Upon becoming aware of the FDA Inspection, the Research Coordinator should complete the following activities:

1. **Notify key stakeholders:**
   - PI and study team members/co-investigators (the FDA may request to meet with any individual during the inspection)
   - Sponsor
   - CRO (as applicable)
   - Upstate IRB and IRB of record (as applicable)
   - Investigational Pharmacy
   - Clinical Trials Office

2. **Reserve a dedicated and lockable work space for the FDA agent, preferably away from research or clinical staff; provide access to a copier, phone and WIFI.**

3. **Prepare the following:**
   - A general overview of the study, including the eligibility criteria (the study coordinator and PI should be prepared to provide this verbally with a reasonable amount of detail);
   - A detailed overview of the informed consent process. Any team member delegated to this activity may be asked to describe the process to the agent. May be asked to provide site-specific SOP;
   - List of all study personnel and delegated responsibilities;
   - List of SAEs with the timeline for when each was reported. This is for study personnel review and <u>should only be provided</u> upon request;
   - List of all subjects enrolled, including name, study number, date enrolled and completed, medical record number;
   - List of all subjects screened;
   - If any enrolled subjects did not complete the study, be prepared to explain why;
   - List of Principal Investigator's current active studies and all studies that were active during the last 5 years.

4. **Gather and organize the following documents:**
   - Organize all Regulatory Files by general heading arranged in a chronologic order
     - Protocol, all versions
     - Investigator's Brochure, all versions
     - Informed Consent Form(s), all versions
     - Protocol Amendments

    - Form FDA 1572 or Declaration of Investigator (device studies), all versions
    - CVs for PI and Sub-investigators listed on all versions of Form FDA 1572 or Declaration of Investigator (device studies)
    - Any corrective actions/CAPA activities put into place in response to protocol violations/errors
- Communications
    - Sponsor Correspondence
    - CRO Correspondence
    - Monitoring Logs
- IRB files
    - Approval Letters, for all actions
    - Approved Informed consents, all versions
    - Interim event reports and IRB acknowledgement letters
    - Be prepared to show the Agent items in IRBNet (do not share log-in or passwords)
- Laboratory
    - Laboratory Certification and normal ranges, or waiver as applicable
    - CV of laboratory director
- Drug Accountability- drug log to include:
    - Receipt of Drug
    - Dispensing
    - Return
- Device Accountability- device log to include:
    - Receipt of Device
    - Dispensing (where applicable, includes implants)
    - Return
- Subject Documents
    - Informed Consents for screened/enrolled subjects
    - Consents obtained prior to any study procedures?
    - Source documents for each subject enrolled (including labs, x-rays, scans, etc.)

5. For each subject enrolled review (and note any issues to discuss with PI):

- Inclusion/Exclusion Criteria
- Document reason for excluded subjects
- CRFs completed for each enrolled subject
- Source documentation for all CRF entries
- Data Clarification issues satisfied
- Consent obtained for all subjects screened/enrolled

- Verify correct version of Informed consent signed
- Confirm 'Notes to File' present as appropriate
- Condition of subject at time of entry into the study
- Concomitant medications
- Laboratory reports
- Diagnostic tests
- Dose Modifications
- Adverse Events/Deaths (were these reported on time)
- Protocol Exceptions
- Early Termination

6. **When the FDA inspector arrives on site:** (VERY IMPORTANT)
   - Request to see credentials
   - Show them to the assigned workspace. Provide a brief tour (restrooms, copier, where you will be or how to reach you)
   - Only provide study data requested- don't volunteer extra information and limit chit chat.
   - If you don't know the answer avoid the term "I don't know" instead respond with "I will get that for you" or "Let me check on that".