to communicate with the subject via the contact information the subject provided. This includes situations when the enrolled subjects did not show up to the next research visit, the research team was unable to contact them due to their phones being disconnected or letters were returned to the sender. The purpose of this section is NOT to describe planned follow up procedures of the study (that is done in Section VII.E.6).

VII.E.7 Will you attempt to recontact subjects who are lost to follow-up?

- ○ No - followup is not required in this study
- ○ No - those lost to followup will not be recontacted
- ◉ Yes

VII.E.8 Describe - any procedures need to be included in the consent:

- In studies where no follow-up is required, the 1st option above applies.
- If a subject is lost to follow-up and the investigator will not make any attempts to reach him/her, the 2nd option applies.
- If the researcher will attempt to contact a subject whose contact information has changed, the researcher should choose 'Yes' - the 3rd option - and Section VII.E,8 will open.

Section VII.E.8 should describe specifically how the investigator plans to re-contact enrolled subjects whose contact information is no longer valid, for example, the use of on-line databases, web-based searches, commercial services, etc. The Informed Consent Document must also include this information so subjects are aware of this plan.

For more information, log onto the HawkID Login for ICON Courses for Researchers on the Human Subjects Office website, select *Courses for UI/VA Researchers and non-UI Research Partners* and view the HawkIRB Section VII.E. Project Description video.

FYI FOR YOUR INFORMATION

Please Note

Due to the temporary reduction in our staff and the upcoming AAHRPP site visit, the IRB Connection will now be published on a bimonthly basis.

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