PI WORKSHEET: Investigator Quality Improvement Assessment

The purpose of this worksheet 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)

General Research (Not Clinical Trials)

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| **Basic Information** | **Quality Improvement Details** |
| Principal Investigator | Click or tap here to enter text. |
| Protocol Name | Click or tap here to enter text. |
| Name of Person Completing Worksheet | Click or tap here to enter text. |
| Date Completed | Click or tap here to enter text. |

1. Regulatory Documentation for Each Study

|  |  |
| --- | --- |
| **Response** | **Regulatory Document** |
| [ ]  Yes [ ]  No [ ]  NA | Grant |
| [ ]  Yes [ ]  No [ ]  NA | Annual progress reports for grant |
| [ ]  Yes [ ]  No [ ]  NA | Most recent version of the IRB approved protocol |
| [ ]  Yes [ ]  No [ ]  NA | Previously IRB approved versions of the protocol |
| [ ]  Yes [ ]  No [ ]  NA | IRB approved amendments to the protocol  |
| [ ]  Yes [ ]  No [ ]  NA | Most recent version of the IRB approved consent document |
| [ ]  Yes [ ]  No [ ]  NA | Previous versions of the IRB approved consent document |
| [ ]  Yes [ ]  No [ ]  NA | Most recent versions of the IRB approved information provided to subjects |
| [ ]  Yes [ ]  No [ ]  NA | Previous versions of IRB approved information provided to subjects |
| [ ]  Yes [ ]  No [ ]  NA | Currently approved recruitment materials |
| [ ]  Yes [ ]  No [ ]  NA | Previous versions of approved recruitment materials |
| [ ]  Yes [ ]  No [ ]  NA | IRB roster associated with each approval letter |
| [ ]  Yes [ ]  No [ ]  NA | Correspondence with the IRB on file: (look for signature and date when needed for submission) |
| [ ]  Yes [ ]  No [ ]  NA | Initial IRB application |
| [ ]  Yes [ ]  No [ ]  NA | Continuing review applications. **Number:** Click or tap here to enter text. |
| [ ]  Yes [ ]  No [ ]  NA | Modification applications: **Number:** Click or tap here to enter text. |
| [ ]  Yes [ ]  No [ ]  NA | Initial IRB approval |
| [ ]  Yes [ ]  No [ ]  NA | Continuing review approvals |
| [ ]  Yes [ ]  No [ ]  NA | Modification approvals |
| [ ]  Yes [ ]  No [ ]  NA | Interim reports |
| [ ]  Yes [ ]  No [ ]  NA | Notifications of IRB disapproval, deferral, modifications required to secure approval |
| [ ]  Yes [ ]  No [ ]  NA | Responses to IRB actions |
| [ ]  Yes [ ]  No [ ]  NA | Suspension of IRB Approval or Termination of IRB Approval |
| [ ]  Yes [ ]  No [ ]  NA | Copies of email correspondence with the IRB |
| [ ]  Yes [ ]  No [ ]  NA | Other communications with the IRB |
| [ ]  Yes [ ]  No [ ]  NA | Records of investigator and staff training |
| [ ]  Yes [ ]  No [ ]  NA | Signed agreements/contracts between parties |
| [ ]  Yes [ ]  No [ ]  NA | Correspondences to and from the funding agency |

1. Document Retention

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| **Response** | **Retention Requirement** |
| [ ]  Yes [ ]  No [ ]  NA | In accordance with [UC Office of the President policy](https://www.ucop.edu/research-policy-analysis-coordination/policies-guidance/record-retention/index.html), research records must be retained for 10 years after the end of the calendar year in which the research is completed unless otherwise specified in the award agreement.If research involves the investigation of [FDA regulated](https://www.fda.gov/about-fda/fda-basics/what-does-fda-regulate) products: Information/biospecimens must be retained for two years after an approved marketing application. If approval is not received, the information/biospecimens will be kept for 2 years after the investigation is discontinued and the FDA is notified per [FDA sponsor requirements.](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=312&showFR=1&subpartNode=21:5.0.1.1.3.4) |

