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| **FDA Inspections: Quick Tips** |

The U.S. Food and Drug Administration (FDA) conducts two types of inspections, Routine and For Cause, which may be announced or unannounced.

* If announced, typically occur within 10 days of notice, PI and essential staff need to adjust schedules to be there
* In the case of unannounced, the inspector should be asked to remain in the lobby with security or administration until the PI and CTO management are contacted and an appropriate room can be secured

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| **During the inspection** |

The inspector will verify (among other things):

* 100% of consents
* Who performed various aspects of the study (eligibility, consenting) and is was there appropriate delegation
* Where trial procedures were performed
* If the PI followed the IRB approved protocol, deviations documented and submitted to IRB
* How and where data were recorded and is there source to support all data entered
* How were study staff trained on the study and drug product
* Drug accountability: Documentation for the receipt, storage, administration and return of the investigational drug
* Prompt and complete reporting of AE’s to IRB and sponsor, PI assessed relationship to the drug
* Adequate monitoring of the study

**Any links to other studies or patients that the investigator sees or hears during their review can open up their investigation.**

The inspector may request to inspect the facilities and interview the PI and study staff.

* Answer the questions honestly and completely to the best of your knowledge.
* Answers should be clear and concise and only answer the question that is asked-**NEVER volunteer additional information.**
* Get comfortable with silence, don’t need to fill it
* If you don’t know the answer, it’s okay. Just state you don’t know, write it down and get the correct answer as soon as possible from someone who has the information.
* If the question is unclear, please ask for clarification or additional details to ensure you understand before answering.
* You should never guess, speculate or argue with the inspector ☺

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| **Additional tips** |

* Audit room should be away from all hospital/patient clinic records, close to a copier, internet access and a phone
* Only provide charts that have been requested, but provide everything that is requested. If the inspectors ask you for additional documents, never give them without first running it by management
* Everything regarding the inspection will be documented in an inspection file. Any copies requested (and there will be many copies) will be made in duplicate: one for our file and one for FDA. Remove patient identifiers, stamp “confidential” on inspectors copy and stamp “copy” on our copy.
* We can offer water to the inspectors, but no other food or refreshments and we shouldn’t act socially / casually with the inspector during the audit
* When they request to review electronic medical records, someone from CTO should sit with them to make sure they only have access to the study patient record-HIPPA
* Please pay attention to conversations while they are here (aka bathroom stall situations), know that even if they are auditing at PCH they can request to come here so keep area clean, PHI hidden and computers locked
* Know your study and the CTO SOPS. Know the status of the study, where patients are on study, etc.

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| **Remember** |

* Document! Document! And Document some more. Documenting in the patient charts now will save a lot of headache down the road.
* Remember ALCOA: Documentation should be Attributable, Legible, Contemporaneous, Original, Accurate