Inspection Readiness Guidance

Drexel University

Research Quality Assurance Program
Office of Research & Innovation

Triggers for Inspection

- Routine: Submission of data to an agency in support of a marketing application or amendment to an existing application

- For Cause: Investigate a specific problem or area of concern
  - Complaints from participant(s) or others
  - Reports of Unanticipated Problems
  - Reports of Serious and/or Continuing Non-Compliance

Inspection Goals

Demonstrate:

Participant/Animal safety and wellbeing is a priority

Commitment to research and data integrity

Compliance with regulations

Interaction Guidelines

- Be professional
- Ensure cell phones are off/on vibrate
- Answer questions honestly, factually, to the best of your knowledge
  - Avoid guessing/speculating answers – it is okay to say “I don’t know the answer, but I will find someone who does”
  - Do not offer unsolicited comments – answer the question that is asked
  - Do not offer personal views or comments
  - Avoid generalities – e.g., “We typically do it this way”

Interaction Guidelines

- Be comfortable with silence
- Do not argue with the inspector – be respectful if there is a difference in opinion
- Do not place blame
- Do not refuse to provide requested documentation
- Do not refuse to allow the Inspector to speak with study team or those who were involved in the study
- Do not appear to be defensive
- Do not imply deficiencies are due to lack of resources

During the Inspection

Be prepared to provide information related to:

- PI's familiarity with the study, PI involvement and oversight
- Informed consent process – who was involved, how was consent obtained, how was it documented
- Who performed protocol procedures
  - appropriate delegation and training
  - verification of eligibility criteria
  - study endpoint procedures
  - IP accountability, AE collection
  - data collection and entry
- Adherence to the protocol – how ere deviations tracked and reported
- Monitoring of the study

Opening Meeting

- Verify the identity of the Inspector
- The PI will receive a Notice of Inspection
- Introduce study team members
- Review general information about the inspection/process
- Inspector may have general questions
  - Number of participants enrolled and their status
  - Number of studies PI has
- Begin review of study documents
  - Provide documents as requested by the Inspector

Daily Meetings

The Inspector may hold daily debriefing meetings to:

- Discuss open items or open questions
- Request for documents
  - Documents may be requested as paper copies or to provide on encrypted flash drive

Wrap-up Meeting and Debrief

- Discuss observations found during the inspection
- If observations were identified, notify the appropriate parties, e.g., OSP, IRB, Sponsor
- The QA Program can provide assistance in response to the inspection observations