1. Informed Consent

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| **Response** | **Informed Consent Requirement** |
| [ ]  Yes [ ]  No [ ]  NA | An investigator seeks consent only under circumstances that provide the prospective subjects or the Legally Authorized Representative (LAR) sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. |
| [ ]  Yes [ ]  No [ ]  NA | The information given to the subjects or the LAR is in language understandable to the subject or the LAR. |
| [ ]  Yes [ ]  No [ ]  NA | Investigators do not disclose any exculpatory language, through which the subject or the LAR 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. |
| [ ]  Yes [ ]  No [ ]  NA | Investigators disclose to the subject the information in the consent document. |
| [ ]  Yes [ ]  No [ ]  NA | Investigators give either the subject or LAR adequate opportunity to read the consent document before it is signed. |
| [ ]  Yes [ ]  No [ ]  NA | A copy of the signed and dated consent document is given to the person signing the document. |
| [ ]  Yes [ ]  No [ ]  NA | 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. **(NA if research is subject to Pre-2018 Requirements)** [ ]  **NA** |
| [ ]  Yes [ ]  No [ ]  NA | The Informed consent document begins with a concise and focused presentation of the key information that is most likely to assist a prospective subjects 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. **(NA if research is subject to Pre-2018 Requirements)** [ ]  **NA** |
| [ ]  Yes [ ]  No [ ]  NA | 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. **(NA if research is subject to Pre-2018 Requirements)** [ ]  **NA** |

1. Informed Consent Disclosures

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| --- | --- |
| **Informed Consent Requirement** | **Response** |
| **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.(**NA if research is subject to Pre-2018 Requirements) NA:** [ ]  |
| **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. (**NA 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. (**NA 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). (**NA 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.[[1]](#endnote-2)[ ]  When the study involves genetic testing, a statement that outlines the protections afforded to the subject under the Genetic Information Nondiscrimination Act (GINA). |

Clinical Trials

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| **Basic Information** | **Quality Improvement Details** |
| Principal Investigator | Click or tap here to enter text. |
| Protocol Name | Click or tap here to enter text. |
| Name of Person Completing Worksheet | Click or tap here to enter text. |
| Date Completed | Click or tap here to enter text. |

