

Glossary

Adverse Event

Any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have a causal relationship with this treatment.
e.g. Abnormal laboratory finding, headaches, fatigue.

Competing interest

A set of conditions in which professional judgment concerning a primary interest tends to be influenced by a secondary interest. Competing interests may conflict when the secondary interest is perceived to unduly influence the primary interest. It is important to avoid, minimize or mitigate conflicts of interest that Investigators may have with respect to a proposed research project
e.g. Ownership in the company sponsoring the research, proprietary interest in the tested product.

Continuing non-compliance

A pattern of reports of minor non-compliance that, if unaddressed, may compromise the integrity of the HRPP. The pattern may reflect a lack of knowledge or a lack of commitment to human participant protection by the research team.
e.g. Failure to answer to REB requests, frequent minor deviation from the protocol.

Human Research Protection Program (HRPP)

Any element that contributes to the protection of research participants.
e.g. Training, procedures, audit.

Minor non-compliance

Non-compliance that is neither serious nor continuing.

Minor protocol deviation

Protocol deviation that do not affect the risk/benefit analysis and/or the participant rights, safety or welfare and/or the integrity of the resultant data.
e.g. Study visit performed slightly out of window (if the visit was not critical)

New safety information:

Any information that could affect research participant protection.
e.g. Newly safety information from publications, interim data analysis showing greater risks than expected.

Non-compliance

Failure to comply with the HRPP - including IRB/REB policies and procedures.



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Serious Adverse Event (SAE)

Any untoward medical occurrence that at any dose:

- results in death,
- is life-threatening,
- requires inpatient hospitalization or prolongation of existing hospitalization,
- results in persistent or significant disability/incapacity, or
- is a congenital anomaly/birth defect

e.g. heart attack; liver destruction.

Serious non-compliance

A failure to comply with the HRPP that increases the risk to participants, or adversely affects their rights and welfare.

e.g. Failure to report an Unexpected and Related SAE, performing research procedures without proper IRB/REB approval.

Significant protocol deviation

An event that affects

- the risk/benefit analysis and/or,
- the participant's or other's rights and/or,
- safety or welfare and/or,
- and/or the integrity of the resultant data.

e.g. Use of prohibited medication, Incorrect study medication or dosing, enrolling a participant outside the inclusion/exclusion criteria

Unanticipated Problem

Any problem, event, or information that was

- unforeseen and
- harmed one or more participants or others, or
- placed/places one or more participants or others at increased risk of harm.

e.g. Breach of confidentiality (e.g. lost or stolen research data), incarceration of a participant in a protocol not approved to enrol prisoners; principal investigator death; change in labeling or withdrawal of marketing

Unexpected and related AE/SAE

Events not described in the product monograph, research protocol, scientific literature, etc.

