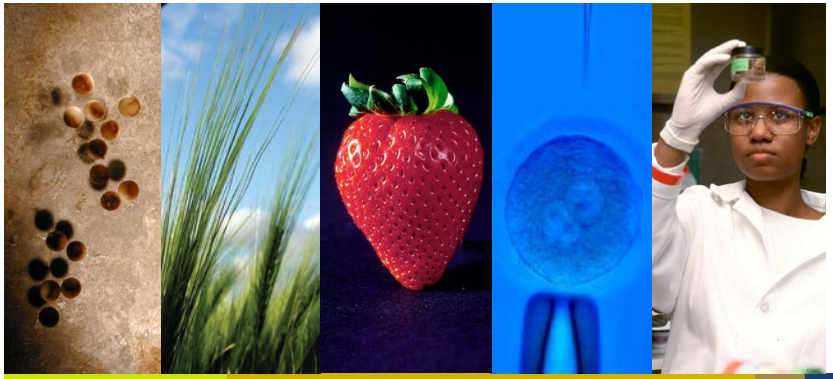


UC DAVIS OFFICE OF RESEARCH

HRP-214: Reportable New Information

June 6, 2013
Jun Porter
Designated Reviewer

UCDAVIS
OFFICE OF RESEARCH

HRP-214: Reportable New Information

What to Report

- SAE/AE (Drug and Device)
- Deviation/Violation

  Patients vs. research staff
- Monitoring Report(s)
- Temporal Closure to Accrual

  Temp vs. Permanent
- Breach of confidentiality
- Federal agency audit, inspection and resulting report(s)
- Non-compliance with the federal regulations governing human research or with the requirements or determinations of the IRB, or such an allegation of such non-compliance
- Complaint of a subject that cannot be resolved by the research staff

Type of Notice

- Acknowledgement – electric signature of the reviewer and return to the research team

- HRP-519 (Letter) – this comes from a full board that reviewed New Reportable Information

HRP-214: Reportable New Information

What the IRB is looking for

- Deviation

  When it had happened, what had happened, any harm to subjects occurred as a result of this deviation

- Closure

  Letter from the sponsor (including email)

- Monitoring Report

  Has deviation(s) already reported to the IRB?

HRP-214: New Reportable Information

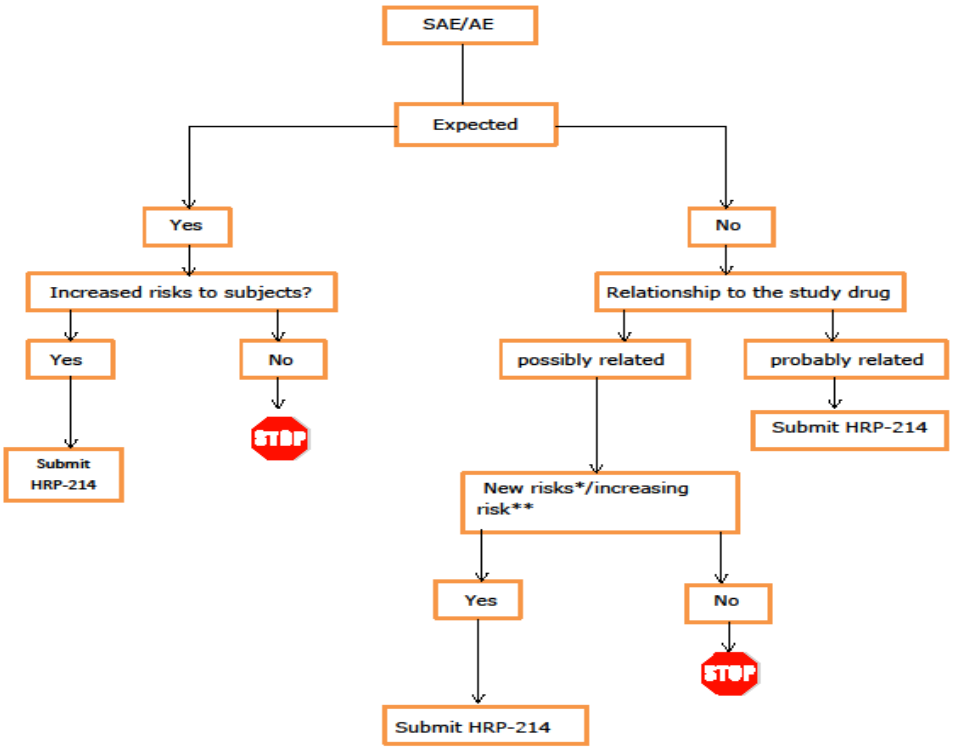
SAE/AE occurred at an external site

- Investigator determined that “causal relationship” exist, but the sponsor needs more information (whether the event is possibly or probably related is not clear.
- Investigator determined that the event was possibly related to the study drug, and the sponsor states no changes are necessary.
- Investigator determined that the event was probably related, and the sponsor states no changes are necessary at this time.

HRP-214: Reportable New Information

Questions?

HRP-214: Reportable New Information



- *New risks-not listed in IB/consent
- **Increasing risks: e.g., changing risk level from less likely to highly likely
- Submit HRP-214 only when the sponsor requires the IRB acknowledgement

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