



| CHECKLIST: Investigator Quality Improvement Assessment | | |
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The purpose of this checklist is to allow investigators to conduct a quality improvement self-assessment and for IRB staff to conduct a quality improvement assessment of investigators. (LAR = "subject's Legally Authorized Representative")¹

**General Research
(Not Clinical Trials)**

| | |
|--|--|
| Principal Investigator | |
| Protocol Name | |
| Name of Person Completing Checklist | |
| Date Completed | |

| | |
|---|---|
| 1 Regulatory Documentation for Each Study | |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Grant |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Annual progress reports for grant |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Most recent version of the IRB approved protocol |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Previously IRB approved versions of the protocol |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | IRB approved amendments to the protocol |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Most recent version of the IRB approved consent document |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Previous versions of the IRB approved consent document |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Most recent versions of IRB approved information provided to subjects |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Previous versions of IRB approved information provided to subjects |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Currently approved recruitment materials |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Previous versions of approved recruitment materials |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | IRB roster associated with each approval letter |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Correspondence with the IRB on file: (look for signature and date when needed for submission) |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Initial IRB application |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Continuing review applications. Number: |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Modification applications. Number: |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Initial IRB approval |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Continuing review approvals |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Modification approvals |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Interim reports |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Notifications of IRB disapproval, deferral, modifications required to secure approval |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Responses to IRB actions |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | <u>Suspension of IRB Approval</u> or <u>Termination of IRB Approval</u> |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Copies of email correspondence with the IRB |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Other communications with the IRB |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Records of investigator and staff training |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Signed agreements/contracts between parties |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Correspondences to and from the funding agency |
| 2 Document Retention | |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Consent documents are retained for 3 years after completion of the research. |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Records for sponsored is retained until the sponsor authorized destruction of the records. |
| 3 Informed Consent | |

¹ This document satisfies AAHRPP elements I.5.A, I.5.B, I.5.D, I-9



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| | |
|---|--|
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | An investigator seeks consent only under circumstances that provide the prospective subject or the <u>LAR</u> sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | The information given to the subject or the <u>LAR</u> is in language understandable to the subject or the <u>LAR</u> . |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Investigators do not disclose any exculpatory language through which the subject or the <u>LAR</u> is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence. |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Investigators disclose to the subject the information in the consent document. |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Investigators give either the subject or <u>LAR</u> adequate opportunity to read the consent document before it is signed. |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | A copy of the signed and dated consent document is given to the person signing the document. |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Investigators provide the prospective subject or the LAR with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information. (N/A if research is subject to Pre-2018 Requirements) N/A: <input type="checkbox"/> |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | The Informed consent document begins with a concise and focused presentation of the key information that is most likely to assist a prospective subject or LAR in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension. (N/A if research is subject to Pre-2018 Requirements) N/A: <input type="checkbox"/> |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Informed consent as a whole presents information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or LAR's understanding of the reasons why one might or might not want to participate. (N/A if research is subject to Pre-2018 Requirements) N/A: <input type="checkbox"/> |

4 Informed Consent Disclosures



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- Required:** (*Can be omitted if there are none.)
- The study involves research.
 - The purposes of the research.
 - The expected duration of the subject's participation.
 - The procedures to be followed.
 - Identification of any procedures, which are experimental.*
 - Any reasonably foreseeable risks or discomforts to the subject.*
 - Any benefits to the subject or to others, which may reasonably be expected from the research.*
 - Appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.*
 - The extent, if any, to which confidentiality of records identifying the subject will be maintained.*
 - How to contact the research team for questions, concerns, or complaints about the research.
 - How to contact someone independent of the research team for questions, concerns, or complaints about the research; questions about the subjects' rights; to obtain information; or to offer input.
 - Whom to contact in the event of a research-related injury to the subject.
 - Participation is voluntary.
 - Refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled.
 - The subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
 - One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:
 - A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the LAR, if this might be a possibility; or
 - A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

(N/A if research is subject to Pre-2018 Requirements)
 N/A:

- Required for More than Minimal Risk Research**
- Whether any compensation is available if injury occurs and, if so, what it consists of, or where further information may be obtained.
 - Whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.

- Additional:** (Include when appropriate.)
- The particular treatment or procedure may involve risks to the subject, which are currently unforeseeable.
 - If the subject is or becomes pregnant, the particular treatment or procedure may involve risks to the embryo or fetus, which are currently unforeseeable.
 - Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.
 - Any additional costs to the subject that may result from participation in the research.
 - The consequences of a subject's decision to withdraw from the research.
 - Procedures for orderly termination of participation by the subject.
 - Significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation will be provided to the subject.
 - Approximate number of subjects involved in the study.
 - Amount and schedule of all payments.
 - A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit. **(N/A if research is subject to Pre-2018 Requirements)**
 - A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions. **(N/A if research is subject to Pre-2018 Requirements)**
 - For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen). **(N/A if research is subject to Pre-2018 Requirements)**
 - Any additional information which should be given to subjects when in the IRB's judgement the information would meaningfully add to the protection of the rights and welfare of subjects.ⁱ
 - When the study involves genetic testing, a statement that outlines the protections afforded to the subject under the Genetic Information Nondiscrimination Act (GINA).



