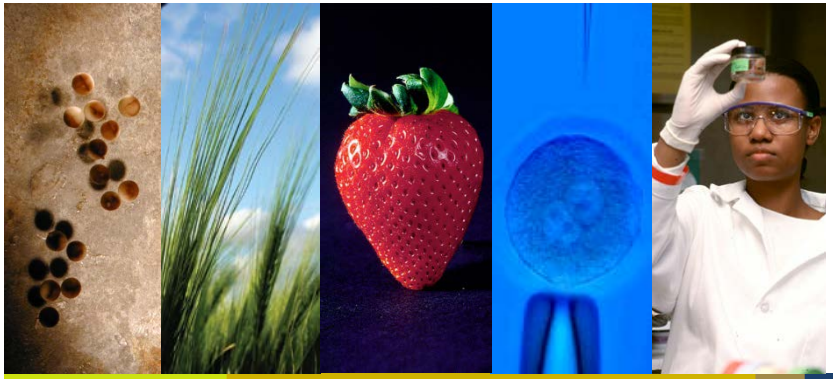

UC DAVIS OFFICE OF RESEARCH

AAHRPP Preparation
UC Davis Human Research
Part IX – Reportable New Information

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Objectives

- Define adverse events and unanticipated problems
- Describe the reportable new information categories
- Discuss reporting timelines to the IRB

Definitions

Adverse Event

Any untoward medical occurrence associated with the use of a drug in humans, whether or not considered drug related.

Definitions

Unanticipated Problems Involving Risks to Subjects or Others (UPIRTSOs)

Any incidents, experiences, or outcomes that are serious, unexpected, and reasonably (probably or greater) related to the research

Definitions

An adverse event is considered serious if:

- Death occurs
- Life-threatening reactions
- Inpatient hospitalization or prolongation of hospitalization
- Results in a persistent or significant disability/incapacity
- Results in a congenital anomaly/birth defect
- *Jeopardizes the subject*
- *Breach of confidentiality that may have a negative consequence*

Definitions

Unexpected

A harm is unexpected when its specificity or severity are inconsistent with risk information previously reviewed and approved by the IRB in terms of nature, severity, frequency, and characteristics of the study population.

Definitions

Probably Related

Any adverse effect that may reasonably be regarded as caused by, or probably caused by, the drug.

Definitions

Unanticipated Adverse Device Effect (UADE)

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

Definitions

Serious Non-Compliance

An action or omission taken by an Investigator (noncompliance) that any other reasonable Investigator would have foreseen as compromising (adversely affecting) the rights and welfare of the subject

Definitions

Continuing Non-Compliance

A pattern of noncompliance that suggests the likelihood that, without intervention, instances of noncompliance will recur, a repeated unwillingness to comply, or a persistent lack of knowledge of how to comply.

Reportable New Information: Categories

1. Information that indicates a new or increased risk, or a new safety issue
2. Serious harm experienced by a subject or other individual, which in the opinion of the investigator is **unexpected** and **probably related** (>50% likely; "Don't know" = <50%) to the research procedures.
3. Non-compliance with the federal regulations governing human research or with the requirements or determinations of the IRB, or an allegation of such non-compliance
4. Failure to follow the protocol due to the action or inaction of the investigator or research staff
5. Change to the protocol done without prior IRB review to eliminate an apparent immediate hazard to a subject.
6. Breach of confidentiality

Reportable New Information: Categories <cont.>

7. Complaint of a subject that cannot be resolved by the research team
8. Premature suspension or termination by the sponsor, investigator, or institution
9. Incarceration of a subject in a study not approved by the IRB to involve prisoners
10. Audit, inspection, or inquiry by a federal agency or other entity and any resulting reports (e.g., FDA Form 483)
11. Written reports of study monitors and/or data safety reports
12. Unanticipated adverse device effect (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)

Reporting Times for Reportable New Information (HRP-214)

- ONLY information that falls into one or more of the aforementioned categories should be reported to the IRB within 5 business days of becoming aware of the event.

Thank you – Don't miss Part X of this continuing series!