

Human Subjects Research in the News:

[Do Clinical Trials Work?](#)
NY Times, July 13, 2013

[Hungry Aboriginal Children, Adults Used as Nutritional Subjects](#)
The Canadian Press, July 16, 2013

[America's NIH Suspends Clinical Trials in India](#)
The Economic Times, July 28, 2013

[NIH Makes Privacy Agreement with Henrietta Lacks' Family](#)
USA Today, August 7, 2013

HAWKIRB

Upcoming Presentations

[After IRB Approval...](#)
September 18, 2013:
3-4:30PM
HP Smith Conference Room
(W256 GH)

[Course-Related Student Research Projects: Learning How to Conduct Human Subjects Research](#)
September 16, 2013:
3026 Seamans Center
September 17, 2013:
Bralley Conference Room

[How to Create a New Project Application](#)
October 10, 2013: 2-4:30PM
Hardin Info Commons EAST

[HSO Office Hours](#)
Wednesdays 2-4PM and
Thursdays 10-12PM in
101 Hardin Library
Fridays 10-12pm in
N186 Lindquist Center
No appointment necessary

HSO Mainline Questions: What does "Exempt" mean?

In the film [The Princess Bride](#), the character Vizzini exclaims "inconceivable!" with each new plot development; another character accuses Vizzini of misunderstanding what the term "inconceivable" means. Vizzini isn't the only one who struggles with terms. Too often, we incorrectly use the term *exempt* when referring to human subjects research. This confusion comes from a misunderstanding of regulatory terminology (it happens to us all). [Merriam-Webster](#) defines exempt as "free or released from some liability or requirement to which others are subject." For example, if someone tells you they are exempt from jury duty, it means they don't have to serve as a juror. In the world of [federal regulations](#) regarding human subjects

research, we use two definitions for the term "exempt." First, if a research project doesn't involve human subjects, the project is *exempt from the IRB review process*. IRB Chairs

*"You keep using that word. I do not think it means what you think it means."
- Inigo Montoya*

formally make this determination after receiving a completed [Human Subjects Research Determination \(HSRD\)](#) form in HawkIRB. The second definition refers to a research project meeting requirements in one of [six categories provided in the federal regulations](#). Using the term in this manner means the project is *exempt from an annual continuing review by the IRB*. Projects reviewed as *exempt*

may use an information sheet that includes all of the [required elements of consent](#), rather than a full signed consent document. However, if there are changes to the project after initial approval by the IRB, including research team changes, researchers are still required to submit a modification to the IRB prior to implementation. HSO staff are making extra efforts to ensure projects eligible for exempt review are accurately described in HawkIRB. In fact, the designation of projects that fall within this category has increased in frequency by as much as 50% in recent months. Now you can exclaim

"exempt!" and it will indeed mean what you think it means.



-Sarah Heady
IRB Assistant

The Mailed Consent Process: "What should I do if there are errors?"

Investigators conducting a mailed consent process, in which there is no in-person contact with potential subjects prior to signing the Informed Consent Document (ICD), are likely to encounter errors in obtaining proper documentation of consent. Furthermore, if the mailed ICD accompanies a data or sample collection kit that the subject will mail to the research team, issues with completion are also likely to occur. When consent and/or data collection are conducted by mail, the details of the process and any follow-up with the subject must be described in HawkIRB and approved by the IRB prior to implementation. Researchers should anticipate the possibility that materials may be returned incomplete or incorrectly completed.

If documents will be returned to the subject for corrections, the research team must describe how this will occur in [Sections VII.D.29](#) (for adults) and/or [VII.D.30](#) (for parents/guardians of minors) in HawkIRB. To assist researchers with this process, the HSO offers a template [Mailed Correction Letter](#). This letter provides suggested language and instructions for returning an ICD, data or sample collection instrument to the subject for corrections. The template letter should be edited to address the specifics of the study and attached to HawkIRB, along with any other printed communication sent to the subject, prior to use. Investigators can find the template on the Attachments page of HawkIRB under the Miscellaneous attachments category.



