

CHECKLIST: Post Approval Monitoring Self-Assessment – Drug or Device Clinical Trial

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The purpose of this checklist is to allow investigators to conduct a quality improvement self-assessment of their research study specific to clinical trial requirements and is indicative of what the Human Research Protection Program would expect to see per clinical trial requirements when performing on site monitoring of your research study.

- FDA Definition Of Clinical Trial: A type of clinical study in which participants are assigned to groups that receive one or more intervention/treatment (or no intervention) so that researchers can evaluate the effects of the interventions on biomedical or health-related outcomes. Participants may receive diagnostic, therapeutic, or other types of interventions.
- NIH Definition Of Clinical Trial: A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes. To determine if your study meets the NIH definition of a clinical trial, go to <https://grants.nih.gov/policy/clinical-trials/definition.htm>

Instructions: Please complete the applicable sections below if your study is a clinical trial, involves an Investigational New Drug (IND) and/or Investigational Device Exemption (IDE). You may print and handwrite answers, or you can complete this form electronically. Please note, eIRB does not serve as an electronic version of your study file. The regulatory binder (where you keep all the documents related to your study) should be centralized and can be maintained within an electronic format (saved pdfs and Word/Excel documents) or within a binder (printed paper copies stored in a three-ring binder). If your answers to the questions are "no" please provide a brief explanation in the comments area of each section. Additionally, if "n/a" is indicated and you feel that further clarification is needed, please address them in the comments area as well.

IND/IDE

Principal Investigator	
Protocol Number	
Name of Person Completing Checklist	
Date Checklist Completed	

Study Information

Did the Principal Investigator write the main study protocol (i.e. is the study investigator-initiated)?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Other (specify): _____
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1 General Record Keeping, Correspondence, and Reporting: Please complete this section for both drug and device clinical trials. Indicate whether the PI has the following documentation on file.

<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	1. Decoding or unblinding procedures for blinded trials.
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	2. Site initiation report / visit documentation: Trial specific information is provided to the investigator and staff prior to study startup, as well as an assessment of resources and capability to conduct the study. The sponsor's Monitors discuss study obligations under Good Clinical Practice (GCP) and United States Food and Drug Administration (USFDA or FDA) requirements (if applicable). The initiation report outlines the site's ability to adhere to these requirements as well as sponsor policies, practices and procedures for the conduct of the trial. Any training materials or presentations from the site initiation visit are stored with regulatory materials.
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	3. Site closeout report / visit documentation: The closeout report / visit documentation is filed once all subjects at that site have completed the study and all data queries have been resolved. The report contains a summary of study results, final participant enrollment status, significant findings and any reportable information resulting in increased risk/harm to participants.

