LSUHSC IRB Presents:

LUNCH & LEARN

FDA'S LOCAL IRB INSPECTION: A POST-MORTEM

September 6, 2023

Objectives

- To educate study teams on FDA Inspections of IRBs
- To inform study teams of the observations from the most recent IRB Inspection done by the FDA
- To inform study teams of the IRB's planned corrective actions and how that may impact them

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FDA IRB Inspections

Why does the FDA inspect IRBs?

- FDA conducts IRB inspections to determine if IRBs are operating in compliance with current FDA regulations and statutory requirements and if the IRBs are following their own written procedures.

When are IRB inspections conducted?

- FDA inspections of IRBs generally fall into one of two categories:
  - Surveillance inspections (*Routine*) – periodic, scheduled inspections to review the overall operations and procedures of the IRB.
  - Directed inspections (*For Cause*) – unscheduled inspections focused on the IRB's review of a specific clinical trial or trials, generally resulting from a complaint, clinical investigator misconduct, or safety issues pertaining to a trial or site.

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Conduct of an IRB Inspection

IRB Inspections are conducted similarly to a study-specific inspection.

- Institution is contacted by FDA Personnel to schedule a visit
- FDA Personnel (1-2 inspectors) arrive, present credentials, and issue FDA 482 – Notice of Inspection to the IRB Chair
- Inspector(s) interview appropriate people and obtain information about IRB's policies and procedures
- Throughout the inspection, the inspector(s) typically review and copy:
  - Records of IRB Membership
  - IRB procedures and guidelines
  - Minutes of the IRB Meetings (past 1-3 years)
  - Documents related to a certain number of studies regulated by the FDA
  - Any other relevant materials
- At the end of the inspection, an exit interview is conducted with institutional and IRB representatives to discuss findings.

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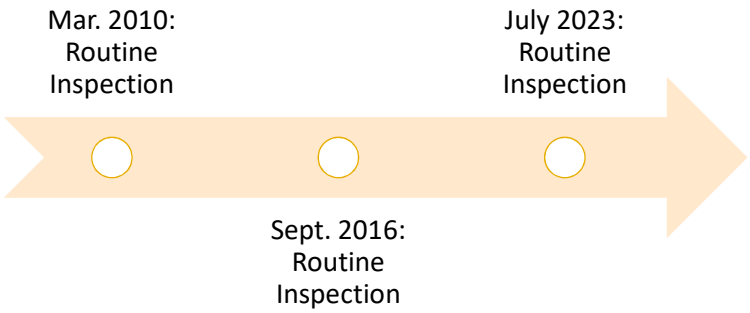
History of LSUHSC IRB Inspections

The LSUHSC-NO IRB has been inspected by the FDA on three occasions:



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Inspector's Observations

During this most recent inspection, the following observations were made by the Inspector:

- The IRB occasionally failed to document non-significant/significant risk determinations for device trials
- The IRB did not follow written procedures for ensuring prompt reporting to the FDA of the following:
  - Serious or Continuing Non-Compliance
  - Suspension of IRB Approval
  - Termination of IRB Approval

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Corrective Action Plans

The IRB occasionally failed to document NSR/SR risk determinations for device trials.

- All device trials will now be reviewed and discussed at a convened IRB meeting to ensure that a risk determination or concurrence is properly made and documented.
- Administrative reviewers will request formal documentation from the Sponsor when the Sponsor has decided on the risk determination to assist the Board in determining concurrence.

What does this mean for you?

- If your study involves use of a device regulated by the FDA (whether investigational or approved for marketing), please submit it as a Full Board application.
- Please provide all documentation from the sponsor related to the device (i.e., brochures, FDA letters, etc.)

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Corrective Action Plans

The IRB did not follow written procedures for ensuring prompt reporting of serious or continuing non-compliance to the FDA.

- Policy 4.03 will be revised to state, "Two or more lapses in IRB approval is considered continuing non-compliance and requires prompt reporting to the institutional official and relevant agencies."
- Enrollment of subjects or any interaction with subjects during a lapse that is not pre-approved by the IRB will be considered serious non-compliance and require prompt reporting to the institutional official and relevant agencies.

What does this mean for you?

- Submit your renewals/closure requests in a timely fashion (i.e., 30 days in advance of continuing review date for Full Boards, 15 days in advance for Expedited/Exempt)
- Do not conduct any study activities during a lapse in approval unless it is in the subject's best interest/safety. This must be reported to and approved by the IRB.

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Corrective Action Plans

The IRB did not follow written procedures for ensuring prompt reporting of <u>suspension or termination of IRB approval</u> to the FDA.

- The IRB will report to the FDA all instances of suspended IRB approvals, and administrative closures of studies that involve misconduct or fail to submit a renewal within 60 days of approval lapse.

What does this mean for you?

- Submit your renewals/closure requests in a timely fashion (i.e., 30 days in advance of continuing review date for Full Boards, 15 days in advance for Expedited/Exempt).
- Do not conduct any study activities during a lapse in approval unless it is in the subject's best interest/safety. This must be reported and approved by the IRB.
- If your study is administratively closed, respond promptly to IRB inquiries about any study activities that may have occurred during a lapse.

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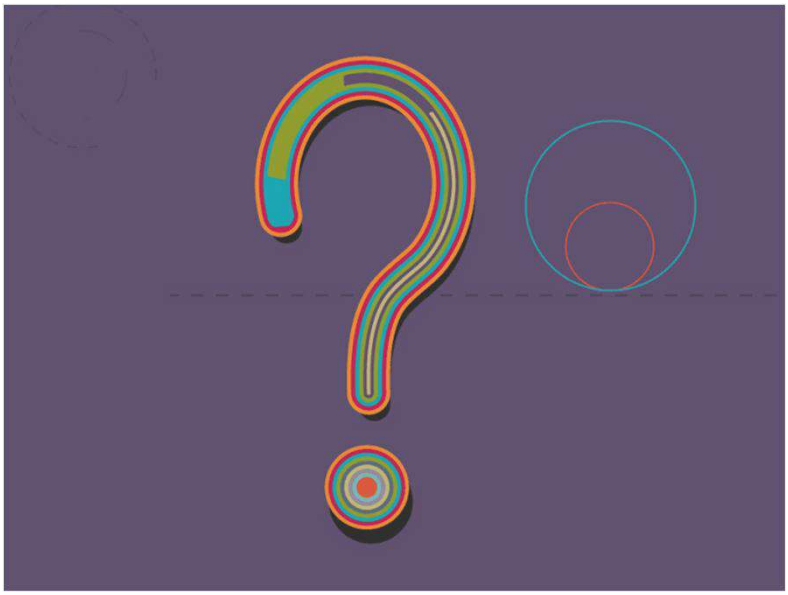

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Save the Date!

October Lunch & Learn

Date: October 4, 2023
Time: 12:00 PM
Topic: Exempt Determinations & Limited IRB Review

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