Researchers can generate the template, edit and attach the letter in the miscellaneous category on the Attachments page of HawkIRB. Investigators utilizing a mailed consent process may also tailor the signature block of ICD so the research team can indicate whether consent was obtained in person, over the phone, or if no conversation took place between a member of the research team and the subject. Investigators may refer to the appendix section of the template ICD to insert the appropriate signature block into the consent document. The research team must also remember to include a second copy of the ICD whenever the consent process is conducted by mail so subjects may retain a copy.

NEWS FLASH!

Course-Related Student Project Policy Revision

Effective June 2013, the UI IRB revised its policy on student projects conducted in the classroom. [The Course-Related Student Project Policy](#) applies to all human subjects research activity conducted for purposes of teaching research methods at the UI. This policy explains when students should submit a HawkIRB application for IRB approval and when a project may fall under the course-related student project policy, which does not require IRB review. The revised policy was implemented along with a new tool, [a checklist for course-related student projects](#) to help students and course instructors determine if IRB approval is required.

Read more about the policy [here](#).

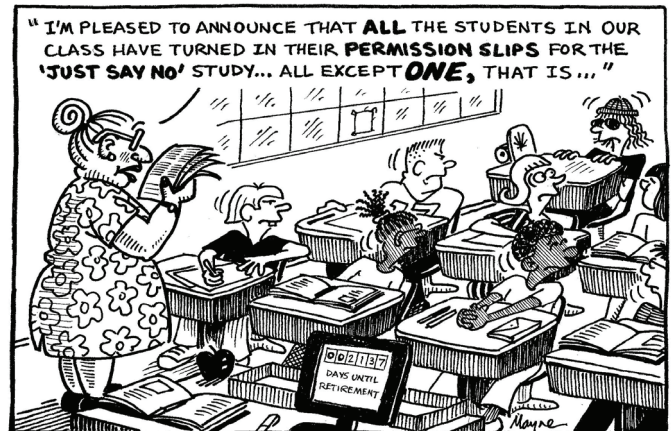
Back to School: Human subjects research in the classroom

As students return to school this fall, UI investigators may be preparing to conduct research in public schools. Investigators who wish to conduct human subjects research in this setting, including research activities in UI classrooms, have some additional responsibilities to ensure that the appropriate permission to conduct research in the classroom is obtained and documented for IRB review.

[Section VII.A.1](#) of the HawkIRB application requests the location of study procedures. If research activities are conducted outside the UI, the name and location of the school or facility should be provided in this section. Additionally, the investigator must provide documentation to indicate that s/he has permission to conduct research at the location. Typically, researchers attach a [Letter of Agreement \(LOA\)](#); a signed letter on letterhead or an

email from an individual who has the authority to grant the investigator permission to conduct research on the school's premises. Additionally, research involving the use of students' educational records is subjected to regulations in the [Family Educational Rights and Privacy Act \(FERPA\)](#). FERPA is a federal law that protects the privacy of personally identifiable information within a student's educational record. It applies to all kindergarten through postsecondary educational agencies or institutions that receive funds from the US. FERPA

requires that a student (or parent if the student is a minor) provide written permission before an educational agency or institution releases any personally identifiable information (beyond what is available in the [public directory](#)) from the student's education record. Investigators conducting research involving the access of students' educational records will need to have a plan described in [Section VII.D. 30](#) of the HawkIRB application and approved by the IRB for obtaining parental permission to access the non-directory information for research purposes.



*See the IRB Policy Reminder of the Month about using your own students as research subjects.

IRB Policy Reminder of the Month

UI Students as Research Subjects

Investigators should take precautions to avoid unintentional or subliminal coercion that may occur when a potential research subject is also a student. Generally, researchers should avoid using their own students as subjects. Investigators who wish to use their own students must provide a good scientific reason, rather than convenience, for selecting those students as subjects. The research project should be relevant to the topic of the class, and participation should be part of the learning experience for the students. In instances where investigators can provide a rationale for using their own students in their

research, someone other than the investigator (the instructor) should obtain informed consent and collect the data. When this is not possible, other methods must be arranged for obtaining consent and collecting data that do not reveal to the instructor whether or not a student participated in the research until after final grades have been determined. The students should be informed of what these procedures are in the ICD. The IRB may approve projects that give extra credit to students who participate in the research only when alternative means of obtaining equivalent extra credit with equivalent effort is made available to students who do not wish to volunteer as research subjects.

Human Subjects Office

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