1. Regulatory Documentation for Each Study

|  |  |
| --- | --- |
| **Response** | **Regulatory Documentation Category** |
| [ ]  Yes [ ]  No [ ]  NA | Grant |
| [ ]  Yes [ ]  No [ ]  NA | Annual progress reports for grant |
| [ ]  Yes [ ]  No [ ]  NA | Most recent version of the IRB approved protocol |
| [ ]  Yes [ ]  No [ ]  NA | Previously IRB approved versions of the protocol |
| [ ]  Yes [ ]  No [ ]  NA | IRB approved amendments to the protocol  |
| [ ]  Yes [ ]  No [ ]  NA | Most recent version of the IRB approved consent document |
| [ ]  Yes [ ]  No [ ]  NA | Previous versions of the IRB approved consent document |
| [ ]  Yes [ ]  No [ ]  NA | Most recent versions of the IRB approved information provided to subjects |
| [ ]  Yes [ ]  No [ ]  NA | Previous versions of IRB approved information provided to subjects |
| [ ]  Yes [ ]  No [ ]  NA | Currently approved recruitment materials |
| [ ]  Yes [ ]  No [ ]  NA | Previous versions of approved recruitment materials |
| [ ]  Yes [ ]  No [ ]  NA | IRB roster associated with each approval letter |
| [ ]  Yes [ ]  No [ ]  NA | Correspondence with the IRB on file: (look for signature and date when needed for submission) |
| [ ]  Yes [ ]  No [ ]  NA | Initial IRB application |
| [ ]  Yes [ ]  No [ ]  NA | Continuing review applications. **Number:** Click or tap here to enter text. |
| [ ]  Yes [ ]  No [ ]  NA | Modification applications: **Number:** Click or tap here to enter text. |
| [ ]  Yes [ ]  No [ ]  NA | Initial IRB approval |
| [ ]  Yes [ ]  No [ ]  NA | Continuing review approvals |
| [ ]  Yes [ ]  No [ ]  NA | Modification approvals |
| [ ]  Yes [ ]  No [ ]  NA | Interim reports |
| [ ]  Yes [ ]  No [ ]  NA | Notifications of IRB disapproval, deferral, modifications required to secure approval |
| [ ]  Yes [ ]  No [ ]  NA | Responses to IRB actions |
| [ ]  Yes [ ]  No [ ]  NA | Suspension of IRB Approval or Termination of IRB Approval |
| [ ]  Yes [ ]  No [ ]  NA | Copies of email correspondence with the IRB |
| [ ]  Yes [ ]  No [ ]  NA | Other communications with the IRB |
| [ ]  Yes [ ]  No [ ]  NA | Records of investigator and staff training |
| [ ]  Yes [ ]  No [ ]  NA | Signed agreements/contracts between parties |
| [ ]  Yes [ ]  No [ ]  NA | Subject screening log **Number screened:** Click or tap here to enter text. |
| [ ]  Yes [ ]  No [ ]  NA | Subject identification code list |
| [ ]  Yes [ ]  No [ ]  NA | Subject enrollment log **Number enrolled:** Click or tap here to enter text. |
| [ ]  Yes [ ]  No [ ]  NA | Record of retained body fluids/tissue samples |
| [ ]  Yes [ ]  No [ ]  NA | Correspondences to and from the sponsor or CRO |
| [ ]  Yes [ ]  No [ ]  NA | Letters |
| [ ]  Yes [ ]  No [ ]  NA | Meeting notes |
| [ ]  Yes [ ]  No [ ]  NA | Notes of telephone calls |
| [ ]  Yes [ ]  No [ ]  NA | CVs or other relevant documents evidencing qualifications of PI, co-investigators, and all study personnel |
| [ ]  Yes [ ]  No [ ]  NA | CVs or other relevant information have been updated within the past two years |
| [ ]  Yes [ ]  No [ ]  NA | CVs or other relevant information are signed and dated |
| [ ]  Yes [ ]  No [ ]  NA | Instructions for handling of investigational product(s) and trial-related materials (if not in protocol or investigator’s brochure) |
| [ ]  Yes [ ]  No [ ]  NA | Decoding procedures for blinded trials |
| [ ]  Yes [ ]  No [ ]  NA | Normal lab values |
| [ ]  Yes [ ]  No [ ]  NA | Updates to normal lab values |
| [ ]  Yes [ ]  No [ ]  NA | Lab certification (e.g., CLLIA)? |
| [ ]  Yes [ ]  No [ ]  NA | Updates to lab certification (e.g., CLIA)? |
| [ ]  Yes [ ]  No [ ]  NA | Lab director’s CV |
| [ ]  Yes [ ]  No [ ]  NA | Updates to lab director’s CV |
| [ ]  Yes [ ]  No [ ]  NA | Monitoring/auditing log. How often is monitoring taking place: Click or tap here to enter text. |
| [ ]  Yes [ ]  No [ ]  NA | Site Initiation report or visit documentation |
| [ ]  Yes [ ]  No [ ]  NA | Study close-out report or visit documentation |
| [ ]  Yes [ ]  No [ ]  NA | DSMB reports |
| [ ]  Yes [ ]  No [ ]  NA | Staff signature log |
| [ ]  Yes [ ]  No [ ]  NA | Signature log reflects current staff working on the study |
| [ ]  Yes [ ]  No [ ]  NA | Staff working on the study are IRB approved |
| [ ]  Yes [ ]  No [ ]  NA | Delegation of responsibility (The Investigator maintains a list of appropriately qualified persons to whom the investigator has delegated significant trial-related duties.) |
| [ ]  Yes [ ]  No [ ]  NA | Most recently approved sample case report forms (CRF) |
| [ ]  Yes [ ]  No [ ]  NA | For marketed products, a package insert/product information |

1. Study Records (IND studies)

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| --- | --- |
| **Response** | **Study Record Category** |
| [ ]  Yes [ ]  No [ ]  NA | A signed current FDA 1572 |
| [ ]  Yes [ ]  No [ ]  NA | Previous signed versions of FDA 1572 |
| [ ]  Yes [ ]  No [ ]  NA | A current signed financial disclosure form submitted to the sponsor |
| [ ]  Yes [ ]  No [ ]  NA | Previous versions of signed financial disclosure forms submitted to the sponsor |
| [ ]  Yes [ ]  No [ ]  NA | Valid licensure for each investigator/staff member listed on the 1572 or in the Investigator Statement |
| [ ]  Yes [ ]  No [ ]  NA | Current investigator brochure |
| [ ]  Yes [ ]  No [ ]  NA | Previous versions of or updates to the investigator brochure |
| [ ]  Yes [ ]  No [ ]  NA | There is shipping log for each drug. These include: |
| [ ]  Yes [ ]  No [ ]  NA | Date shipment received |
| [ ]  Yes [ ]  No [ ]  NA | Shipment number from packing slip study drug or device |
| [ ]  Yes [ ]  No [ ]  NA | Batch number, lot number, code mark |
| [ ]  Yes [ ]  No [ ]  NA | Expiration date |
| [ ]  Yes [ ]  No [ ]  NA | Number of boxes, kits, or devices per lot number |
| [ ]  Yes [ ]  No [ ]  NA | Number of bottles, vials, inhalers, or devices per box or kit |
| [ ]  Yes [ ]  No [ ]  NA | Condition of study drug or device shipment (Intact, damaged) |
| [ ]  Yes [ ]  No [ ]  NA | Receiver’s name |
| [ ]  Yes [ ]  No [ ]  NA | There is an accountability log for each drug under investigation. These include: |
| [ ]  Yes [ ]  No [ ]  NA | Subject ID number, initials, or name |
| [ ]  Yes [ ]  No [ ]  NA | Lot or kit number |
| [ ]  Yes [ ]  No [ ]  NA | Number of bottles, vials, etc. |
| [ ]  Yes [ ]  No [ ]  NA | Amount of study drug per bottle, vial, etc.. |
| [ ]  Yes [ ]  No [ ]  NA | Total amount dispensed |
| [ ]  Yes [ ]  No [ ]  NA | Initials |
| [ ]  Yes [ ]  No [ ]  NA | Date dispensed |
| [ ]  Yes [ ]  No [ ]  NA | Number of bottles, vials, etc. returned |
| [ ]  Yes [ ]  No [ ]  NA | Total amount returned |
| [ ]  Yes [ ]  No [ ]  NA | Balance: number dispensed less number returned |
| [ ]  Yes [ ]  No [ ]  NA | Comments: subject lost, discarded, etc. |
| [ ]  Yes [ ]  No [ ]  NA | Person who dispensed the drug |
| [ ]  Yes [ ]  No [ ]  NA | The investigator furnishes all reports to the sponsor of the drug |
| [ ]  Yes [ ]  No [ ]  NA | 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.  |
| [ ]  Yes [ ]  No [ ]  NA | An investigator shall provide the sponsor with an adequate report shortly after completion of the investigator’s participation in the investigation. |

