**FDA Site Inspection Preparation - Interview Question Template**

During an inspection, the Investigator and some members of the study team (e.g., involved in protocol execution) will be interviewed by the Inspector. Since any member of the team could be individually interviewed, the entire team should be prepared for an interview.

The Inspector will ask many of the same questions during individual interviews, and it is important to provide consistent, accurate responses. It is also important that interviewees do not provide guesses to questions they either don’t know the answer to, or should be answered by another individual who would be more appropriate to address the subject at hand. This tool includes the questions that the Investigator and study team members must be prepared to answer as it applies to their role.

Use this template to document the response that each study team member should be familiar with, and ready to provide in the event of an inspection. Completing this template and making it available to study team members at the start and for the duration of study conduct is also an excellent way to communicate expectations and ensure compliance. Document the response and how you plan to address this issue during inspection.

**Note:** This document is **not** to be filed in the Investigator Site File. It should be filed in a location where they can be referenced anytime during study conduct, and before, during, and after an inspection.

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| **These questions are likely to be asked of the Investigator and other team members during the course of the inspection.** | **Response** |
| **Roles, Trial-related Duties, and Qualifications** | |
| * How long have you been doing clinical trials? * Are you still doing clinical trials? * How many interventional trials do you now have? |  |
| What qualifies you to be a Principal Investigator?  *(Length of service at this organization, credentials, therapeutic area/research experience (CV review))* |  |
| How did the study sponsor find you? |  |
| Describe your role as well as that of your Sub-Investigators and other study personnel. |  |
| Please explain the role each Sub-Investigator and study team member played/is playing in the study.  *(Be familiar with the dates they were involved with the study.)* |  |
| What are each of the study team members’ qualifications/preparation for their role in the study? |  |
| How do you ensure the personnel working on the study are adequately trained/prepared? |  |
| What was the process for opening this study here at this site? |  |
| How was the PI trained on the protocol? Was the training presented live or remotely? |  |
| What was the process for closing the study? |  |
| What training have the PI and site personnel received on ICH GCP and relevant local regulatory requirements? |  |
| How are study team members trained as amendments occurred in the study? |  |
| **Subject Enrollment and Consent Process** | |
| Where do your trial participants come from? |  |
| Was an advertisement used to aid recruitment? |  |
| * Were these all your patients? * Did you see them personally? * Did someone see them on your behalf? |  |
| Did you request medical charts from subject’s primary physician? |  |
| How does the consent process go? Who consents the patient? |  |
| What is the step-by-step process for enrolling a patient? |  |
| How do you verify whether an individual meets the legal criteria to act as a legally authorized representative or guardian?  What is the age that a child is no longer considered a minor (per local regulations)? |  |
| How do you verify enrollment with the Sponsor? |  |
| How do you receive verification from the Sponsor confirming randomization? |  |
| How many patients are/were enrolled and the number of screen fails?  How many patients withdrew consent, and how many were withdrawn from the study by the Investigator? |  |
| How do you perform the review and sign-off of eligibility criteria? How is this done if certain data is available at a later date? |  |
| Do you see the patients at each visit? When do you review source documents, lab results, patient questionnaires, adverse events, etc.? |  |
| **Adverse Events** | |
| Which study team members monitor patients for adverse events? |  |
| How are adverse events assessed?  *(Be prepared to answer questions regarding the specific adverse events.)*  *(Know what the policy/procedure is for handling SAEs, AEs and reporting. Ensure your response aligns with it.)*  *(Know if Event Reports are/were reviewed in a timely manner by the PI; ensure all are signed off.)* | Be aware of all of the details surrounding each SAE. If there was any disconnect and the staff wasn’t notified in a timely manner by the PI/Sub-I/team member (even though s/he knew about the SAE) be prepared, and document the incident as a protocol deviation. |
| Were there any instances where you were late in reporting? |  |
| **Communication** | |
| * How do you communicate with the study team members? * How does the study team communicate with each other? * How do you lead the team in human subject safety? * Do you have evidence of discussions with staff, e.g., minutes documenting any meetings or content discussed?   (*For example:*   * *We have weekly meetings where we go over events that have happened and key information which are attended by all clinical and investigator staff. We keep minutes of these meetings.* * *Emails will go out to the participating team members when there is new information which is important to the safety of our participants.* * *We communicate directly with the PI and the Sub-Is involved and they share this information with other Sub-Is. We document these conversations.)* |  |
