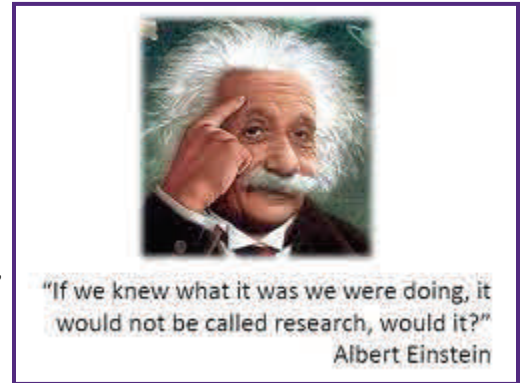


Reportable Events for Social/Behavioral Research Edition

What are Reportable Events?

During the course of a research study, events or problems may occur that investigators neither expect nor anticipate. Investigators may not even be aware that certain events need to be reported to the IRB. *Reportable events* are not defined in the [federal regulations](#), but the University of Iowa requires investigators to report incidents in which the regulations, [IRB policies](#), and IRB determinations related to the protection of human subjects were not followed, when unanticipated problems occur, or when serious adverse events occur. Although adverse events, unfavorable medical occurrences in human subjects, happen most commonly in biomedical research, they do on occasion occur in the context of social and behavioral research. Adverse events encompass both physical and psychological harms. In the conduct of social and behavioral research, there are three categories of reportable events at the UI that need to be reported to the IRB by the Principal Investigator (PI) via a Reportable Event Form (REF) in [HawkIRB](#). PIs must report events that meet the UI IRB's criteria of a reportable event to the IRB within 10 working days of the incident or the PI becoming aware of the incident.



Investigators and research team members often struggle with how to apply the criteria provided in each category and knowing whether or not to submit a REF for a specific situation. To assist investigators in their assessment of events that may qualify as reportable events, this special edition of the *IRB Connection* will provide additional information regarding the reporting criteria, as well as real examples of reportable events submitted by UI investigators that met the UI IRB's reporting criteria. Events that do not meet the IRB's reporting criteria can be summarized at the time of continuing review rather than reported in HawkIRB via a REF.

Reportable Event #1

Receipt of new information (including risk or benefit)

that may impact the willingness of subjects to participate or continue participation in the research study

UI IRB Reporting Criteria	What Does it Mean?	Examples
During the course of a study, researchers may become aware of new information, positive or negative, that would impact a subject's decision to participate, or continue participating in the study.	The information was not previously known to the investigator and is not described in the IRB-approved application or Informed Consent Document.	The PI submitted a REF describing subject reports of various problems with their personal vehicles after the installation of an on-board computer data collection system. Subjects reported problems ranging from the vehicle's battery draining to electrical issues. Additionally, the research team learned that a particular vehicle had a display that was affected by the installation. The ownership of this specific vehicle was added to the exclusion criteria for the study via a modification to the HawkIRB application. Due to the nature of the problems, this reportable event could fall in either the new information or unanticipated problems reporting categories. As a result of the REF, the HawkIRB application and Informed Consent Document (ICD) were modified to include additional risks related to subject safety and financial implications resulting from installation.
	The information may affect the conduct of the study and may need to be communicated to research subjects.	

Reportable Event #2

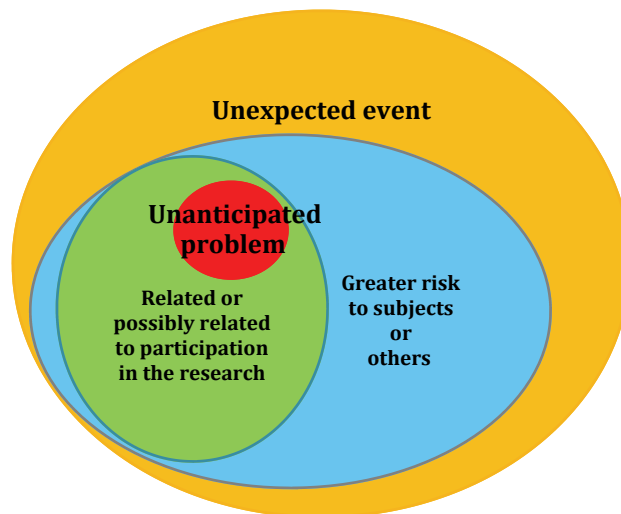
Unanticipated problem involving risks to subjects or others which occur at the UI or that impact subjects or the conduct of the study

UI IRB Reporting Criteria	What Does it Mean?	Examples
The problem is unexpected in terms of the nature, severity, or frequency given the research procedures described in the study-related documents, such as the IRB-approved application or the Informed Consent Document.	The event is not consistent with the expected side effects, symptoms, or outcomes. "Expected" means what has been observed in the past and included in the HawkIRB application and Informed Consent Document. Effects are more severe, more serious, or occur more often than what has been observed in the past.	The PI submitted a REF to report that an incorrect Qualtrics survey link was distributed to subjects via mass e-mail. As the incorrect link was caused by IT changes to the e-mail message and was not a problem the PI anticipated, the event met the criteria for reporting to the IRB. The distribution of the incorrect link caused subjects to complete a survey form that did not contain the correct logic. This resulted in the research team discarding all of the survey responses received from subjects except for one question. The HawkIRB application was not modified and subjects were not notified of the problem as the PI felt it may confuse subjects who had already completed the survey or new subjects who had not yet completed the survey. The REF was filed by the IRB Chair with no further required actions as the PI proposed a corrective action plan to correct the link and contact ITS to avoid future errors.
The problem suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.	The problem results in new circumstances that increase risk of harm to subjects. These events are unexpected in terms of the characteristics of the subject population being studied.	
The problem is related or possibly related to participation in the research.	There is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research.	