1. Study Records (IDE studies)

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| **Response** | **Study Record Category** |
| [ ]  Yes [ ]  No [ ]  NA | A signed Investigator Statement |
| [ ]  Yes [ ]  No [ ]  NA | Previous versions of signed Investigator Statements |
| [ ]  Yes [ ]  No [ ]  NA | A current signed financial disclosure form submitted to the sponsor |
| [ ]  Yes [ ]  No [ ]  NA | Previous versions of signed financial disclosure forms submitted to the sponsor |
| [ ]  Yes [ ]  No [ ]  NA | Valid licensure for each investigator/staff member listed on the 1572 or in the Investigator Statement |
| [ ]  Yes [ ]  No [ ]  NA | There is shipping log for each device. These include: |
| [ ]  Yes [ ]  No [ ]  NA | Date shipment received |
| [ ]  Yes [ ]  No [ ]  NA | Shipment number from packing slip study device |
| [ ]  Yes [ ]  No [ ]  NA | Batch number, lot number, code mark |
| [ ]  Yes [ ]  No [ ]  NA | Expiration date |
| [ ]  Yes [ ]  No [ ]  NA | Number of boxes, kits, or devices per lot number |
| [ ]  Yes [ ]  No [ ]  NA | Number of bottles, vials, inhalers, or devices per box or kit |
| [ ]  Yes [ ]  No [ ]  NA | Condition of study drug or device shipment (Intact, damaged) |
| [ ]  Yes [ ]  No [ ]  NA | Receiver’s name |
| [ ]  Yes [ ]  No [ ]  NA | There is an accountability log for each device under investigation. These include: |
| [ ]  Yes [ ]  No [ ]  NA | Subject ID number, initials, or name |
| [ ]  Yes [ ]  No [ ]  NA | Study device lot, batch number, or code mark |
| [ ]  Yes [ ]  No [ ]  NA | Date dispensed |
| [ ]  Yes [ ]  No [ ]  NA | Device disposition  |
| [ ]  Yes [ ]  No [ ]  NA | Comments, such as malfunctions, device failure, disposition of unused devices (returned to sponsor or destroyed) or any other pertinent information concerning the device. |
| [ ]  Yes [ ]  No [ ]  NA | Person who dispensed the device |
| [ ]  Yes [ ]  No [ ]  NA | Correspondence with another investigator, an IRB, the sponsor, a monitor, or FDA, including required report |
| [ ]  Yes [ ]  No [ ]  NA | 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 investigation as soon as possible, but in no event later than 10 working days after the investigator first learns of the effect. |
| [ ]  Yes [ ]  No [ ]  NA | 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 investigation. |
| [ ]  Yes [ ]  No [ ]  NA | Progress reports. The investigator submits progress reports on the investigation to the sponsor, the monitor, and the reviewing IRB at regular intervals, but in no event less often than yearly. |
| [ ]  Yes [ ]  No [ ]  NA | 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. |
| [ ]  Yes [ ]  No [ ]  NA | 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. |
| [ ]  Yes [ ]  No [ ]  NA | Final report. The investigator, within 3 months after termination or completion of the investigation or the investigator’s part of the investigation, submits a final report to the sponsor and the reviewing IRB. |