| How does the Principal Investigator communicate with you and maintain oversight of the study and supervision of study staff?  *(i.e. SIV, PIV, staff in service meeting, weekly team/census meetings, amendment updates, in-person conversations, email, phone calls).*  ***Note:*** *this is especially important when the PI is conducting the study across two or more locations and with external Service Providers.* |  |
| How do you communicate with the study Sponsor? |  |
| How are you made aware of new safety information for the study? |  |
| **Study Data** | |
| How is study data collected in source records? |  |
| Was data extracted from patient specific source records and input/transcribed into study records?  Describe which data was transcribed. All the location(s) of all source data for the trial documented? How? Where is this record? |  |
| How do you know if the record has been changed? |  |
| How is study data transmitted to the Sponsor? |  |
| How do you correct inaccurate data or update a study record with new data? |  |
| Is the Principal Investigator made aware of data changes in the (e)CRF? |  |
| Where are the records stored? Who has access to the storage area? What’s in place in the case of a leak? Flood? Fire? |  |
| What is the process you used to oversee and review patient reported outcome data? |  |
| **Investigational Product** | |
| How was investigational product sent to this site? |  |
| How was investigational product received by this site? |  |
| What records are kept for investigational product at this site? |  |
| How was the investigational product prepared? Packaged? Dispensed? |  |
| What was your role in the preparation and dispensing of the investigational product? |  |
| What SOPs do you use in your department to manage IP that includes dispensation, temperature monitoring, etc.? |  |
| How was the investigational product stored? Who has access? What type of security do you employ? (e.g. lock and key, keycard access) |  |
| What is the process for resolving equipment issues (e.g. refrigerator failure [stops working]).  Do you have a disaster recovery plan? (e.g., loss of electricity – back-up generator for IP storage area) |  |
| Where was the investigational product prepared and dispensed? |  |
| Do you have adequate separation between this IP and those of other companies? |  |
| When can I tour the storage (and preparation) facilities? |  |
| How did you know the investigational product was treated appropriately during shipment, e.g., temperature monitoring during transit, chain of custody, etc.? |  |
| How do you receive notification of investigational product shipment? |  |
| Were there any problems or issues in this trial with the investigational product (i.e. inadequate supply, drug shortages, shipment problems, etc.)?  If yes, were any subjects’ treatment(s) interrupted due to this(ese) issue(s)? |  |
| What was the policy of the study for drug return/destruction? Can you show me in the protocol/pharmacy manual for this trial where that is? |  |
| What is the end-to-end process for dispensing drug to subjects from the time a subject comes on site to the time they return at their next visit? |  |
| What is the process for unblinding a patient, if it is necessary? |  |
| **Other Logistics** | |
| How is (the specific trial endpoint) determined; in collaboration with the Sponsor? By the Principal Investigator alone? |  |
| Were there any team members who have caused significant non-compliance with the trial? How did you handle that? |  |
| How do you handle study amendments (what is your step-by-step process, especially when the amendment results in ICF changes? |  |
| How do you maintain the security of the paper records? |  |
| How frequently did you meet with the site monitor? |  |
| **Monitoring** | |
| Did you meet with study monitors when they came? |  |
| How did the site monitor provide issues to resolve?  How did you share that information with the site staff? |  |
| Were there any problems brought to your attention by the monitor that you recall? |  |
| **Computer Systems** |  |
| What type of computer system(s) is used by the clinical site for this trial? |  |
| How do you maintain the security of the electronic records? |  |
| Are the electronic records 21Part11 Compliant? Are they validated?  Can you provide me with the manufacturer letter/certificate documenting the electronic record is 21Part11 Compliant?  Can you provide me with the site/institution letter to the FDA stating electronic signatures are being used in study-related documents as outlined in 21Part11 100 (c)?  I’d like to have unsupervised access; will that be a problem (MHRA)? |  |
| What type of training did you receive on this (these) system(s)? |  |
| Can you show me the training materials? |  |
| What do you do if you need help with the computer system?  *(If there is a “?” on the database and this is where questions are answered be prepared to point it out and demonstrate.)* |  |
| Were there any software updates, system failures, error messages, performance patches, security problems, etc.? |  |
| Regarding all technology:  What equipment do you have?  Is it calibrated? How often?  Do you have a certificate of calibrations that cover the time the study was conducted? |  |

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|  | This form was adapted from the AVOCA Group Quality Consortium template.  <http://theavocagroup.com/quality-consortium> |