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| Clinical Trials | |
|-------------------------------------|--|
| Principal Investigator | |
| Protocol Name | |
| Name of Person Completing Checklist | |
| Date Completed | |

| 5 Regulatory Documentation | |
|---|--|
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Grant |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Annual progress reports for grant |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Most recent version of the IRB approved protocol |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Previously IRB approved versions of the protocol |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | IRB approved amendments to the protocol |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Most recent version of the IRB approved consent document |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Previous versions of the IRB approved consent document |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Most recent versions of IRB approved information provided to subjects |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Previous versions of IRB approved information provided to subjects |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Currently approved recruitment materials |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Previous versions of approved recruitment materials |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | IRB roster associated with each approval letter |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Correspondence with the IRB on file: (look for signature and date when needed for submission) |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Initial IRB application |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Continuing review applications. Number: |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Modification applications. Number: |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Initial IRB approval |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Continuing review approvals |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Modification approvals |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Interim reports |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Notifications of IRB disapproval, deferral, modifications required to secure approval |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Responses to IRB actions |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | <u>Suspension of IRB Approval</u> or <u>Termination of IRB Approval</u> |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Copies of email correspondence with the IRB |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Other communications with the IRB |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Records of investigator and staff training |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Signed agreements/contracts between parties |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Subject screening log Number screened: |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Subject identification code list |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Subject enrollment log Number enrolled: |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Record of retained body fluids/ tissue samples |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Correspondences to and from the sponsor/CRO |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Letters |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Meeting notes |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Notes of telephone calls |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | CVs or other relevant documents evidencing qualifications of PI, co-investigators, and all study personnel |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | CVs/other relevant information have been updated within the past two years |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | CVs/other relevant information are signed and dated |



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| | | | |
|--------------------------------------|-----------------------------|------------------------------|--|
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A | Instructions for handling of investigational product(s) and trial-related materials (if not in protocol or investigator's brochure) |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A | Decoding procedures for blinded trials |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A | Normal lab values |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A | Updates to normal lab values |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A | Lab certification (e.g. CLIA)? |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A | Updates to lab certification (e.g. CLIA)? |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A | Lab director's CV |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A | Updates to lab director's CV |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A | Monitoring/auditing log. How often is monitoring taking place: |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A | Site Initiation report/visit documentation |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A | Study close-out report/visit documentation |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A | DSMB reports |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A | Staff signature log |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A | Signature log reflects current staff working on the study |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A | Staff working on the study are IRB approved |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A | Delegation of responsibility (The investigator maintains a list of appropriately qualified persons to whom the investigator has delegated significant trial-related duties.) |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A | Most recently approved sample case report forms (CRF) |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A | For marketed products, a package insert/product information |
| 6 Study Records (IND studies) | | | |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A | A signed current FDA 1572 |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A | Previous signed versions of FDA 1572 |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A | A current signed financial disclosure form submitted to the sponsor |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A | Previous versions of signed financial disclosure forms submitted to the sponsor |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A | Valid licensure for each investigator/staff member listed on the 1572 or in the Investigator Statement |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A | Current investigator brochure |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A | Previous versions of or updates to the investigator brochure |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A | There is shipping log for each drug. These include: |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A | Date shipment received |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A | Shipment # from packing slip study drug/device |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A | Batch#/lot #/code mark |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A | Expiration date |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A | # of boxes, kits, or devices per lot # |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A | # of bottles, vials, inhalers, or devices per box or kit |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A | Condition of study drug/device shipment (Intact/damaged) |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A | Receiver's name |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A | There is an accountability log for each drug under investigation. These include: |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A | Subject ID #, initials, or name |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A | Lot or kit number |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A | # Bottles, vials, etc. |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A | Amount of study drug per bottle, vial, etc. |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A | Total amount dispensed |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A | Initials |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A | Date dispensed |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A | Date dispensed |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A | # Of bottles, vials, etc. Returned |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A | Total amount returned |



