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
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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?
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- SAE/AE
  - Expected
    - Yes
      - Increased risks to subjects?
        - Yes
          - Submit HRP-214
        - No
          - STOP
    - No
      - Relationship to the study drug
        - possibly related
          - STOP
        - probably related
          - Submit HRP-214
      - New risks*/increasing risk**
        - Yes
          - Submit HRP-214
        - No
          - STOP

* 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