1. Document Retention

|  |  |
| --- | --- |
| **Response** | **Requirement** |
| [ ]  Yes [ ]  No [ ]  NA | In accordance with [UC Office of the President policy](https://www.ucop.edu/research-policy-analysis-coordination/policies-guidance/record-retention/index.html), research records must be retained for 10 years after the end of the calendar year in which the research is completed unless otherwise specified in the award agreement.If research involves the investigation of [FDA regulated](https://www.fda.gov/about-fda/fda-basics/what-does-fda-regulate) products: Information/biospecimens must be retained for two years after an approved marketing application. If approval is not received, the information/biospecimens will be kept for 2 years after the investigation is discontinued and the FDA is notified per [FDA sponsor requirements.](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=312&showFR=1&subpartNode=21:5.0.1.1.3.4) Refer to the following sections. |

1. Document Retention (IND studies)

|  |  |
| --- | --- |
| **Response** | **Requirement** |
| [ ]  Yes [ ]  No [ ]  NA | 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 investigation is discontinued and FDA is notified. |

1. Document Retention (IDE studies)

|  |  |
| --- | --- |
| **Response** | **Requirement** |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | An investigator or sponsor shall maintain the records required by this subpart during the investigation and for a period of 2 years after the latter of the following two dates: The date on which the investigation 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. |

1. 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:

|  |  |
| --- | --- |
| **Informed Consent Requirement** | **Response** |
| **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. (**NA if research is subject to Pre-2018 Requirements) NA:** [ ]  [ ] [ ]  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.(**NA if research is subject to Pre-2018 Requirements) NA:** [ ]  |
| **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. |
| **Required for Clinical Trials that Follow ICH-GCP**  | [ ]  [ ]  The approval of the IRB.[ ]  [ ]  The trial’s investigational product(s) and probability for random assignment to each treatment, if applicable.[ ]  [ ]  What is expected of the participants.[ ]  [ ]  When applicable, the reasonably foreseeable risks or inconveniences to the participant’s partner, to an embryo, fetus, or nursing infant.[ ]  [ ]  When applicable, the reasonably expected benefits to the participant’s partner or to an embryo, fetus, or nursing infant.[ ]  [ ]  When there is no intended clinical benefit to the participant, the participant should be made aware of this. [ ]  The process by which the participant’s data will be handled, including in the event of withdrawal or discontinuation of participation in accordance with regulatory requirements.[ ]  [ ]  That by agreeing to participate in the trial, the participant or their legally authorized representative allows direct access to source records, based on the understanding that the confidentiality of the participant’s medical record will be safeguarded. This access is limited for the purpose of viewing trial activities and/or reviewing or verifying data and records by the regulatory authority(ies) and the sponsor’s representative, for example, monitor(s), or auditor(s), and in accordance with applicable regulatory requirements, the IRB/IEC(s).[ ]  [ ]  If the results of the trial are published, the participant’s identity will remain confidential. The trial may be registered on publicly accessible and recognized databases, per applicable regulatory requirements. [ ]  Trial results and information on the participant’s actual treatment, if appropriate, will be made available to them should they desire it. |
| **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 or 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. (**NA 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. (**NA 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). (NA 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.[[2]](#endnote-3)[ ]  [ ]  When the study involves genetic testing, a statement that outlines the protections afforded to the subject under the Genetic Information Nondiscrimination Act (GINA). |

1. Study Conduct (IND studies)

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| --- | --- |
| **Response** | **Study Conduct Category** |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | Investigators are responsible for the control of drugs under investigation. |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | Investigators administer the drug only to subjects under their personal supervision or under the supervision of a sub-investigator responsible to the investigator. |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | Investigators do not supply the investigational drug to any person not authorized to receive it. |