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|--------------------------------------|-----------------------------|------------------------------|--|
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A | Balance: number dispensed less number returned |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A | Comments: subject lost, discarded, etc. |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A | Person who dispensed the drug |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A | The investigator furnishes all reports to the sponsor of the drug |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A | An investigator shall promptly report to the sponsor any adverse effect that may reasonably be regarded as caused by, or probably caused by, the drug. If the adverse effect is alarming, the investigator shall report the adverse effect immediately. |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A | An investigator shall provide the sponsor with an adequate report shortly after completion of the investigator's participation in the <u>investigation</u> . |
| 7 Study Records (IDE studies) | | | |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A | A signed Investigator Statement |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A | Previous versions of signed Investigator Statements |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A | A current signed financial disclosure form submitted to the sponsor |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A | Previous versions of signed financial disclosure forms submitted to the sponsor |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A | Valid licensure for each investigator/staff member listed on the 1572 or in the Investigator Statement |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A | There is shipping log for each device. These include: |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A | Date shipment received |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A | Shipment # from packing slip study device |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A | Batch#/lot #/code mark |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A | Expiration date |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A | # of boxes, kits, or devices per lot # |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A | # of bottles, vials, inhalers, or devices per box or kit |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A | Condition of study drug/device shipment (Intact/damaged) |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A | Receiver's name |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A | There is an accountability log for each device under investigation. These include: |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A | Subject id #, initials, or name |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A | Study device lot , batch #, or code mark |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A | Date dispensed |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A | Device disposition |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A | Comments, such as malfunctions, device failure, disposition of unused devices (returned to sponsor/destroyed,) or any other pertinent information concerning the device. |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A | Person who dispensed the device |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A | Correspondence with another investigator, an IRB, the sponsor, a monitor, or FDA, including required report |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A | Reports of unanticipated adverse device effects. The investigator submits to the sponsor and to the reviewing IRB a report of any unanticipated adverse device effect occurring during an <u>investigation</u> as soon as possible, but in no event later than 10 working days after the investigator first learns of the effect. |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A | Reports of withdrawal of IRB approval. The investigator reports to the sponsor, within 5 working days, a withdrawal of approval by the reviewing IRB of the investigator's part of an <u>investigation</u> . |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A | Progress reports. The investigator submits progress reports on the <u>investigation</u> to the sponsor, the monitor, and the reviewing IRB at regular intervals, but in no event less often than yearly. |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A | Reports of 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 subject in an emergency. Such notice is given as soon as possible, but in no event 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 subjects, FDA and IRB is required. |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A | 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 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 | Final report. The investigator, within 3 months after termination or completion of the <u>investigation</u> or the investigator's part of the <u>investigation</u> , submits a final report to the sponsor and the reviewing IRB. |



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| 8 Document Retention | |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | An investigator retains records required to be maintained under this part for a period of 2 years following the date a marketing application is approved for the drug for the indication for which it is being investigated; or, if no application is to be filed or if the application is not approved for such indication, until 2 years after the <u>investigation</u> is discontinued and FDA is notified. |
| 9 Document Retention (IND studies) | |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | An investigator retains records required to be maintained under this part for a period of 2 years following the date a marketing application is approved for the drug for the indication for which it is being investigated; or, if no application is to be filed or if the application is not approved for such indication, until 2 years after the <u>investigation</u> is discontinued and FDA is notified. |
| 10 Document Retention (IDE studies) | |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | An investigator or sponsor shall maintain the records required by this subpart during the <u>investigation</u> and for a period of 2 years after the latter of the following two dates: The date on which the <u>investigation</u> is terminated or completed, or the date that the records are no longer required for purposes of supporting a premarket approval application or a notice of completion of a product development protocol. |
| 11 Informed Consent Disclosures: Both the informed consent discussion and the written informed consent form and any other written information to be provided to subjects includes explanations of the following: | |



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- Required:** (*Can be omitted if there are none.)
- The form begins with a concise and focused presentation of the key information that is most likely to assist a prospective subject or LAR in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension. (N/A if research is subject to Pre-2018 Requirements) N/A:
 - The study involves research.
 - The purposes of the research.
 - The expected duration of the subject's participation.
 - The procedures to be followed.
 - Identification of any procedures, which are experimental.*
 - Any reasonably foreseeable risks or discomforts to the subject.*
 - Any benefits to the subject or to others, which may reasonably be expected from the research.*
 - Appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.*
 - The extent, if any, to which confidentiality of records identifying the subject will be maintained.*
 - How to contact the research team for questions, concerns, or complaints about the research.
 - How to contact someone independent of the research team for questions, concerns, or complaints about the research; questions about the subjects' rights; to obtain information; or to offer input.
 - Whom to contact in the event of a research-related injury to the subject.
 - Participation is voluntary.
 - Refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled.
 - The subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
 - One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:
 - A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the LAR, if this might be a possibility; or
 - A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

