

## Human Subjects Research in the News:

[DoD Establishes First Brain Tissue Bank to Study Brain Injuries](#)  
U.S. DoD, June 14, 2013

[An Experimental Drug's Bitter End](#)  
The NY Times, June 6, 2013

[Sibling Aggression Linked to Poor Mental Health](#)  
Science Daily, June 17, 2013

[7 Takeaways from Supreme Court's Gene Patent Decision](#)  
National Geographic, June 14, 2013

[Hospitals Want to Test Drug with No Consent](#)  
The Boston Globe, June 8, 2013

## HAWKIRB

### Upcoming Presentations

Fall HawkIRB training sessions are being scheduled now. Check the [HSO website](#) for the Fall schedule.

**HSO Office Hours  
Summer 2013**  
Wednesdays, 2-4PM  
101 Hardin Library  
No appointment necessary.

## Enrolling Minors: What Happens When They "Age Up"?

Informed consent is an ongoing process, continuing throughout the duration of a research project. For studies that propose to enroll minors, the IRB is responsible for protecting the autonomy of these individuals. When a minor initially enrolled in research with parental or guardian permission subsequently [reaches the legal age of consent](#), the subject's participation is no longer covered by parental/guardian permission and subject [assent](#) as required by [45 CFR 46.408](#).

Investigators must have an IRB-approved plan to give these new adults an opportunity to consent for their continued participation or to withdraw and have their data removed when they reach the age of majority. The term "age up" describes the point at which a minor attains the age they are able to give legally effective informed consent for participation in a research study. In the State of [Iowa](#), this age is 18 unless the minor becomes emancipated sooner by



marriage (childbirth does not emancipate minors). This UI IRB policy applies to all studies which continue to meet the definition of [human subjects research](#). Ongoing activities with minors who have aged up include:

- Interaction with subjects
- Analysis of identifiable data or samples
- Collection of new data from medical records or other sources

Up until the time the minor turns 18, the investigator can conduct research activities with the minor's data or samples with parental or guardian permission to do so. Once the minor ages up, unless the IRB has granted a [waiver of consent](#)

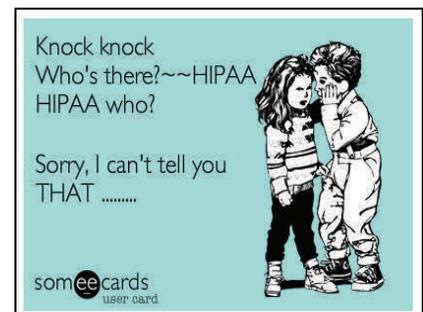
(not available to FDA-regulated research), all research activities must cease until the investigator has obtained legally effective informed consent from the subject. Investigators who propose to enroll minors and will have ongoing activities with these subjects must describe a plan to obtain consent from subjects when they turn 18. This plan must be detailed in [Section VII.D.29](#) of the HawkIRB application and be approved by the IRB prior to implementation. Alternately, the investigator may request a [waiver of informed consent](#) in [Section IV.3](#) for some subjects and provide justification as to why it would be [impracticable](#) to obtain consent from subjects who age up during the study. The UI IRB may also approve a waiver of consent for the storage and future use of data/tissue for banking studies that acquire data and/or samples from young children, but then have no further interactions with, or acquisitions of samples and data, from the subjects in later years.

## HIPAA/HITECH Act Omnibus Final Rule

[Hybrid entities](#) such as the University of Iowa must comply with the [HIPAA/HITECH Omnibus Final Rule](#) by September 23, 2013. The rule makes sweeping changes to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules required by the [HITECH Act](#) and to the [HIPAA Privacy Rule](#) as required by [GINA](#). The [Department of Health and Human Services](#) (HHS) made a number of changes to make the rules consistent with other HHS regulations. Key changes include the following:

- Expanded definition of "business associate"
- Expanded liability and obligations of business associates
- Elimination of the "significant risk of harm" standard as the threshold for breach notification
- Stricter limitations on marketing communications, fundraising, and the sale of protected health information (PHI)
- Changes to enforcement rules
- Changes to Notices of Privacy practices

Read a summary of the Final Omnibus Rule [here](#).  
Review the differences between the old rule and new rule [here](#).



## Human Subjects Research Data and Sample Identification Terms

When submitting a HawkIRB application, investigators are asked to describe how data and samples collected from human subjects are identified. These descriptions must be carefully worded to help ensure that data/sample collection is conducted with IRB approval and accurately described in HawkIRB and the Informed Consent Document. Specific terms are used by IRBs to describe the identification of data and samples. However, these terms are often confused. To help investigators avoid this pitfall, below are the definitions used by the HSO/IRB to describe the identification of human subjects research data and samples.

|                      |  |
|----------------------|--|
| <b>Identified</b>    | Samples or data that are attached to a readily available subject <b>identifier</b> such as a name, social security number (SSN), address, telephone number, or medical record number (MRN).  |
| <b>Coded</b>         | Identifying information such as a name, SSN, MRN, or ID code that enables the investigator to readily ascertain the identity of the individual to whom the private information or specimens pertain. The identifying information is replaced with a number, letter, symbol, or combination thereof (i.e., the code); and a key to decipher the code exists, enabling linkage of the identifying information to the private information or specimens.   |
| <b>De-identified</b> | Data or samples initially collected with identifiers, but have been irreversibly stripped of all identifiers by use of an arbitrary or random alphanumeric code and the key to the code is destroyed, thus making it impossible for anyone to link the samples to the sources. Once data or samples have been <b>de-identified</b> , restoring the link is not possible and the information or specimens cannot be reconnected to the individual from whom they were collected. Investigators may choose to de-identify data or specimens at the end of the research study for future use. In such cases, the future use of the data or specimens may meet the <b>criteria for a waiver of consent</b> or may not meet the <b>regulatory definition of human subjects research</b> and thus may not require IRB review prior to use. |
| <b>Anonymous</b>     | Samples or data collected without identifiers of any kind. At no point in the research can the investigator have access to this information. Samples or data may retain demographic or diagnostic information and still be considered anonymous if such information cannot be used to reveal the identity of the source.   |



### IRB Policy Reminder of the Month

#### **Case Report Forms (CRFs) Should not be Attached to the HawkIRB Application**

CRFs, paper or electronic forms typically used in clinical trial research, are a tool used by the sponsor to collect data from each participating site. All data on each subject participating in a clinical trial are documented in the CRF. Unless a form is completed by the subject in order to collect data directly from the individual, CRFs should not be attached to the HawkIRB application. Rather, the information collected on CRFs should be described in the attached protocol. The rationale for

this policy is to avoid duplication of documentation for IRB review. Additionally, if CRFs are attached, a Modification to the HawkIRB application needs to be submitted each time the attached CRF is revised. Blank and completed CRFs should be available for monitoring if the IRB wishes to review the forms. If a data collection instrument only exists as a CRF, the questions administered to the subject should be extracted from the form and attached to or described in the HawkIRB application.

### Human Subjects Office

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