1. Study Conduct (IDE studies)

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| --- | --- |
| **Response** | **Study Conduct Category** |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | Investigators permit an investigational device to be used only with subjects under the investigator’s supervision. |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | Investigators do not supply an investigational device to any person not authorized to receive it. |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | Upon completion or termination of a clinical investigation or the investigator’s part of an, or at the sponsor’s investigation request, investigators return to the sponsor any remaining supply of the device or otherwise dispose of the device as the sponsor directs. |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | If the investigation is terminated, suspended, discontinued, or completed, investigators return the unused supplies of the drug to the sponsor, or otherwise provide for disposition of the unused supplies of the drug as authorized by the sponsor. |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | 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: |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | Any unanticipated adverse device effect occurring during an investigation. (Within 5 working days.) |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | Withdrawal of approval by the reviewing IRB of the investigator’s part of an investigation. (Within 5 working days.) |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | Progress reports on the investigation. (At least yearly.) |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | 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.) |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | Use of a device without obtaining informed consent (within 5 working days after the use occurs). |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | A final report. (Within 3 months after termination or completion of the investigation or the investigator’s part of the investigation.) |
|  | Investigators prepare and submit the following reports to the IRB: |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | Any unanticipated adverse device effect occurring during an investigation. (As soon as possible, but in no event later than 10 working days after first learning of the effect.) |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | Progress reports on the investigation. (At least yearly.) |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | 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.) |
|  [ ]  Yes [ ]  No [ ]  NA | Use of a device without obtaining informed consent (within 5 working days after the use occurs). |
|  [ ]  Yes [ ]  No [ ]  NA | A final report (within 3 months after termination or completion of the investigation or the investigator’s part of the investigation). |
| [ ]  | Investigators prepare and submit the following reports to the study monitor: |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | Progress reports on the investigation. (At least yearly.) |

1. IND Sponsor-Investigator Requirements

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| **Response** | **Requirement** |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | The investigator submits a completed Form FDA 3454 attesting to the absence of financial interests and arrangements for all participating clinical investigators. |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | 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). |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | 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. |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | The investigator selects qualified investigators. |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | The investigator provides participating investigators with the information they need to conduct an investigation properly. |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | The investigator ensures that the investigation(s) is conducted in accordance with the general investigational plan and protocols contained in the IND. |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | The investigator maintains an effective IND with respect to the investigations. |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | The investigator ensures that FDA is promptly informed of significant new adverse effects or risks with respect to the drug. |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | The investigator ensures that all participating investigators are promptly informed of significant new adverse effects or risks with respect to the drug. |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | The investigator selects only investigators qualified by training and experience as appropriate experts to investigate the drug. |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | The investigator ships investigational new drugs only to investigators participating in the investigation. |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | Before permitting an investigator to begin participation in an investigation, the investigator obtains the following: |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | A signed investigator statement (Form FDA-1572). |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | 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 investigation of the drug for the use under investigation. |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | Sufficient accurate financial information to allow the investigator to submit complete and accurate certification or disclosure statements. |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | The investigator selects a monitor qualified by training and experience to monitor the progress of the investigation. |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | The investigator provides each participating clinical investigator an investigator brochure. |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | The investigator ensures, as the overall investigation 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. |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | The investigator monitors the progress of all clinical investigations being conducted under the IND. |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | 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. |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | If the investigator’s participation in the investigation is ended, the investigator ensures that the investigator dispose of or returns the investigational drug and notifies the FDA. |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | The investigator reviews and evaluates the evidence relating to the safety and effectiveness of the drug as it is obtained from the investigator(s). |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | If the investigator determines that the investigational drug presents an unreasonable and significant risk to subjects, the investigator: |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | Ensures discontinuation of those investigations that present the risk.  |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | Notifies the FDA, all institutional review boards, and all investigators who have at any time participated in the investigation of the discontinuance. |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | Ensures the disposition of all stocks of the drug outstanding. |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | Furnishes the FDA with a full report of the investigator’s actions. |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | 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. |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | 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. |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | 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. |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | 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. |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | 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 investigation being conducted under the IND. |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | The investigator submits, upon written request by the FDA, the records or reports (or copies of them) to the FDA. |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | The investigator discontinues shipments of the drug to any investigator who has failed to maintain or make available records or reports of the investigation 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: |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | 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. |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | 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. |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | The investigator ensures the return of all unused supplies of the investigational drug from each individual investigator whose participation in the investigation is discontinued or terminated. |