- Required for Clinical Trials that Follow ICH-GCP**
- The approval of the IRB.
 - The probability for random assignment to each treatment.
 - The subject's responsibilities.
 - When applicable, the reasonably foreseeable risks or inconveniences to an embryo, fetus, or nursing infant.
 - The important potential benefits and risks of the alternative procedures or courses of treatment that may be available to the subject.
 - When there is no intended clinical benefit to the subject, a statement to this effect.
 - The monitors, auditors, IRB, and regulatory authorities will be granted direct access to the subject's original medical records for verification of clinical trial procedures and data, without violating the confidentiality of the subject, to the extent permitted by applicable laws and regulations and that, by signing the consent document, the subject or LAR is authorizing such access.
 - If the results of the trial are published, the subject's identity will remain confidential.
- Required for FDA-Regulated Research**
- The possibility that the Food and Drug Administration may inspect the records.
 - The data collected on the subject to the point of withdrawal remains part of the study database and may not be removed.
 - The investigator should ask a subject who is withdrawing whether the subject wishes to provide further data collection from routine medical care.
 - For controlled drug/device trials (except Phase I drug trials) and pediatric device surveillance trials: "A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time."
- Additional:** (Include when appropriate.)
- The particular treatment or procedure may involve risks to the subject, which are currently unforeseeable.
 - If the subject is or becomes pregnant, the particular treatment or procedure may involve risks to the embryo or fetus, which are currently unforeseeable.
 - Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.
 - Any additional costs to the subject that may result from participation in the research.
 - The consequences of a subject's decision to withdraw from the research.
 - Procedures for orderly termination of participation by the subject.
 - Significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation will be provided to the subject.
 - Approximate number of subjects involved in the study.
 - Amount and schedule of all payments.
 - A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit. (N/A if research is subject to Pre-2018 Requirements)
 - A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions. (N/A if research is subject to Pre-2018 Requirements)
 - For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (*i.e.*, sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen). (N/A if research is subject to Pre-2018 Requirements)
 - Any additional information which should be given to subjects when in the IRB's judgement the information would meaningfully add to the protection of the rights and welfare of subjects.ⁱⁱ
 - When the study involves genetic testing, a statement that outlines the protections afforded to the subject under the Genetic Information Nondiscrimination Act (GINA).



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| <p>(N/A if research is subject to Pre-2018 Requirements) N/A: <input type="checkbox"/></p> <p>Required for More than <u>Minimal Risk</u> Research</p> <p><input type="checkbox"/> Whether any compensation is available if injury occurs and, if so, what it consists of, or where further information may be obtained.</p> <p><input type="checkbox"/> Whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.</p> | |
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| 12 Study Conduct (IND studies) | |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Investigators are responsible for the control of drugs under investigation. |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Investigators administer the drug only to subjects under their personal supervision or under the supervision of a sub-investigator responsible to the investigator. |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Investigators does not supply the investigational drug to any person not authorized to receive it. |
| 13 Study Conduct (IDE studies) | |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Investigators permit an investigational device to be used only with subjects under the investigator's supervision. |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Investigators do not supply an investigational device to any person not authorized to receive it. |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Upon completion or termination of a clinical <u>investigation</u> or the investigator's part of an <u>investigation</u> , or at the sponsor's request, investigators return to the sponsor any remaining supply of the device or otherwise dispose of the device as the sponsor directs. |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | If the <u>investigation</u> is terminated, suspended, discontinued, or completed, investigators returns the unused supplies of the drug to the sponsor, or otherwise provides for disposition of the unused supplies of the drug as authorized by the sponsor. |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | If an investigational drug is subject to the Controlled Substances Act, investigators take adequate precautions, 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. |
| Investigators prepare and submit the following reports to the sponsor: | |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Any unanticipated adverse device effect occurring during an <u>investigation</u> . (As soon as possible, but in no event later than 10 working days after first learning of the effect.) |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Withdrawal of approval by the reviewing IRB of the investigator's part of an <u>investigation</u> . (Within 5 working days.) |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Progress reports on the <u>investigation</u> . (At least yearly.) |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Any deviation from the investigational plan to protect the life or physical well-being of a subject in an emergency. (As soon as possible, but in no event later than 5 working days after the emergency occurred.) |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Use of a device without obtaining informed consent (within 5 working days after the use occurs). |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | A final report. (Within 3 months after termination or completion of the <u>investigation</u> or the investigator's part of the <u>investigation</u> .) |
| Investigators prepare and submit the following reports to the IRB: | |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Any unanticipated adverse device effect occurring during an <u>investigation</u> . (As soon as possible, but in no event later than 10 working days after first learning of the effect.) |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Progress reports on the <u>investigation</u> . (At least yearly.) |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Any deviation from the investigational plan to protect the life or physical well-being of a subject in an emergency. (As soon as possible, but in no event later than 5 working days after the emergency occurred.) |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Use of a device without obtaining informed consent (within 5 working days after the use occurs). |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | A final report (within 3 months after termination or completion of the <u>investigation</u> or the investigator's part of the <u>investigation</u>). |
| Investigators prepare and submit the following reports to the study monitor: | |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Progress reports on the <u>investigation</u> . (At least yearly.) |



