Continuing Non-Compliance – a pattern of non-compliance that, in the judgment of the IRB Chair or convened IRB, suggests a likelihood that instances of non-compliance will continue without intervention. Continuing non-compliance also includes failure to respond to a request to resolve an episode of non-compliance.

Deviation/Violation – A protocol deviation or violation occurs when there is a variance in a research study between the protocol and the activities being performed. Protocol deviations and violations may be minor or major.

Emergency Exception – A deviation that in the opinion of the PI is required to eliminate an apparent immediate hazard to a research subject or group of subjects. The researcher should proceed with the changes are needed to protect the safety and welfare of the subjects and may do so without prior IRB review. Following the Emergency Exception, the PI must report the exception to the WVU IRB within 5 days of the deviation.

Minor protocol deviations – Reported at the time of Continuing Review
- The deviation has no substantive effect on the risks or benefits to the individual research subject, AND
- The deviation has no substantive effect on the value of the data collected, AND
- The deviation did not result from willful or knowing misconduct on the part of the investigator(s) or study staff.

Major protocol deviations or violations – Reported to the IRB within 5 working days
- The deviation has harmed or posed a significant risk of substantive harm to the individual research subject and increased the risk/benefit ratio, OR
- The deviation has compromised the scientific integrity of the data collected for the study, OR
- There is evidence of willful or knowing misconduct on the part of the investigator(s) or study staff, OR
- The investigator(s) or study staff demonstrated other serious or continuing noncompliance with federal, state or local research regulations.

Enrollment Exception – An enrollment exception (waiver) is the sponsor’s prospective approval for the enrollment of a research subject that fails to meet currently approved protocol inclusion criteria, or falls under protocol exclusion criteria. Enrollment exceptions only apply to a single individual. Such requests should be rare and justified in terms of serving the best interests of the potential study participant and must be reported to the WVU IRB 3 working days in advance.

Non-compliance – any action or activity associated with the conduct or oversight of research involving human participants that fails to comply with either the research plan as approved by a designated IRB, or federal regulations or institutional policies governing human subject research. Non-compliance may be minor or sporadic or it may be serious or continuing. Note: Once a finding of non-compliance is proven, it must be categorized as serious, non-serious, or continuing.

Non-significant risk device (NSR) – An investigational device that does not pose a significant risk to human subjects.

Protocol Exception – An intentional or planned deviation from the protocol that should be considered justified in terms of serving in the best interest of the study subject. This type of exception (waiver) must be reported to the WVU IRB 3 working days in advance.

Related – An event is related to a research procedures, if it was more likely than not to be caused by the research procedures or if it is more likely than not that the event affects the rights and welfare of current participants.

Serious – any event that results in death, is life-threatening, requires hospitalization or prolongation of hospitalization, results in persistent or significant disability/incapacity or is a congenital anomaly/birth defect.
Serious Adverse Event – Any adverse event temporally associated with the subject’s participation in research that meets any of the following criteria:

1. results in death;
2. is life-threatening (places the subject at immediate risk of death from the event as it occurred);
3. requires inpatient hospitalization or prolongation of existing hospitalization;
4. results in a persistent or significant disability/incapacity;
5. results in a congenital anomaly/birth defect; or
6. any other adverse event that, based upon appropriate medical judgment, may jeopardize the subject’s health and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition.

Serious Non-compliance – failure to follow any of the regulations and HRPP SOPs or failure to follow the determinations of the IRB and which, in the judgment of either the IRB Chair or the convened IRB, increases risks to participants, decreases potential benefits, or compromises the integrity of the Office of Research Integrity and Compliance. Research being conducted without prior IRB approval or participation of subjects in research activities without their prior consent (in studies where consent was not specifically waived by the IRB) is considered serious noncompliance. A single instance of non-compliance may be determined by the IRB to be serious non-compliance.

Significant risk device (SR) - Significant risk device is an investigational device that: (1) is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject; (2) is for use in supporting or sustaining human life and represents a potential for serious risk to the health, safety, or welfare of a subject; (3) 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 (4) otherwise presents a potential for serious risk to a subject.

Unanticipated adverse device effect (UADE) – For studies of medical devices, the investigational device exemption regulations define an unanticipated adverse device effect as “any serious 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” (21 CFR 812.3(s)). UADE reporting applies to both significant and non-significant risk (NSR) device studies.

Unanticipated Event – Unanticipated event is a broad term to include research related events that were unexpected.

Unanticipated Problems Involving Risk To Subjects or Others (UPIRTSO) – A UPIRTSO is an unanticipated problems involving risks to subjects or others, refer to any incident, experience, outcome, or new information that:

a. Is unexpected or unanticipated at the time of its occurrence and is:
   1. not already described as potential risks in the approved research protocol or consent document
   2. not listed in the Investigator Brochure
   3. not due to an underlying disease
   4. occurring at an increased frequency or at an increased severity than expected
b. Is related or possibly related to participation in the research, and,
c. Indicates that subjects or others are at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

Note: The event must meet all criteria to be considered a UPIRTSO.

Unexpected – An event is unanticipated or unexpected when its frequency, severity, or specificity is not consistent with the current investigator brochure, protocol, consent form, package insert or label, the expected natural progress of any underlying disease, disorder, or condition of the subject(s) experiencing the event and the subject’s predisposing risk factor profile for the event.