1. **PURPOSE**

1.1. This guidance describes the information to promptly report to the OHSU IRB when the research is subject to oversight by the OHSU IRB.

1.2. For research overseen by an IRB other than the OHSU IRB, investigators should follow the requirements of that IRB.

2. **GUIDANCE**

2.1. Submit the following Reportable New Information to the IRB within 5 business days:

2.1.1. Any of the following new risks to subjects or others:

2.1.1.1. Any new or increased risk related to the research,\(^1\) including adverse events or IND safety reports that require a change to the protocol or consent, and Data Safety Monitoring Board/Committee letters recommending changes or discussing new risks

2.1.1.2. Unanticipated adverse device effect\(^2\)

2.1.1.3. Unauthorized disclosure of confidential subject information\(^3\)

2.1.2. Protocol deviation(s), <Noncompliance>, or <Allegations of Noncompliance> that:

2.1.2.1. Harmed a subject or placed a subject at risk of harm, or;

2.1.2.2. Occurred due to the action or inaction of the investigator or research staff and may represent <Serious Noncompliance> or <Continuing Noncompliance>\(^4\), or;

2.1.2.3. Were made without prior IRB approval to eliminate an immediate hazard to a subject.

2.1.3. Any of the following types of written reports:

2.1.3.1. Reports of audits, inspections, or formal inquiries by a federal agency (e.g. FDA, DOD), regardless of findings, or reports, audits or inspections by internal or external entities (e.g., state agency, funding source, etc.), if any deficiencies were noted

2.1.3.2. Study monitoring reports (e.g. action letters) if any deficiencies were noted

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\(^1\) For example, new risk identified in a data safety monitoring report; information, change, or event that adversely affects subject safety; new risk in an investigator brochure; FDA black box warning; publications indicating a new risk; or information, change, or event that adversely affects the conduct of the research. This does NOT include events that are unrelated to participation in the research, such as those related to an underlying disease. This also does NOT include adverse events that were anticipated as part of the research.

\(^2\) 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.

\(^3\) This means any disclosure about a subject that is made in violation of applicable law, regulation, OHSU policy, or the approved study protocol. It is not necessarily limited to disclosures of PHI. If appropriate, the IRB will share these reports with the OHSU Information Privacy and Security Office, which will follow up with the research team as needed and may require additional information and/or corrective actions.

\(^4\) See HRP-001 POLICY: Definitions. Items that should be reported as potential Serious or Continuing Noncompliance may include, but are not limited to: protocol deviations that affected the rights or welfare of a subject, including causing an adverse event, resulted in intervention for the subject, or resulted in loss or invalidation of study data; repeated protocol deviations that suggest a pattern of noncompliance, such as two or more of the same deviation or several different deviations; and failure to follow previously instituted corrective or preventative action plans.
2.1.3.3. <Findings of Noncompliance> made by any entity

2.1.4. Other:
   2.1.4.1. Significant or unresolved subject complaint
   2.1.4.2. Suspension or premature termination by the sponsor, investigator, or institution
   2.1.4.3. Incarceration of a subject in a research study not approved to involve prisoners
   2.1.4.4. State medical board or hospital Medical Staff actions against a study team member

2.2. When relying on an external IRB, submit the following Reportable New Information to the OHSU IRB within 5 business days:
   2.2.1. Any finding of the external IRB of <Serious Noncompliance>, <Continuing Noncompliance>, an <Unanticipated Problem Involving Risks to Subjects or Others>, a <Suspension of IRB Approval>, or a <Termination of IRB Approval>
   2.2.2. Reports of audits, inspections, or formal inquiries of an OHSU site by a federal agency (e.g. FDA form 483)
   2.2.3. Unauthorized disclosure of confidential information about an OHSU subject or by an OHSU study team member\(^5\)
   2.2.4. State medical board or hospital Medical Staff actions against an OHSU study team member
   2.2.5. Any other item specified by the OHSU IRB.\(^6\)

2.3. Information not listed above does not require prompt reporting to the OHSU IRB, but may require reporting at Continuing Review.

3. REFERENCES
   3.1. 21 CFR §56.108(b)
   3.2. 45 CFR §46.103(b)(5)

\(^5\) This means any disclosure about a subject that is made in violation of applicable law, regulation, OHSU policy, or the approved study protocol. It is not necessarily limited to disclosures of PHI. If appropriate, the IRB will share these reports with the OHSU Information Privacy and Security Office, which will follow up with the research team as needed and may require additional information and/or corrective actions.

\(^6\) Depending on OHSU’s reliance agreement with the external IRB, the OHSU IRB may be responsible for handling additional Reportable New Information. The OHSU IRB will communicate these requirements to the study team as applicable.