1. PURPOSE
	1. This guidance describes the information to promptly report to the [Organization’s] local IRB when the research is subject to oversight by the [Organization’s] local IRB.
	2. For research overseen by an IRB other than [Organization’s] local IRB, investigators should follow the requirements of that IRB.
2. GUIDANCE
	1. Report the following information items to the IRB within 5 days:
		1. New or increased risk[[1]](#footnote-1)
		2. Protocol deviation due to the action or inaction of the investigator or research staff
		3. Protocol deviation that harmed a subject or placed subject at risk of harm
		4. Protocol deviation made without prior IRB approval to eliminate an immediate hazard to a subject
		5. Audit, inspection, or inquiry by a federal agency
		6. Written report of a federal agency (e.g., FDA Form 483)
		7. Written report of a study monitor
		8. <Allegation of Noncompliance> or <Finding of Noncompliance>
		9. Unauthorized disclosure of confidential information
		10. Unresolved subject complaint
		11. Suspension or premature termination by the sponsor, investigator, or institution
		12. Incarceration of a subject in a research study not approved to involve prisoners
		13. Adverse event or IND safety report that requires a protocol or consent change
		14. State medical board or hospital medical staff actions
		15. Unanticipated adverse device effect[[2]](#footnote-2)
	2. When relying on an external IRB report the following information items to the HRPP Office within 5 days:
		1. Audit, inspection, or inquiry by a federal agency
		2. Written report of a federal agency (e.g., FDA Form 483)
		3. Written report of a study monitor
		4. Unauthorized disclosure of confidential information
		5. State medical board or hospital medical staff actions
	3. Information not listed above does not require prompt reporting to the [Organization’s] local IRB.
3. REFERENCES
	1. 21 CFR §56.108(b)
	2. 45 CFR §46.103(b)(5)
1. For example, publications indicating a new risk, new risk in an investigator brochure, FDA black box warning, new risk identified in a data safety monitoring report, information or change that adversely affects subject safety, or information or change that adversely affects the conduct of the research. [↑](#footnote-ref-1)
2. Unanticipated adverse device effect means any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects. [↑](#footnote-ref-2)