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| 14 IND Sponsor-Investigator Requirements | | |
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| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | The investigator submits a completed Form FDA 3454 attesting to the absence of financial interests and arrangements for all participating clinical investigators. | |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | For any participating clinical investigator for whom the investigator does not submit a completed Form FDA 3454, the investigator submits a completed Form FDA 3455 (Disclosure Statement). | |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | The investigator maintains on file information pertaining to the financial interests of clinical investigators for 2 years after the date of approval of the application. | |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | The investigator selects qualified investigators. | |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | The investigator provides participating investigators with the information they need to conduct an <u>investigation</u> properly. | |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | The investigator ensures that the <u>investigation(s)</u> is conducted in accordance with the general investigational plan and protocols contained in the IND. | |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | The investigator maintains an effective IND with respect to the <u>investigations</u> . | |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | The investigator ensures that FDA is promptly informed of significant new adverse effects or risks with respect to the drug. | |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | The investigator ensures that all participating investigators are promptly informed of significant new adverse effects or risks with respect to the drug. | |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | The investigator selects only investigators qualified by training and experience as appropriate experts to investigate the drug. | |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | The investigator ships investigational new drugs only to investigators participating in the <u>investigation</u> . | |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Before permitting an investigator to begin participation in an <u>investigation</u> , the investigator obtains the following: | |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | A signed investigator statement (Form FDA-1572). | |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | A curriculum vitae or other statement of qualifications of the investigator showing the education, training, and experience that qualifies the investigator as an expert in the clinical <u>investigation</u> of the drug for the use under investigation. | |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Sufficient accurate financial information to allow the investigator to submit complete and accurate certification or disclosure statements. | |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | The investigator selects a monitor qualified by training and experience to monitor the progress of the <u>investigation</u> . | |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | The investigator provides each participating clinical investigator an investigator brochure. | |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | The investigator ensures, as the overall <u>investigation</u> proceeds, that each participating investigator is informed of new observations discovered by or reported to the investigator on the drug, particularly with respect to adverse effects and safe use. | |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | The investigator monitors the progress of all clinical <u>investigations</u> being conducted under the IND. | |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | 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 <u>investigation</u> . | |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | If the investigator's participation in the <u>investigation</u> is ended, the investigator ensures that the investigator dispose of or returns the investigational drug and notifies the FDA. | |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | The investigator reviews and evaluates the evidence relating to the safety and effectiveness of the drug as it is obtained from the investigator(s). | |
| | If the investigator determines that the investigational drug presents an unreasonable and significant risk to subjects, the investigator: | |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Ensures discontinuation of those <u>investigations</u> that present the risk. | |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Notifies the FDA, all institutional review boards, and all investigators who have at any time participated in the <u>investigation</u> of the discontinuance. | |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Ensures the disposition of all stocks of the drug outstanding. | |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Furnishes the FDA with a full report of the investigator's actions. | |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | The investigator maintains adequate records showing the receipt, shipment, or other disposition of the investigational drug, including, as appropriate, the name of the investigator to whom the drug is shipped, and the date, quantity, and batch or code mark of each such shipment. | |



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| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | The investigator retains these records and reports for 2 years after a marketing application is approved for the drug; or, if an application is not approved for the drug, until 2 years after shipment and delivery of the drug for investigational use is discontinued and FDA has been so notified. |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | The investigator retains reserve samples of any test article and reference standard identified in, and used in any bioequivalence or bioavailability studies and release the reserve samples to the FDA upon request. |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | The investigator retains each reserve sample for a period of at least 5 years following the date on which the application or supplemental application is approved, or, if such application or supplemental application is not approved, at least 5 years following the date of completion of the bioavailability study. |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | The investigator permits, upon request from any properly authorized officer or employee of the Food and Drug Administration, at reasonable times, such officer or employee to have access to and copy and verify any records and reports relating to a clinical <u>investigation</u> being conducted under the IND. |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | The investigator submits, upon written request by the FDA, the records or reports (or copies of them) to the FDA. |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | The investigator discontinues shipments of the drug to any investigator who has failed to maintain or make available records or reports of the <u>investigation</u> as required. |
| | 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 investigator ensures: |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Upon the request of a properly authorized employee of the Drug Enforcement Administration of the Department of 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 | 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. |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | The investigator ensures the return of all unused supplies of the investigational drug from each individual investigator whose participation in the <u>investigation</u> is discontinued or terminated. |



