

Definitions

Adverse Event

Any untoward medical occurrence or event

Serious Adverse Event

Results in death, is life threatening, requires inpatient hospitalization (or prolonged hospitalization), causes significant disability/incapacity, is a congenital anomaly/birth defect, or a medically important event

Unanticipated Problems (UAP) Criteria

As outlined in Federal Regulations and Guidance, an event must be all three

Unexpected



In nature, severity, or frequency based on study documents (e.g., protocol, informed consent form) and participant characteristics

Related/Possibly Related



Has a reasonable possibility of being caused by the research procedures

Suggest Greater Risk



Incident places subjects or others at a greater risk of harm (physical, psychological, economic or social) than previously known

Examples of UAPs

This is not an all-inclusive list



A participant experiences a severe allergic reaction to a drug which was not described in the ICF



A laptop was stolen from the locked car of an investigator



A complete data set including participant identifiers was sent to a PI when they were to receive a limited data set



A medication error occurs whereby participants were given expired drug in a clinical trial



A data breach occurs when unauthorized access to identifying information is granted to a contractor without a DUA

SMART IRB SERIOUS NONCOMPLIANCE

Serious noncompliance is any noncompliance that increases risk of harm to subjects; adversely affects the rights, safety, or welfare of subjects; or adversely affects the integrity of the data and research. Apparent serious noncompliance describes an event that appears to constitute serious noncompliance, and so requires reporting to an appropriate IRB for consideration, but the IRB has not yet made a formal assessment of the event.

CPHS Definitions: SNC and CNC

Noncompliance is the failure to follow regulations, IRB/institutional policy, or IRB approval

- **Serious Noncompliance:**

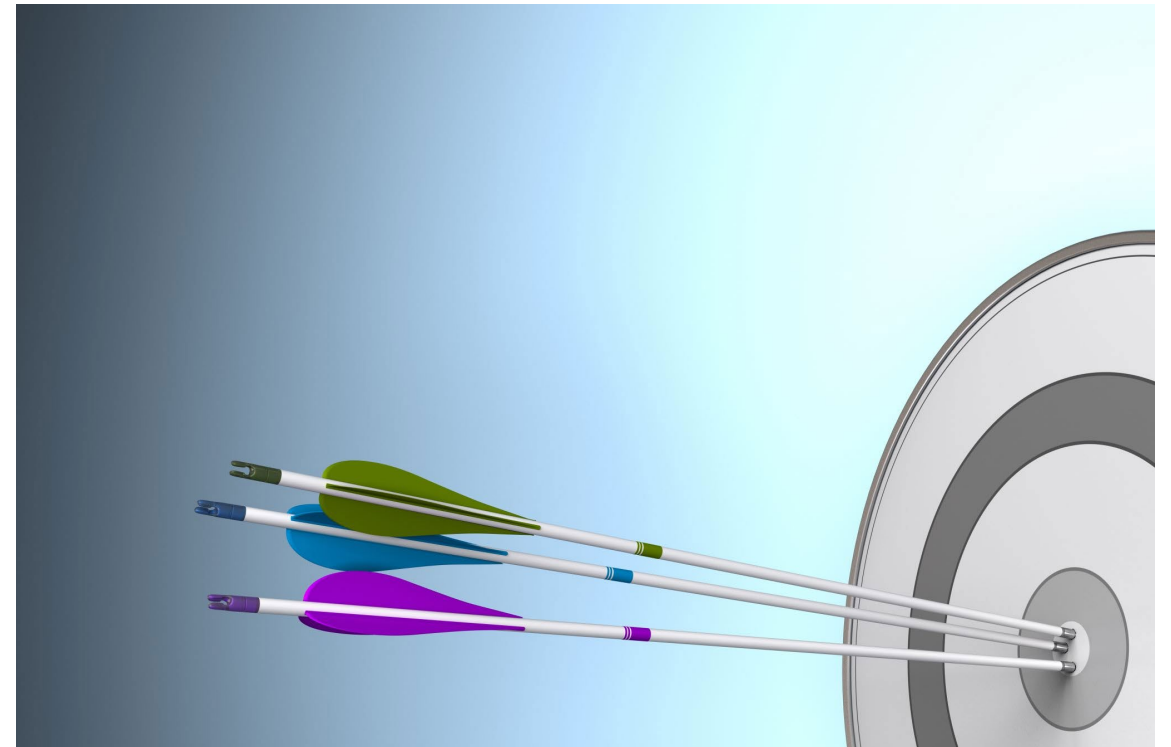
- Increases risk to subjects
- Undermines rights or welfare
- Compromises data integrity

- **Continuing Noncompliance:**

- Repeated or persistent noncompliance
- Pattern over time

IRBs are required to assess seriousness and pattern:

- Single minor deviation may not be SNC
- Repeated minor deviations may indicate CNC
- IRB must assess both severity and frequency



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