New Safety Information SOPs

Committee Member Training

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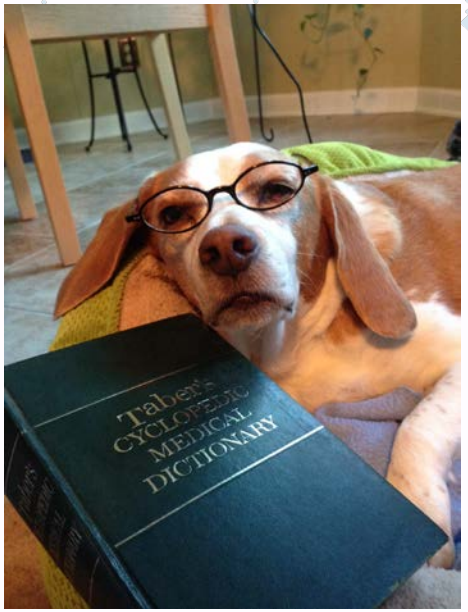
LEARNING OBJECTIVES

- What constitutes “new safety information”
- How is new safety information is processed within the OHRE



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What to Report to the UNC IRB?

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New or Increased Risk = New Safety Information

- Adverse Events
- New findings
- Deviations
- Noncompliance
- Other

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Adverse Events*

- Adverse Events, Internal:
  - unexpected, ***and***
  - related or possibly related, ***and***
  - serious OR suggest new/increased risk

- Adverse Events, External:
  - unexpected, ***and***
  - related or possibly related, ***and***
  - serious OR suggest new/increased risk, ***and***
  - warrant a change to the protocol, subject notification, or re-consent

* Includes unanticipated adverse device effect

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New Safety “Findings”

- Interim analysis
- DSMB report
- Findings from related studies
- Hold or early closure due to safety concerns

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Protocol Deviations

Increased Risk

Actual Harm

Eliminate Hazard

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Noncompliance

- Conduct research without IRB approval or exemption
  - Start before approval letter received
  - During a lapse in approval
- Fail to obtain informed consent or to re-consent w/ new risk
- Deviate from the approved consent or recruitment process
- Initiate changes to the protocol without IRB approval
- Fail to complete required human subjects protection training
- Over-enroll in a study that is greater than minimal risk

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"Other" New Safety Information

- Breach or potential breach of confidentiality or privacy
- Subject complaint
  - Rights, welfare, or safety adversely affected, ***or***
  - Cannot be resolved by the investigator
- Incarceration of subject in study not approved to include prisoners
- Audit, inspection, or written report by a federal agency (FDA 483)
- State board action (e.g., suspension of professional license)
  - Affects the ability to conduct the study as approved, ***or***
  - Increases risks to subjects or others

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New Safety Information - UNC cedes review

- Unanticipated Problem Involving Risk to Subjects or Others (UPIRSO) determination ***when the event involved UNC subjects or researchers***
- Serious Noncompliance determination ***when the event involved UNC subjects or researchers***
- Continuing Noncompliance determination ***when the event involved UNC subjects or researchers***
- Suspension
- Termination

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When to Report?

***Calendar days**

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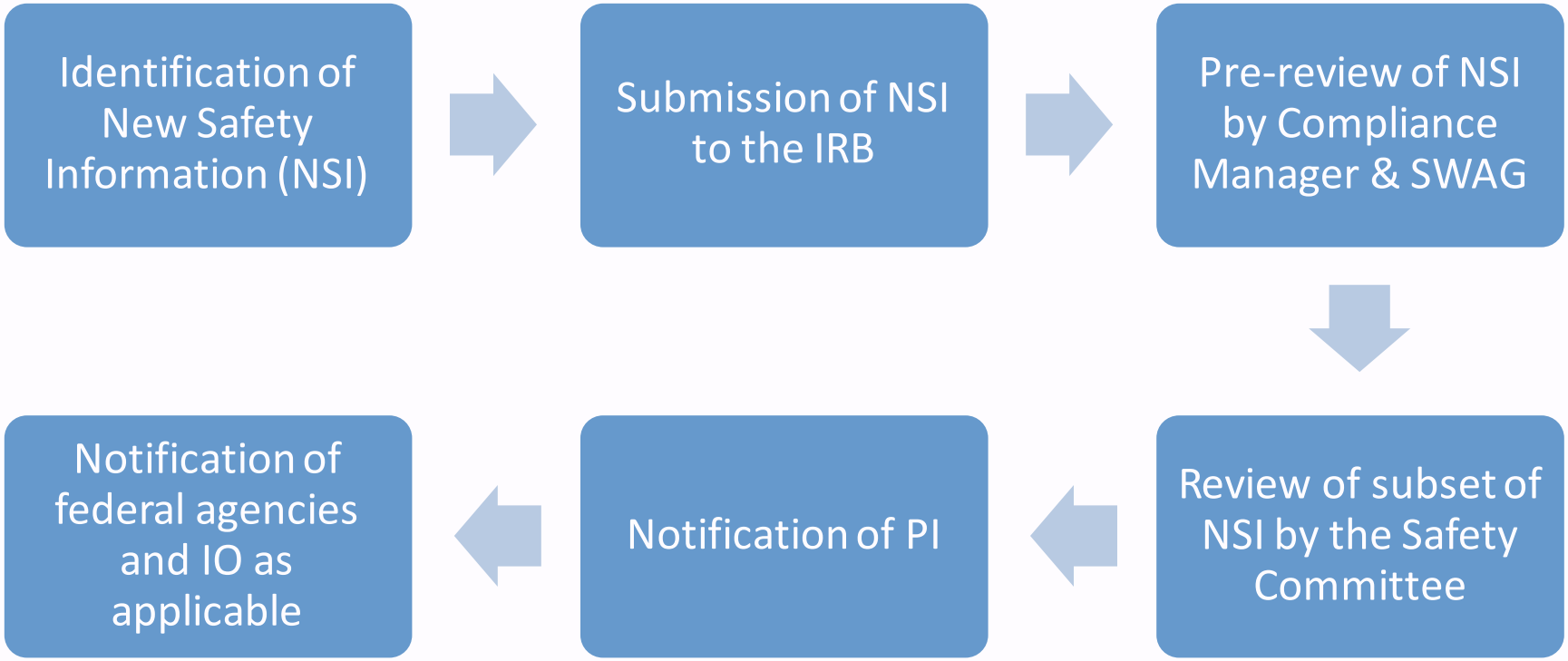
Flow of Information



