Protocol Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Protocol Number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Sponsor: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Principal Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Site Location Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Meeting Date (DD/MMM/YY)/Start Time: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 **Completed Notes**

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| --- |
| **Immediately Upon Being Contacted by the FDA** |
| What are the dates/how many days will be needed for the inspection? |  |  |
| Speak with the inspectors to determine:* How many inspectors are coming?
* Is a room with phone and internet acceptable or are other items needed?
* List of protocols being inspected.
* Who should be in attendance?
* Who should remain in the room with/escort the inspector?
* What parts of the facility will need to be toured?
* Is there a document list available?
 |  |  |
| Notify:* Office of Clinical Research (clinicalresearch@utrgv.edu)
* Executive Director of Research Compliance
* Associate Vice President for Research Operations
* PI and ALL study staff
* Sponsor, if applicable
* Staff in facilities that need to be toured
* Staff in any areas where study was conducted
* Research Finance/Post Award/Revenue Cycle
* Medical Records
 |  |  |
| Once the above-mentioned details have been confirmed: Send an invitation to **all** attendees (including the PI, Sub-Is, and their administrative assistants to make sure it is on everyone’s calendar.) |  |  |
| **Preparing for the Audit** |
| Provide detailed instructions to the inspector(s) on how to get to the location. Identify a person on the study staff to be the escort for the inspectors. This person will need to be readily available at all times for the duration of the inspection. |  |  |
| Reserve a room that meets the requirements of the inspection. Identify a nearby copy machine that can be used during the inspection. |  |  |
| Request Medical Records/Medical Records Access. Begin the Florence access process for the inspector(s). |  |  |
| Determine if the FDA requires identifiers on records. If not, redact paper records. |  |  |

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| Review all study documentation for:* + - * Comprehensiveness, accuracy, and compliance;
			* Weakness/gaps (and correct those that can be corrected [i.e., file violations, draft notes-to-file, locate missing documents, etc.]); and
			* Unresolved or outstanding issues (and develop a corrective action plan for any unresolved/outstanding issues).
 |  |  |
| Review agreements and contracts for specific details regarding FDA Inspections |  |  |
| Verify the FDA inspector’s credentials upon arrival. |  |  |
| The PI or the PI’s designee must be available to meet with the inspector and receive and sign the FDA Form 482 “Notice of Inspection” |  |  |
| Tour the inspector(s) around all areas required for the inspection. Remain with the inspector at ALL TIMES during the tour.  |  |  |
| Answer all questions directly and honestly. If you are unsure, it is acceptable to say you don’t know the answer. |  |  |
| If the inspector(s) request copies, make a separate copy for yourself of each document. Keep the copies in a shadow file and mark them as copies. |    |  |
| If the inspector insists on taking photographs or other video or audio recordings, take and retain duplicates at the same time. If the inspector requests to take samples, ask for a receipt of the samples, and pull and retain identical samples at the same time. |   |  |
| Take notes during the inspection. Write down all questions asked by the inspector. Keep these notes in the inspection shadow file. |  |  |
| Ensure the PI is available during their scheduled time with the inspector(s). |  |  |

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| The FDA inspector will hold an exit interview with the PI at the conclusion of the Inspection. Other key research staff members may also attend. |  |  |
| Continue to take notes during the exit interview.  |  |  |
| If there are any deficiencies, the inspector will note these on FDA Form 483 and give them to the PI. |  |  |
| **Do not sign** any affidavits provided to you but the inspector. If the inspector presents an affidavit for signature, politely decline to sign, and tell the inspector that you are not permitted to sign documents on behalf of the institution, but you will identify the appropriate person and report back. After that contact (1) Office of Clinical Research and (2) UTRGV Legal Counsel and Chief Compliance Officer. |  |  |
| Maintain all documentation in the inspection shadow file. |  |  |
| Email an exit interview summary to your manager, the PI, the Office of Clinical Research, the Executive Director of Research Compliance and the Associate VP for Research Operations. |  |  |
| **Response to 483, if applicable:** |  |  |
| Contact the Office of Clinical Research for guidance. |  |  |
| The written response should include the following information:* + - * Determine if a finding was an oversight/single occurrence or if it is a systematic problem requiring a change of procedure/process.
			* Describe corrective actions in a Corrective and Preventative Action Form. This should include justification of why the proposed response would correct this problem and prevent it from reoccurring. Include a timeline for the corrective actions.
			* The Inspector may provide their own CAPA form or format. If not, use the UTRGV CAPA.
			* Address each specific finding, point by point.
			* Send response to UTRGV legal for review, copying OCR
 |  |  |
| The response should be sent to the FDA within 15 business days. |  |  |
| Maintain all inspection documentation on site until the Establishment Inspection Report (EIR) is received. |  |  |