**Definitions**

**University Indemnification (UI)**: Determination of the level of risk when Saint Louis University is responsible for liability coverage. If the research could result in permanent disability or death, the protocol receives a “high” UI determination. Protocols with all other levels of risk receive a “not high” UI determination.

**Noncompliance**

* 1. *Noncomplianc*e is defined as conducting research in a manner that disregards or violates federal regulations or institutional policies and procedures applicable to human subjects research. Noncompliance includes failure to adhere to the approved research protocol, except for minor or technical violations which result from inadvertent errors, inattention to detail, or failure to follow operational procedures which do not pose risk to subjects and/or violate subject’s rights and welfare.
  2. *Continuing noncompliance* is a persistent failure to adhere to the laws, regulations, or policies governing human research including persistent failure to adhere to an approved research protocol.
  3. *Serious noncompliance* is a failure to adhere to the laws, regulations, or policies governing human research that may reasonably be regarded as:
     1. Involving substantive harm, or a genuine risk of substantive harm, to the safety, rights, or welfare of human research subjects, research staff, or others; or
     2. Substantively compromising the effectiveness of a facility’s human research protection or human research oversight programs.

**Significant Risk (SR) and Non-Significant Risk (NSR) Device**

Under 21 CFR 812.3(m), an SR device means an investigational device that:

* Is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject;
* Is purported or represented to be for use supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a subject;
* Is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject; or
* Otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.

An NSR device study is one that does not meet the definition for an SR device study.