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Who is SWAG?

Safety Welfare Analysis Group (SWAG)

- Reviews all New Safety Information
- Includes ≥ 3 members who have experience with research
  - Vicki Bae-Jump, MD, PhD, Associate Professor OBGYN-GynOnc , LCCC
  - Luigi Troiani, PA, Clinical Instructor, Department of Neurology
  - Jeanne Lovmo, MA, OHRE Compliance Manager
- This is NOT an IRB

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SWAG's Review Process

- Requests additional information
- Evaluates information
- Works with Investigators to Develop Sufficient Corrective and Preventative Actions (CAPA) Plans
- Resolves submission that does not represent UPIRSO, Serious or Continuing Noncompliance.
- Refers information to Safety Committee.

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Who is the Safety Committee?

Serves as an IRB in accordance with 45 CFR 46, and 21 CFR 50 and 56 (SOP 401).

- At least five members of varying backgrounds who are qualified through experience and expertise
- One scientist, one nonscientist, one unaffiliated member, one member who represents the general perspective of a participant

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Regulatory Determinations

- Serious Noncompliance (SNC)
- Continuing Noncompliance (CNC)
- Unanticipated Problem Involving Risk to Subjects or Others (UPIRSO)
- Suspension of IRB Approval
- Termination of IRB approval

Considerations

- Modification of protocol and/or consent document
- Reconsent, Notification
- Modification of continuing review schedule
- Additional monitoring or training
- If suspension/termination – participant transfer, refer for care outside study, follow-up continue under independent monitoring
- Additional resources to support the research recommended/required?
- Recommendations for the Vice Chancellor for Research (IO)

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PI Notification

- Determination(s)
- Rationale for the determination(s)
- Any actions requested and recommended by the committee.

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IRB Reporting Requirement to Federal Agencies

FDA Regulated Research

Federally Funded Research

[45 CFR 46.103(b)(5) and 21 CFR 56.108(b)]

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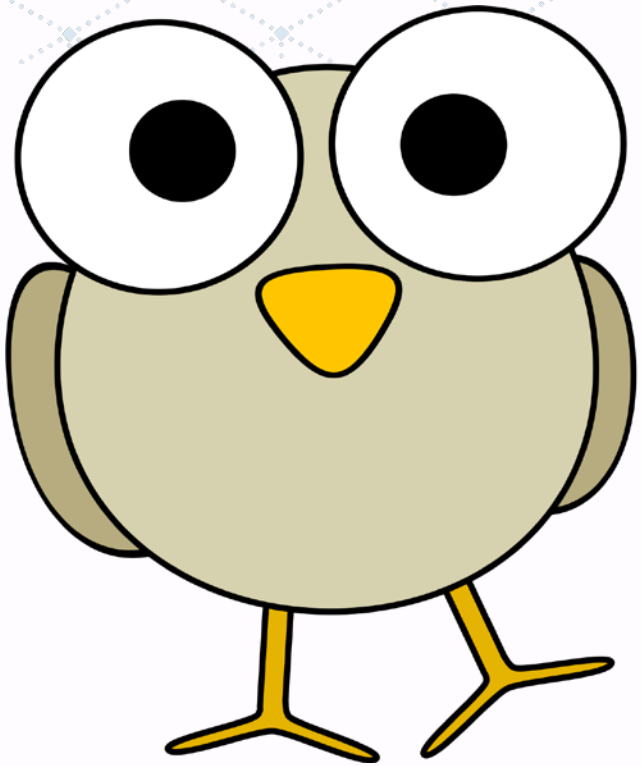
THANK YOU!



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