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

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| --- | --- |
| **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)

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| --- | --- |
| **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)

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| **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:

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| **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)

|  |  |
| --- | --- |
| **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)

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| --- | --- |
| **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

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| **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

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| **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

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

1. Data Collection Source Documents

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| --- | --- |
| 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)