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<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	4. All reportable events were reported within the Rutgers University IRB timelines. a. Death of a participant, or a participant at a site that has ceded IRB review to the Rutgers IRB that is unanticipated and related to the research must be reported within 24 hours of knowledge or notification, b. Unanticipated Problems, c. Serious or Continuing Non-Compliance, d. Suspension or Termination of IRB Approval when relying on an external IRB.
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	5. Reports of emergency deviations from the investigational plan: the investigator notifies the sponsor and the reviewing IRB of any deviation from the investigational plan to protect the life or physical well-being of a participant in an emergency. Such notice is given as soon as possible, but no later than 5 working days after the emergency occurred. Except in such an emergency, prior approval by the sponsor is required for changes in or deviations from a plan, and if these changes or deviations may affect the scientific soundness of the plan or the rights, safety, or welfare of human participants, notification of the FDA and IRB is required.
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	6. Inspection reports (e.g., Form FDA 483): The FDA, sponsor, and/or internal auditing group determines the investigator's compliance with the protocol, federal regulations, and institutional policies through an inspection / audit of the investigator's research facility, handling of investigational products (if applicable) and regulatory documentation. Inspection reports, including form FDA 483, outlining observations findings and correction actions may be issued as part of the inspection process.
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	7. Withdrawal of IRB approval: If the IRB withdrew approval of an investigation or a part of an investigation, did the investigator notify the sponsor or FDA within 5 working days after receipt of the withdrawal of approval?
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	8. Withdrawal of FDA approval: If the FDA withdrew approval of the investigation, did the investigator notify the IRB, and participating investigators if applicable, within 5 working days after receipt of notice of the withdrawal of approval?
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	9. Final report: Did the investigator submit a final report to the IRB?
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	10. Shipping and accountability logs for the investigational drug(s)/device(s).
Section 1 Additional Comments	
2 IND Sponsored Research: Please complete this section if the research study is an industry or externally sponsored clinical trial of an investigational drug . Indicate whether the PI has the following documentation on file; electronic documentation is acceptable. If responses to any of the questions are "no" or "n/a", please provide additional information in the comment area below this section. If this section is n/a, check here <input type="checkbox"/>	
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	1. All signed versions of form FDA 1572 (Statement of Investigator).
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	2. Valid licensure for each credentialed investigator/staff member listed on form FDA 1572.
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	3. Signed financial disclosure form submitted to the sponsor from each investigator listed on form FDA 1572.
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	4. All versions of the investigator brochure(s) or product information (e.g. package insert(s), full prescribing information, sample label(s)).
Section 2 Additional Comments	
3 IND Sponsor-Investigator Research: Please complete this section if the research study is an RU investigator-initiated clinical trial of an investigational drug . Indicate whether the PI has the following documentation on file; electronic documentation is acceptable. If responses to any of the questions are "no" or "n/a", please provide additional information in the comment area below this section. If this section is n/a, check here <input type="checkbox"/>	

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<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	1. Copy of all IND application and maintenance submissions.
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	2. FDA clinical hold letters.
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	3. If the study was placed on clinical hold(s), research was not conducted during the hold(s). If research was conducted during clinical hold(s), please provide an explanation below.
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	4. Copies of correspondence and letters from the FDA.
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	5. All current and previous signed versions of form FDA 1572 (Statement of Investigator) for each participating site. If the investigator discovers that an investigator is not complying with the signed agreement (Form FDA-1572), the general investigational plan, or other applicable requirements; the investigator promptly either secures compliance or discontinues shipment of the investigational new drug to the investigator and ends the investigator's participation in the investigation.
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	6. Completed form FDA 3454 , attesting to the absence of financial interests and arrangements for all participating clinical investigators, OR a completed form FDA 3455 financial disclosure statement for each participating clinical investigator. If another method of documenting financial disclosure, please provide an explanation below.
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	7. Completed form FDA 3674 : Current signed certification of compliance with requirements of ClinicalTrials.gov.
<input type="checkbox"/> Yes <input type="checkbox"/> No	8. All protocol version(s) approved/acknowledged by the FDA are consistent with all protocol version(s) approved by the IRB.
<input type="checkbox"/> Yes <input type="checkbox"/> No	9. The study did not begin until the IRB and the FDA both approved the study.
If an investigational new drug is a substance listed in any schedule of the Controlled Substances Act (21 U.S.C. 801; 21 CFR part 1308), the sponsor-investigator ensures:	
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	10. Upon the request of a properly authorized employee of the Drug Enforcement Administration of the US Department of Defense Justice, all records concerning shipment, delivery, receipt, and disposition of the drug, which are required to be kept be made available by the investigator to whom the request is made, for inspection and copying.
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	11. That adequate precautions are taken, including storage of the investigational drug in a securely locked, substantially constructed cabinet, or other securely locked, substantially constructed enclosure, access to which is limited, to prevent theft or diversion of the substance into illegal channels of distribution.
Questions 12 through 15 apply if the PI is the sponsor investigator.	
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	12. Annual report submitted to the FDA within 60 days of the anniversary date of the effective date of the IND.
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	13. Modifications/amendments to the protocol were submitted to the FDA.
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	14. Study was appropriately monitored.
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	15. Serious adverse events were promptly reported to the FDA.
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	16. If a multicenter study, the contract agreement with a designated CRO, if one exists.
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	17. If a multicenter study, documentation of the Site Initiation Visit for each site to include a roster of attendees who attending the training, the agenda, and the content of the training.
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	18. If a multicenter study for which RU is the lead PI, investigators of each site were promptly notified about significant new adverse events or risks of the test article(s).
Section 3 Additional Comments	