1. Significant Risk IDE Sponsor-Investigator Requirements

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| **Response** | **Requirement** |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | The investigator ensures that no part of the investigation begins until the IRB and FDA have both approved the application or supplemental application. |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | The investigator selects other investigators qualified by training and experience to investigate the device. |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | The investigator selects monitors qualified by training and experience to monitor the investigational study in accordance with the IDE and other applicable FDA regulations. |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | The investigator ships investigational devices only to qualified investigators participating in the investigation. |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | The investigator obtains a signed agreement from each participating investigator that includes: |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | The participating investigator's curriculum vitae, |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | A statement of the participating investigator's relevant experience, including the dates, location, extent, and type of experience, where applicable, |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | 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, |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | A statement of the participating investigator's commitment to:* 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.
 |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | 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. |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | 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.) |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | The investigator supplies all participating investigators with copies of the investigational plan and a report of prior investigations of the device. |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | 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. |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | 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. |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | 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: |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | All correspondence including required reports, |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | Records of receipt, use or disposition of a device that relate to:* 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.
 |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | Signed investigator agreements including financial disclosure information, |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | Records concerning complaints and adverse device effects whether anticipated or not,  |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | Any other records that FDA requires to be maintained by regulation or by specific requirement for a category of investigation or a particular investigation. |
| [ ]   | The investigator provides the following reports in a timely manner to FDA, the IRBs, and/or the investigators. |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | Unanticipated Adverse Device Effects |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | Withdrawal of IRB Approval |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | Withdrawal of FDA Approval |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | Current list of Investigators |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | Progress Reports |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | Recalls and Device Disposition |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | Final Report |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | Informed consent |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | Significant Risk Device Determination |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | Other Reports |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | The investigational device or its immediate package bears a label with the following information:* 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."
 |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | The label describes all relevant contraindications, hazards, adverse effects, interfering substances or devices, warnings, and precautions. |
| [ ]  Yes [ ]  No [ ]  NA | 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. |
|  [ ]  Yes [ ]  No [ ]  NA | 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. |
|  [ ]  Yes [ ]  No [ ]  NA | The investigator, or any person acting for or on behalf of the investigator does not:* 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.
 |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | 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. |

1. Abbreviated IDE Sponsor-Investigator Requirements

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| **Response** | **Requirement** |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | The device is labeled with the name and place of business of the manufacturer. *21 CFR §812.2(b)(1)(i)* |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | 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)* |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | The labeling describes all relevant contraindications, hazards, adverse effects, interfering substances or devices, warnings, and precautions. *21 CFR §812.2(b)(1)(i)* |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | The investigator has obtained IRB review and approval of the research. *21 CFR §812.2(b)(1)(ii)*  |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | The protocol includes a brief explanation of why the device is not a significant risk device. *21 CFR §812.2(b)(1)(ii)* |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | The IRB has determined that the device is not a significant risk device. *21 CFR §812.2(b)(1)(ii)* |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | The IRB has documented that determination in the minutes along with the IRB’s rationale for making that determination. *FDA Information Sheets for IRBs* |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | The investigator has obtained informed consent of each subject in accordance with 21 CFR §50. *21 CFR §812.2(b)(1)(iii).* |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | 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).* |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | The investigator monitors the investigation for compliance. *21 CFR §812.2(b)(1)(iv)* |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | The investigator immediately conducted an evaluation of any unanticipated adverse device effect. *21 CFR §812.2(b)(1)(iv)* |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | If the investigator determined whether each unanticipated adverse device effect presented an unreasonable risk to subjects. *21 CFR §812.2(b)(1)(iv)* |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | If the investigator terminated all investigations or parts of investigations presenting that risk as soon as possible, not later than 5 working days after making this determination. *21 CFR §812.2(b)(1)(iv)* |
| [ ]  ☐ Yes ☐ No ☐ NA | If the investigator determined whether each unanticipated adverse device effect presented an unreasonable risk to subjects, the investigator has to terminate all investigations or parts of investigations 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)* |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | **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)*** |
| [ ]  [ ]  Yes [ ]  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)* |
| [ ]  [ ]  Yes [ ]  No | The name and intended use of the device and the objectives of the investigation. *21 CFR §812.140(b)(4)(i)* |
| [ ]  [ ]  Yes [ ]  No | A brief explanation of why the device is not a significant risk device. *21 CFR §812.140(b)(4)(ii)* |
| [ ]  Yes [ ]  No | The name and address of each investigator. *21 CFR §812.140(b)(4)(iii)* |
| [ ] [ ]  Yes [ ]  No | The name and address of each IRB that has reviewed the investigation. *21 CFR §812.140(b)(4)(iv)* |
| [ ]  [ ]  Yes [ ]  No | Records concerning adverse device effects (whether anticipated or unanticipated) and complaints. *21 CFR §812.140(b)(5)* |
| [ ]  [ ]  Yes [ ]  No | Records of each subject’s case history and exposure to the device. 21 CFR §812.140(a)(3)(i) |
| [ ]  [ ]  Yes [ ]  No | Case report forms and supporting data. 21 CFR §812.140(a)(3)(i) |
| [ ]  Yes [ ]  No | Signed and dated consent forms. 21 CFR §812.140(a)(3)(i) |
| [ ]  [ ]  Yes [ ]  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) |
| [ ]  [ ]  Yes [ ]  No | Documents evidencing informed consent. 21 CFR §812.140(a)(3)(i) |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | 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) |
| [ ] [ ]  Yes [ ]  No | Documentation that informed consent was obtained prior to participation in the study. 21 CFR §812.140(a)(3)(i) |
| [ ]  [ ]  Yes [ ]  No | **The investigator makes the following reports to FDA: *21 CFR §812.2(b)(1)(v)*** |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | 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. *21 CFR §812.140(a)(1); 21 CFR §812.150(b)(1)* |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | Withdrawal of IRB approval. The investigator notified FDA of any withdrawal of approval of an investigation or a part of an investigation by the IRB within 5 working days after receipt of the withdrawal of approval. *21 CFR §812.140(a)(2); 21 CFR §812.150(b)(2)* |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | Withdrawal of FDA approval. The investigator notified the IRB and participating investigators of any withdrawal of FDA approval of the investigation, and did so within 5 working days after receipt of notice of the withdrawal of approval. *21 CFR §812.150(b)(3)* |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | Progress reports. At regular intervals, and at least yearly, the investigator submitted progress reports to the monitor and the IRB. *21 CFR §812.140(a)(3); 21 CFR §812.150(b)(5)* |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | 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. *21 CFR §812.150(b)(6)* |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | The investigator submitted a final report to the IRB within 6 months after termination or completion. *21 CFR §812.150(b)(7)* |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | 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. *21 CFR §812.140(a)(5); 21 CFR §812.150(b)(8)* |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | 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. *21 CFR §812.150(b)(9)* |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | Other. The investigator, upon request by the IRB or FDA, provided accurate, complete, and current information about any aspect of the investigation. *21 CFR §812.150(b)(10)* |
| [ ]  [ ]  Yes [ ]  No | **The investigator does not:** |
| [ ]  [ ]  Yes [ ]  No | Promote or test market the device. *21 CFR §812.7(a)* |
| [ ]  [ ]  Yes [ ]  No | Commercialize the device by charging the subjects a price larger than that necessary to recover costs of manufacture, research, development, and handling. *21 CFR §812.7(b)* |
| [ ]  [ ]  Yes [ ]  No | Unduly prolong an investigation. *21 CFR §812.7(c)* |
| [ ]  [ ]  Yes [ ]  No | Represent that an investigational device is safe or effective. *21 CFR §812.7(d)* |