Reportable Events: Q & A

Question: How do I know when an unexpected event is an unanticipated problem that should be reported to the IRB?

Answer: When the event falls within all three circles, depicted in the red circle, in the illustration below



Reportable Event #3

Noncompliance with federal regulations or the requirements or determinations of the IRB

UI IRB Reporting Criteria	What Does it Mean?	Examples
Failure to follow the federal regulations (45 CFR 46) with respect to the protection of human subjects in research or failure to follow the determinations of the IRB with respect to conduct of research as approved by the IRB.	<p>The PI or members of the research team conduct human subjects research without IRB review or continuing review of the research.</p> <p>Noncompliance can also involve (but is not limited to):</p> <ol style="list-style-type: none"> 1) Failure to appropriately carry out study procedures as <u>described in the HawkIRB application as approved by the IRB</u> 2) Adding procedures or eliminating procedures designed to monitor subject safety 3) Failure to appropriately document the informed consent process 	<ol style="list-style-type: none"> 1) The PI submitted a REF to report the over enrollment of subjects. The investigator explained that there had been confusion in the reporting of enrollment numbers due to the number of separate, but similar IRB-approved studies. The REF was filed by the IRB Chair with no further required actions as the research team proposed a corrective action plan to reorganize all signed consent documents by study and to verify enrollment numbers in the future. 2) A REF reporting that a 17-year old student signed a consent document to enroll in the study was submitted to the IRB. The project did not have IRB approval to enroll minors. The PI proposed a corrective action plan to verify prospective subjects' ages prior to consent and did not retain the data collected from the minor. 3) The PI reported providing Cambus with an altered IRB-approved recruitment flyer. The REF was reviewed by the Full board which determined that the noncompliance was not serious because the changes to the advertisement did not present new information that would have influenced the willingness of an individual to enroll or continue in the study. All subjects signed a consent document with the required elements of consent. The PI submitted a corrective action plan to prevent a recurrence of the noncompliance.
<p>Continuing noncompliance - Noncompliance that occurs repeatedly to the point of suggesting a pattern or an underlying problem. Continuing noncompliance may occur due to a lack of knowledge (unintentional) or due to deliberate choice to ignore regulations or determinations of the IRB (intentional).</p>	<p>The IRB chair will determine if the reported noncompliance is potentially serious or continuing noncompliance. If so, the REF may then may be scheduled to a Full Board IRB meeting for review which can result in further reporting to federal regulatory agencies by the IRB.</p> <p>The following instance(s) of noncompliance, as defined by the Office of Human Research Protections (OHRP), will always be determined as serious noncompliance:</p> <ul style="list-style-type: none"> • Non-exempt human subjects research being carried out without IRB review and approval or without appropriate informed consent • Substantive modifications to IRB-approved research without IRB approval 	
<p>Serious noncompliance - Noncompliance that materially increases risks or that results in unexpected substantial harm to subjects or others.</p>		



Remember to provide a corrective action plan in your REF submission. You should inform the IRB how the research team is going to prevent the event from occurring again in the future (whenever possible). Also consider if you need to submit a modification to update your Informed Consent Document(s).

Reportable Events: Fast Fact

Although less common in the social and behavioral sciences when compared to the biomedical sciences, reportable events do happen...

In 2012, 21 REFs were submitted to IRB-02

Some Reportable Events are Preventable

Unanticipated events are just that, unanticipated. No one can predict every potential adverse outcome for research subjects. Yet the most common reportable event, over-enrollment, is entirely preventable. Over-enrollment occurs when the number of participating subjects exceeds the number approved for enrollment by the IRB. Once enrollment exceeds the approved number, the PI must submit both a modification, to increase the approved number, and a REF to report noncompliance. Save yourself the hassle, and prevent the problem!

In 2012, 42% of the REFs submitted to IRB-02 reported the over-enrollment of subjects. There are some common, and preventable, denominators that cause over-enrollment:

- **Research team miscommunication:** If enrollment numbers are not tracked in a single place, and more than one research team member is enrolling subjects, over-enrollment may be discovered after it has occurred. **Communicate and track enrollment centrally.**
- **Failure to set enrollment limits:** When using [Mechanical Turk](#) or other web applications, participation rates can very quickly exceed approval numbers. **Be sure to set a limit for the number of participants when initiating the use of web applications.**
- **The IRB considers any subject who consents to be enrolled, regardless of continued participation:** Some subjects may fail post-consent screening, and there are always subjects who decide not to continue with study procedures. **Allow room for attrition when designing your project.**
- **Misunderstanding IRB approval:** The number of subjects in HawkIRB is the enrollment limit, not the minimum number of subjects you may consent. Typos can also lead to over enrollment. If the approved number of subjects is 300, and you intended to indicate you would enroll 3000, the board may consider that serious and/or continuing noncompliance when 3000 subjects participate. **Be sure your application describes your project accurately, and if something needs to be adjusted, submit a modification before overenrolling.**



Reportable Events: Q & A

Question: Why do I need to submit reportable events to the IRB?

Answer: Institutions engaged in human subjects research supported by federal funding (like the UI) must have written procedures for ensuring prompt reporting to the IRB of the following:

- Unanticipated problems involving risks to subjects or others
- Any serious or continuing noncompliance
- Any suspension or termination of IRB approval

This reporting is required by the Department of Health and Human Services ([45 CFR 46.103\(a\)\(b\)](#)) and the Food and Drug Administration ([21 CFR 56.108\(b\)](#)).

Human Subjects Office

Office of the Vice President for Research and
Economic Development
105 Hardin Library for the Health Sciences
600 Newton Rd.
Iowa City, IA 52242-1098

Phone: (319) 335-6564
Fax: (319) 335-7310
E-mail: irb@uiowa.edu

hso.research.uiowa.edu