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| 15 Significant Risk IDE Sponsor-Investigator Requirements | |
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| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | The investigator ensures that no part of the investigation begins until the IRB and FDA have both approved the application or supplemental application. |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | The investigator selects other investigators qualified by training and experience to investigate the device. |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | The investigator selects monitors qualified by training and experience to monitor the investigational study in accordance with the IDE and other applicable FDA regulations. |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | The investigator ships investigational devices only to qualified investigators participating in the investigation. |
| The investigator obtains a signed agreement from each participating investigator that includes: | |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | The participating investigator's curriculum vitae, |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | A statement of the participating investigator's relevant experience, including the dates, location, extent, and type of experience, where applicable, |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | An explanation of the circumstances that led to termination of a study if the participating investigator was involved in an investigation or other research that was terminated, |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | A statement of the participating investigator's commitment to: <ul style="list-style-type: none"> • Conduct the investigation in accordance with the agreement, the investigational plan, the IDE and other applicable FDA regulations, and conditions of approval imposed by the reviewing IRB or FDA, • Supervise all testing of the device involving human subjects, and • Ensure that the requirements for obtaining informed consent are met. |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | The investigator maintains sufficient accurate financial disclosure information to submit a complete and accurate certification or disclosure statement as required under 21 CFR 54, Financial Disclosure by Clinical Investigators. |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | The investigator obtains a commitment from clinical investigators to promptly update this information if any relevant changes occur during the course of the investigation and for one year following completion of the study. (The financial certification or disclosure is submitted in the PMA or Premarket Notification 510(k) application. It should not be submitted in the IDE application.) |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | The investigator supplies all participating investigators with copies of the investigational plan and a report of prior investigations of the device. |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Securing Compliance: If the investigator discovers that a participating investigator is not complying with the signed agreement, the investigational plan, the IDE requirements, any other applicable FDA regulations, or any conditions of approval imposed by the reviewing IRB or FDA, the investigator promptly either secures compliance, or discontinues shipments of the device to the investigator and terminates the investigator's participation in the investigation. A sponsor must also require that the investigator dispose of or return the device, unless this action would jeopardize the rights, safety, or welfare of a subject. |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Unanticipated Adverse Device Effects: The investigator immediately conducts an evaluation of any unanticipated adverse device effect. An investigator who determines that an unanticipated adverse device effect presents an unreasonable risk to subjects terminates all investigations or parts of the investigations presenting that risk as soon as possible. Termination must occur no later than 5 working days after the sponsor makes this determination and no later than 15 working days after the sponsor first received notice of the effect. |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Resumption of Terminated Studies: For significant risk device investigations, an investigator may not resume a terminated investigation without IRB and FDA approval. |
| The investigator must maintain accurate and complete records relating to the investigation. These records include: | |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | All correspondence including required reports, |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Records of receipt, use or disposition of a device that relate to: <ul style="list-style-type: none"> • The type and quantity of the device, the dates of its receipt, and the batch number or code mark. • The names of all persons who received, used, or disposed of each device. • Why and how many units of the device have been returned to the sponsor, repaired, or otherwise disposed of. |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Signed investigator agreements including financial disclosure information, |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Records concerning complaints and adverse device effects whether anticipated or not, |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Any other records that FDA requires to be maintained by regulation or by specific requirement for a category of investigation or a particular investigation. |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | The investigator provides the following reports in a timely manner to FDA, the IRBs, and/or the investigators. |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Unanticipated Adverse Device Effects |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Withdrawal of IRB Approval |



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| | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A | Withdrawal of FDA Approval |
| | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A | Current List of Investigators |
| | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A | Progress Reports |
| | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A | Recalls and Device Disposition |
| | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A | Final Report |
| | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A | Informed consent |
| | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A | Significant Risk Device Determination |
| | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A | Other Reports |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A | The investigational device or its immediate package bears a label with the following information: <ul style="list-style-type: none"> • The name and place of business of the manufacturer, packer, or distributor; • The quantity of contents, if appropriate; and • The statement, "CAUTION -- Investigational device. Limited by Federal (or United States) law to investigational use." | |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A | The label describes all relevant contraindications, hazards, adverse effects, interfering substances or devices, warnings, and precautions. | |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A | The labeling of an investigational device does not contain any false or misleading statements nor imply that the device is safe or effective for the purposes being investigated. | |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A | The investigator provides detailed information on device labeling in the investigational protocol. This information may vary depending on the device and the nature of the study. Product labeling should be sufficient to ensure stability of the test article for the duration of the study (storage requirements, calibration procedures), bear sufficient directions for proper administration, and detail procedures to follow in the event of patient injury. | |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A | The investigator, or any person acting for or on behalf of the investigator does not: <ul style="list-style-type: none"> • Promote or test market an investigational device, until after FDA has approved the device for commercial distribution. • Commercialize an investigational device by charging the subjects or investigators a higher price than that necessary to recover costs of manufacture, research, development, and handling. • Unduly prolong an investigation. If data developed by the investigation indicate that premarket approval (PMA) cannot be justified, the sponsor must promptly terminate the investigation. • Represent that an investigational device is safe or effective. | |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A | Advertisements have been reviewed and approved by the IRB to assure that they are not unduly coercive and do not promise a certainty of cure beyond what is outlined in the consent and the protocol. No claims are made, either explicitly or implicitly, that the device is safe or effective for the purposes under investigation, or that the test article is known to be equivalent or superior to any other device. | |