4 IDE Sponsored Research: Please complete this section if the research study is an **industry or externally sponsored** clinical trial of an **investigational device**. Indicate whether the PI has the following documentation on file; electronic documentation is acceptable. If the questions are "no" or "n/a", please provide additional information in the comment area below this section. If this section is n/a, check here ☐



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<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	1. All signed versions of the Investigator Agreement.
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	2. Valid licensure for each investigator.
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	3. Signed financial disclosure form submitted to the sponsor from each investigator.
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	4. All versions of the device manual or instructions for use.
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	5. Evidence of training prior to use is available.
Section 4 Additional Comments	
5 IDE Sponsor-Investigator Research: Please complete this section if the research study is an RU investigator-initiated clinical trial of a Significant Risk (SR) investigational device . Indicate whether the PI has the following documentation on file; electronic documentation is acceptable. If responses to any of the questions are “no” or “n/a”, please provide additional information in the comment area below this section. If this section is n/a, check here <input type="checkbox"/>	
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	1. Copy of all IDE application and maintenance submissions.
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	2. FDA clinical hold letters.
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	3. Is the study was placed on clinical hold(s), research was not conducted during the hold(s). If research was conducted during clinical hold(s), please provide an explanation below.
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	4. Copies of correspondence and letters from the FDA.
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	5. All current and previous signed versions of an Investigator Agreement for each participating site.
<input type="checkbox"/> Yes <input type="checkbox"/> No	6. All protocol version(s) approved/acknowledged by the FDA are consistent with all protocol version(s) approved by the IRB.
<input type="checkbox"/> Yes <input type="checkbox"/> No	7. The study did not begin until the IRB and the FDA both approved the study.
Section 5 Additional Comments	
6 Abbreviated IDE Requirements: Please complete this section if the research study was IRB approved as a Non-significant Risk (NSR) device clinical trial . Indicate whether the PI has the following documentation on file; electronic documentation is acceptable. If the questions are “no” or “n/a”, please provide additional information in the comment area below this section. If this section is n/a, check here <input type="checkbox"/>	
<input type="checkbox"/> Yes <input type="checkbox"/> No	1. The protocol includes a brief explanation of why the device is a non-significant risk device.
<input type="checkbox"/> Yes <input type="checkbox"/> No	2. The IRB has determined that the device is a non-significant risk device.
<input type="checkbox"/> Yes <input type="checkbox"/> No	3. <i>(FOR IRB USE ONLY)</i> The IRB has documented that determination in the minutes along with the IRB's rationale for making that determination. <i>FDA Information Sheets for IRBs</i>
<input type="checkbox"/> Yes <input type="checkbox"/> No	4. The investigator monitors the investigation for compliance per the requirements of §812.46 .
Section 6 Additional Comments	
7 Additional Device Specific Requirements: Please complete this section if an investigational device is used in this study. If the questions are “no” or “n/a”, please provide additional information in the comment area below this section. If this section is n/a, check here <input type="checkbox"/>	
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	1. Unanticipated adverse device effects: An evaluation of an unanticipated adverse device effect under §812.46(b) was reported to FDA and the IRB within 10 working days after the investigator first receives notice of the effect. Thereafter the investigator submitted additional reports concerning the effect as FDA and/or IRB requested.



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<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	2. Reports of use of the device without informed consent: if the investigator uses a device without obtaining informed consent, the investigator reports such use to the sponsor or FDA and the reviewing IRB within 5 working days after the use occurs.
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	3. Recall and device disposition: The investigator notified the sponsor or FDA and the IRB of any return, repair, or disposal of any units of a device. Such notice occurred within 30 working days after the request was made and stated why the request was made.
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	4. Other: the investigator, upon request by the IRB or FDA, provided accurate, complete, and current information about any aspect of the investigation.
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	5. The device or device packaging is labeled per §812.5 with the statement "CAUTION - Investigational Device. Limited by Federal (or United States) law to investigational use."
Section 7 Additional Comments	