



Reportable New Information Form

Use this form to report information items that are required to be promptly reported to the IRB (refer to page 2)		
IRB #:		
Protocol Name:		
Investigator:		
Primary Contact:		
Description of new information: (Attach supporting documents to this form)		
Brief description of the study status (include current number of subjects enrolled locally, any unexpected trends or occurrences, or other pertinent information that may facilitate IRB Review):		
Identify which specific category (on page 2 of this form) that this new information falls under (i.e. 1b, 6). Note that information that does not fall under any of the listed categories does not require reporting to the IRB.		
Brief description of the corrective action plan to prevent reoccurrence (if 3, 4, 5 or 6 is indicated above otherwise N/A):		
Date you became aware of this information:		
In your opinion does the protocol require revision?	<input type="checkbox"/> Yes <input type="checkbox"/> No	If "Yes," describe above and submit a separate request for modifications.
In your opinion does the consent document require revision?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Investigator Acknowledgement		
I have personally reviewed this information and agree with the above assessment.		
Investigator signature		Date
IRB Use Only		
New Information Involves: (Check all that apply)		
<input type="checkbox"/> An unanticipated problem involving risks to subjects or others		
<input type="checkbox"/> Suspension or termination of IRB approval		
<input type="checkbox"/> Serious non-compliance		
<input type="checkbox"/> Continuing non-compliance		
<input type="checkbox"/> Non-compliance that is neither serious nor continuing		
<input type="checkbox"/> None of the above		
IRB signature		Date

Problems that Require Prompt Reporting to the OSU CHS IRB

Report any of the following information items to the IRB within **five (5)** business days using the Reportable New Information Form:

1. Information that indicates a new or increased risk, for example:
 - a. New information (e.g. interim analysis, safety monitoring report, publication in literature, sponsor report, or investigator finding) that indicates an increase in the frequency or magnitude of a previously known risk or uncovers a new risk.
 - b. An investigator brochure, package insert, or device labeling that has been revised to indicate an increase in the frequency or magnitude of a previously known risk or describes a new risk.
 - c. Withdrawal, restriction, or modification of a marketed approval of a drug, device or biologic used in a research protocol.
 - d. A protocol violation that resulted in harm to a subject(s) or others or indicates subjects or others might be at increased risk of harm.
 - e. A complaint from a subject that indicates subjects or others might be at increased risk of harm.
 - f. Any changes significantly affecting the conduct of the research.
2. Any harm experienced by a subject or other individual, which in the opinion of the investigator, is **unexpected** and **at least probably related to** the research procedures and suggests that the research places subjects or others at **a greater risk of harm than was previously known or recognized**.
 - a. A harm is “**unexpected**” when its specificity and severity are not accurately reflected in the consent document and/or the current investigator brochure.
 - b. A harm is “**at least probably related to** the human subjects research procedures” if in the opinion of the local investigator, the research procedures more than likely caused the harm (greater than a 50% probability).
3. Finding of non-compliance or allegation of non-compliance with research regulations, OSU policy and/or state law.
4. Audit, inspection, or inquiry by a federal agency.
5. Failure to follow the protocol due to the *action or inaction* of the investigator or human research staff.
6. Breach of confidentiality.
7. A change to the protocol, **made without prior IRB review** to eliminate an apparent immediate hazard to a subject.
8. When a subject becomes a prisoner in a study not approved by the IRB to involve prisoners.
9. A complaint that cannot be resolved by the research team.
10. Unanticipated adverse device effect (any serious adverse effect on the health or safety of a subject, or any life threatening problem or death caused by or associated with a device, if the effect, problem, or death was not previously identified in nature, severity or degree of incidence in the investigational plan, supplementary plan or application) or any other unanticipated serious problem associated with the use of a device that relates to the rights, safety or welfare of the subject(s).
11. Revised investigator brochure.