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| 16 Abbreviated IDE Sponsor-Investigator Requirements | | |
|---|--|--|
| <input type="checkbox"/> Yes <input type="checkbox"/> No | The device is labeled with the name and place of business of the manufacturer. 21 CFR §812.2(b)(1)(i) | |
| <input type="checkbox"/> Yes <input type="checkbox"/> No | The device is labeled with the following statement: "CAUTION-Investigational device. Limited by Federal (or United States) law to investigational use." 21 CFR §812.2(b)(1)(i) | |
| <input type="checkbox"/> Yes <input type="checkbox"/> No | The labeling describes all relevant contraindications, hazards, adverse effects, interfering substances or devices, warnings, and precautions. 21 CFR §812.2(b)(1)(i) | |
| <input type="checkbox"/> Yes <input type="checkbox"/> No | The investigator has obtained IRB review and approval of the research. 21 CFR §812.2(b)(1)(ii) | |
| <input type="checkbox"/> Yes <input type="checkbox"/> No | The protocol includes a brief explanation of why the device is not a significant risk device. 21 CFR §812.2(b)(1)(ii) | |
| <input type="checkbox"/> Yes <input type="checkbox"/> No | The IRB has determined that the device is not a significant risk device. 21 CFR §812.2(b)(1)(ii) | |
| <input type="checkbox"/> Yes <input type="checkbox"/> No | The IRB has documented that determination in the minutes along with the IRB's rationale for making that determination. FDA Information Sheets for IRBs | |
| <input type="checkbox"/> Yes <input type="checkbox"/> No | The investigator has obtained informed consent of each subject in accordance with 21 CFR §50. 21 CFR §812.2(b)(1)(iii). | |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Unless waived by the IRB, the investigator has documented informed consent of each subject in accordance with 21 CFR §50. 21 CFR §812.2(b)(1)(iii). | |
| <input type="checkbox"/> Yes <input type="checkbox"/> No | The investigator monitors the <u>investigation</u> for compliance. 21 CFR §812.2(b)(1)(iv) | |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | The investigator immediately conducted an evaluation of any unanticipated adverse device effect. 21 CFR §812.2(b)(1)(iv) | |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | If the investigator determined whether each unanticipated adverse device effect presented an unreasonable risk to subjects. 21 CFR §812.2(b)(1)(iv) | |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | If the investigator terminated all <u>investigations</u> or parts of <u>investigations</u> presenting that risk as soon as possible, not later than 5 working days after making this determination. 21 CFR §812.2(b)(1)(iv) | |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | If the investigator determined whether each unanticipated adverse device effect presented an unreasonable risk to subjects, the investigator has to terminate all <u>investigations</u> or parts of <u>investigations</u> presenting that risk as soon as possible, not later than 5 working days after the investigator makes this determination. 21 CFR §812.2(b)(1)(iv) | |
| <input type="checkbox"/> Yes <input type="checkbox"/> No | The investigator maintains the following records consolidated in one location and available for FDA inspection and copying: 21 CFR §812.2(b)(1)(v)-(vi) | |
| <input type="checkbox"/> Yes <input type="checkbox"/> No | A statement of the extent to which the good manufacturing practice regulation in part 820 will be followed in manufacturing the device. 21 CFR §812.140(b)(4)(v) | |
| <input type="checkbox"/> Yes <input type="checkbox"/> No | The name and intended use of the device and the objectives of the <u>investigation</u> . 21 CFR §812.140(b)(4)(i) | |
| <input type="checkbox"/> Yes <input type="checkbox"/> No | A brief explanation of why the device is not a significant risk device. 21 CFR §812.140(b)(4)(ii) | |
| <input type="checkbox"/> Yes <input type="checkbox"/> No | The name and address of each investigator. 21 CFR §812.140(b)(4)(iii) | |
| <input type="checkbox"/> Yes <input type="checkbox"/> No | The name and address of each IRB that has reviewed the <u>investigation</u> . 21 CFR §812.140(b)(4)(iv) | |
| <input type="checkbox"/> Yes <input type="checkbox"/> No | Records concerning adverse device effects (whether anticipated or unanticipated) and complaints. 21 CFR §812.140(b)(5) | |
| <input type="checkbox"/> Yes <input type="checkbox"/> No | Records of each subject's case history and exposure to the device. 21 CFR §812.140(a)(3)(i) | |
| <input type="checkbox"/> Yes <input type="checkbox"/> No | Case report forms and supporting data. 21 CFR §812.140(a)(3)(i) | |
| <input type="checkbox"/> Yes <input type="checkbox"/> No | Signed and dated consent forms. 21 CFR §812.140(a)(3)(i) | |
| <input type="checkbox"/> Yes <input type="checkbox"/> No | Medical records including, for example, progress notes of the physician, the individual's hospital chart(s), and the nurses' notes. 21 CFR §812.140(a)(3)(i) | |
| <input type="checkbox"/> Yes <input type="checkbox"/> No | Documents evidencing informed consent. 21 CFR §812.140(a)(3)(i) | |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | For any use of a device by the investigator without informed consent, any written concurrence of a licensed physician and a brief description of the circumstances justifying the failure to obtain informed consent. 21 CFR §812.140(a)(3)(i) | |
| <input type="checkbox"/> Yes <input type="checkbox"/> No | Documentation that informed consent was obtained prior to participation in the study. 21 CFR §812.140(a)(3)(i) | |
| The investigator makes the following reports to FDA: 21 CFR §812.2(b)(1)(v) | | |