Clinical Trials Case History (complete for each subject)

|  |  |
| --- | --- |
| **Basic Information** | **Study and Subject Details** |
| Principal Investigator | Click or tap here to enter text. |
| Protocol Name | Click or tap here to enter text. |
| Subject Code | Click or tap here to enter text. |
| Name of Person Completing Worksheet | Click or tap here to enter text. |
| Date Completed | Click or tap here to enter text. |

1. Subject selection

|  |  |
| --- | --- |
| **Response** | **Requirement** |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | There is a completed eligibility worksheet. |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | The eligibility criteria worksheet includes dated signature/initials of the person obtaining the information. |

1. Consent

|  |  |
| --- | --- |
| **Response** | **Requirement** |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | For subjects who did not meet eligibility (e.g. screen-failures), identifiable information was destroyed or authorization obtained to keep subject information. |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | Original copies of all consent forms signed by subjects are on file. |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | There is a current consent form on file. |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | All previous consent forms are on file. |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | Valid IRB-approved consent forms were used. |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | The consent forms on file are the *original* signed and dated version (not a photocopy). |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | All pages of the consent forms are on file for each subject. |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | All yes/no or similar options on the consent forms are completed/initialed. |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | Consent forms are free of any handwritten changes/corrections. |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | The subject signed his/her own consent forms. (Exceptions: IRB-approved surrogate or parental consent) |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | The subject received a copy of the signed and dated consent form. |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | The subject's receipt of a copy of the signed and dated consent form is documented. |

1. Prompt Reporting Requirements

|  |  |
| --- | --- |
| **Response** | **Requirement** |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | All prompt reporting requirements have been fulfilled. |

1. Data Collection Source Documents

|  |  |
| --- | --- |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | Data collection complete/accurate for each subject. (e.g. no blank fields/missing data) |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | Source documentation is available to support data entry. |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | The source documentation/CRF for each subject includes dated signature/initials of the person obtaining the information for each subject. |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | Changes/cross-outs, additional comments (if any) in subject files routinely initialed and dated. |
| [ ]  [ ]  Yes [ ]  No [ ]  NA | 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) |

1. 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. [↑](#endnote-ref-2)
2. 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. [↑](#endnote-ref-3)