ACCR Lecture Series
How to Survive an FDA Audit

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When the FDA Calls...

- My experience as primary facilitator:
  - 1st Audit – Primary Coordinator
    - "Someone from the FDA is on the phone"
    - Prior to IDE submission
      - Top Enrolling Site
      - Participating in multiple studies with sponsor
  - 2nd Audit – Research Manager, listed as back-up CRC on study
    - Voicemail from FDA auditor
    - NDA submission with expedited review status
      - Top Enrolling Site
      - Participating in multiple studies with sponsor
Audit Preparation

- Remember, good study conduct is a daily, on-going process!
  - Checklists are a coordinator's best friend
  - Keep a checklist handy if you anticipate an audit
    - Who, when, why, what
  - Find a comprehensive checklist that you like and will use

- Notify all parties of Inspection (+10)
  - You can ask for audit preparation from your local IRB &/or Compliance departments, & from the sponsor

- Remember that mistakes happen

<table>
<thead>
<tr>
<th>Activity (mCi)</th>
<th>Infusion Start Time (24 hr clock)</th>
<th>Infusion Stop Time (24 hr clock)</th>
</tr>
</thead>
<tbody>
<tr>
<td>09.4</td>
<td>13:15</td>
<td>13:25</td>
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Did the patient void prior to imaging? □ Yes □ No
Acquisition Start Time: 16:45 MSA 17:09 End Time: 17:09
Which one are you...
Lessons Learned

• In-house Tips
  – Ask for help early and often
  • PI to keep records timely
  • From sponsor if the monitoring seems inadequate
    – Compliance Department audit prep from sponsor
  • From other CRC’s
  – The study sponsor does NOT have to be onsite
    • This can be more distracting for the CRC
      – Remember this is an inspection of the PI and site, not the sponsor
  – Clean & tidy binders make a difference
    • No loose leaf paper
    – Daily touch base

• FDA Tips
  – Introduce the study team
  – Less is always more!
    • Don’t guess at answers
  – Walk the auditor through the research participant’s workflow
  – Copying help & stamps
  – Daily touch base

“The only mistake in life is the lesson not learned”

Albert Einstein
Questions?