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|--|---|--|
| <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | <p>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 sponsor first receives notice of the effect. Thereafter the investigator submitted additional reports concerning the effect as FDA requested. <i>21 CFR §812.140(a)(1); 21 CFR §812.150(b)(1)</i></p> |
| | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | <p>Withdrawal of IRB approval. The investigator notified FDA of any withdrawal of approval of an <u>investigation</u> or a part of an <u>investigation</u> by the IRB within 5 working days after receipt of the withdrawal of approval. <i>21 CFR §812.140(a)(2); 21 CFR §812.150(b)(2)</i></p> |
| | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | <p>Withdrawal of FDA approval. The investigator notified the IRB and participating investigators of any withdrawal of FDA approval of the <u>investigation</u>, and did so within 5 working days after receipt of notice of the withdrawal of approval. <i>21 CFR §812.150(b)(3)</i></p> |
| | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | <p>Progress reports. At regular intervals, and at least yearly, the investigator submitted progress reports to the monitor and the IRB. <i>21 CFR §812.140(a)(3); 21 CFR §812.150(b)(5)</i></p> |
| | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | <p>Recall and device disposition. The investigator notified 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. <i>21 CFR §812.150(b)(6)</i></p> |
| | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | <p>The investigator submitted a final report to the IRB within 6 months after termination or completion. <i>21 CFR §812.150(b)(7)</i></p> |
| | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | <p>Informed consent. The investigator submitted to FDA and the IRB a copy of any use of a device without obtaining informed consent, within 5 working days of receipt of notice of such use. <i>21 CFR §812.140(a)(5); 21 CFR §812.150(b)(8)</i></p> |
| | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | <p>Significant risk device determinations. If the IRB determined that a device was a significant risk device, the investigator submitted to FDA a report of the IRB's determination within 5 working days after first learning of the IRB's determination. <i>21 CFR §812.150(b)(9)</i></p> |
| | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | <p>Other. The investigator, upon request by the IRB or FDA, provided accurate, complete, and current information about any aspect of the <u>investigation</u>. <i>21 CFR §812.150(b)(10)</i></p> |
| <input type="checkbox"/> Yes <input type="checkbox"/> No | <p>The investigator does not:</p> | |
| | <input type="checkbox"/> Yes <input type="checkbox"/> No | <p>Promote or test market the device. <i>21 CFR §812.7(a)</i></p> |
| | <input type="checkbox"/> Yes <input type="checkbox"/> No | <p>Commercialize the device by charging the subjects a price larger than that necessary to recover costs of manufacture, research, development, and handling. <i>21 CFR §812.7(b)</i></p> |
| | <input type="checkbox"/> Yes <input type="checkbox"/> No | <p>Unduly prolong an <u>investigation</u>. <i>21 CFR §812.7(c)</i></p> |
| | <input type="checkbox"/> Yes <input type="checkbox"/> No | <p>Represent that an investigational device is safe or effective. <i>21 CFR §812.7(d)</i></p> |



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| Clinical Trials Case History (complete for each subject) | |
|---|--|
| Principal Investigator | |
| Protocol Name | |
| Subject Code | |
| Name of Person Completing Checklist | |
| Date Completed | |

| | |
|---|---|
| 1 Subject Selection | |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | There is a completed eligibility checklist. |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | The eligibility criteria checklist includes dated signature/initials of the person obtaining the information. |
| 2 Consent | |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | For subjects who did not meet eligibility (e.g. screen-failures), identifiable information was destroyed or authorization obtained to keep subject information. |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Original copies of all consent forms signed by subjects are on file. |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | There is a current consent form on file. |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | All previous consent forms are on file. |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Valid IRB-approved consent forms were used. |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | The consent forms on file are the <i>original</i> signed and dated version (not a photocopy). |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | All pages of the consent forms are on file for each subject. |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | All yes/no or similar options on the consent forms are completed/initialed. |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Consent forms are free of any handwritten changes/corrections. |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | The subject signed his/her own consent forms. (Exceptions: IRB-approved surrogate or parental consent) |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | The subject received a copy of the signed and dated consent form. |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | The subject's receipt of a copy of the signed and dated consent form is documented. |
| 3 Prompt Reporting Requirements | |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | All prompt reporting requirements have been fulfilled. |
| 4 Data Collection Source Documents | |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Data collection complete/accurate for each subject. (e.g. no blank fields/missing data) |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Source documentation is available to support data entry. |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | The source documentation/CRF for each subject includes dated signature/initials of the person obtaining the information for each subject. |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | Changes/cross-outs, additional comments (if any) in subject files routinely initialed and dated. |
| <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A | For any changes/cross-outs being made, the original entry is still legible. (e.g. use of white-out or pencil erased entries is not acceptable) |

ⁱ 21 CFR 56.109 (b): (b) An IRB shall require that information given to subjects as part of informed consent is in accordance with 50.25. The IRB may require that information, in addition to that specifically mentioned in 50.25, be given to the subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects.

ⁱⁱ 21 CFR 56.109 (b): (b) An IRB shall require that information given to subjects as part of informed consent is in accordance with 50.25. The IRB may require that information, in addition to that specifically mentioned in 50.25, be given to the subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects.