**Informing Participants about Significant New Information and Findings**

1. Contact participants immediately and tell them about new information; if applicable, implement new safety procedures or tests
2. Submit Reportable Event to the IRB ("Protocol Change to Eliminate Immediate Hazard")
3. Prepare SNIF form and update consent form for future enrollment
4. Submit amendment to IRB for review
5. Have participants sign SNIF form after IRB approval

**Is the New Information Significant Enough to Affect a Participant's Willingness to Continue in the Study?**

- **YES**
  - Are any participants enrolled in the study?
    - **YES**
      - Is there an immediate hazard to participants?
        - **YES**
          - Does the sponsor require participants to sign the updated consent form?
            - **YES**
              - Participant signs SNIF form and updated consent form
            - **NO**
              - Participant signs SNIF form only
        - **NO**
          - Prepare SNIF form
          - Update consent form for future enrollment
          - Submit an amendment to IRB for review
          - Have participants sign SNIF form after IRB approval
    - **NO**
      - Update consent form for future enrollment

- **NO**
  - Update consent form for future enrollment