How to Survive an FDA Audit

Lisa Linn, CIP
Biomedical IRB Manager
Northwestern University
Routine FDA Audit

- Conducted over 7 non-consecutive days between 2/27/2018 – 3/14/2018
- Contacted by FDA Inspector on 2/22/2018
- Focused on Panel Q
  - Projects reviewed between 4/1/2013 – 2/26/2018
  - Four active projects
  - Twelve suspended or terminated projects
  - IRB rosters, member files, minutes and SOPs
  - Observed a panel Q meeting
- Staff Involved
  - The Entire IRB Office
Tips

• Do not commit to the date right away
• Ask to see form 482 and the Inspector’s badge
• Place the Inspector in a space outside of the office
• Have a copy of your last FDA audit response
• Take notes and keep a shadow folder
• Voluntary Corrective Actions
• Do not pay for the inspector’s parking
Resources

Post Approval Monitoring Checklist

• HRP-429: Biomedical Research
• HRP-430: Social Behavioral Research

Call the IRB Compliance Team

• Discuss how to prep regulatory documents
• Gives IRB Office advanced notice to be able to assist with obtaining any IRB documents you may need.