|  |  |
| --- | --- |
| **Protocol Title** |       |
| **Principal Investigator/Faculty Advisor** | Name:       |
| Department:       |
| Telephone Number:       |
| Email Address:       |
| **Student Investigator** | Name:       |
| Current Academic Status (Student, Fellow, Resident):       |
| Department:       |
| Telephone Number:       |
| Institutional Email Address:       |
| **Primary Contact** | Name:       |
| Department:       |
| Telephone Number:       |
| Email Address:       |
| **IRB Study Number** |       |
| **Audit Date(s)** |       |
| **RNI Number** | To be determined |
|  |  |
| **Auditor** | Name:       |
| Telephone Number:       |
| Email Address:       |

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| **Purpose:** The purpose of this checklist is to facilitate human research audits by quality assurance auditors. This checklist is based on the Investigator's Manual,  federal and state laws, regulations, good clinical practice, University policies, and SOPs which are applicable to human research (45 CFR 46, 21 CFR 50, 56, 312, 812, GCP, etc.).This checklist must be used for all non-exempt routine and for-cause audits. The type of research study will determine which sections of the checklist will be used.For studies initially approved within ETHOS, documents required by the IRB will be assessed remotely.  For studies migrated to ETHOS, documents required by the IRB prior to migration will be assessed on-site. |
|  |
|  | **Remote Assessment** | **On-site Assessment** |
|  |  | **Sponsor-Investigator (SI)** |  |
|  | **IRB Performance**  | **Elements of Consent** | **Regulatory - General** | **Regulatory - Trials** | **Drugs & Devices** | **SI IND Requirements** | **Abbrev. SI IDE****& SI IDE Requirements** | **Abbrev.** **SI IDE Requirements** | **SI IDE Requirements** | **Case Histories** |
| **Type of** **Study****Section** | **A** | **B** | **C** | **D** | **E** | **F** | **G** | **H** | **I** | **J** |
| All Studies | X | X | X |  |  |  |  |  |  | X |
| Clinical Trial | X | X | X | X |  |  |  |  |  | X |
| Drug | X | X | X | X | X |  |  |  |  | X |
| Device | X | X | X | X | X |  |  |  |  | X |
| SI IND | X | X | X | X | X | X |  |  |  | X |
| Abbrev. SI IDE | X | X | X | X | X |  | X | X |  | X |
| SI IDE | x | x | x | x | x |  | x |  | x | x |

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| A. IRB Performance |
|  |  |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | The study fulfills the regulatory requirements for being engaged in Human Research. |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | The study fulfills the regulatory requirements for Human Research. |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | The study fulfills the regulatory requirements for exempt review. |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | The study fulfills the regulatory requirements for expedited review. |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | Required training was up to date for investigator and staff at the time of initial IRB approval. |
|  |  | If this is an abbreviated SI IDE study: |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | * The IRB has determined that the device is not a significant risk device.
 |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | * The IRB has documented that determination in the minutes along with the IRB’s rationale for making that determination.
 |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | For studies undergoing federal agency oversight in addition to ICH E6, regulatory requirements are met.  |
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|  | Other | [Additional requirements may apply depending upon the treatment under study] |

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| **B. Elements of Consent**  |
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|  | Elements of Consent - Institutional Requirements |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | The PI is identified. |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | The investigator’s department affiliation is identified. |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | The study sponsor is identified, if applicable. |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | If the study is covered under Certificate of Confidentiality (COC), language informing the participant of the COC is in the consent form. |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | The investigator is in compliance with the IRB-approved conflict determination and/or management plan (e.g., a statement about the PI’s conflict of interest is included in the consent form as required by the IRB). |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | If there is an LAR or parent signature line, the IRB has approved inclusion of adults unable to consent or children. |
|  |  |  |
|  | Elements of Consent - Informed Consent Disclosures |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | The approval of the IRB |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | A statement that the study involves research |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | An explanation of the purposes of the research |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | The expected duration of the subject’s participation |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | A description of the procedures to be followed |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | Identification of any procedures, which are experimental |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | Identification of any reasonably foreseeable risks or discomforts to the subject, if applicable |
|  |  | Benefits: |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | * A description of any benefits to the subject or to others, which may reasonably be expected from the research, if applicable.
 |
|  |  | * For clinical trials: The reasonably expected benefits. When there is no intended clinical benefit to the subject, the subject should be made aware of this.
 |
|  |  | Alternatives: |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | * A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject, if applicable
 |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | * For clinical trials: The important potential benefits and risks of the alternative procedures or courses of treatment that may be available to the subject
 |
|  |  | Confidentiality: |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | * A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained, if applicable
 |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | * The statement “Organizations that may inspect and copy your information include the Institutional Review Board (IRB), the committee that provides ethical and regulatory oversight of research, and other representatives of this institution, including those that have responsibilities for monitoring or ensuring compliance. [Add to this list other organizations that may have access to the participants’ records, such as the medical service providers (for clinical trials), DOD, DHHS, the sponsor, CRO, sponsor’s agent and other collaborating institutions.]”
 |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | * For FDA-regulated studies: A statement that notes the possibility that the Food and Drug Administration may inspect the records
 |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | * For clinical trials: The monitors, auditors, IRB, and regulatory authorities will be granted direct access to the subject’s original medical records for verification of clinical trial procedures and data, without violating the confidentiality of the subject, to the extent permitted by applicable laws and regulations and that, by signing the consent document, the subject or LAR is authorizing such access.
 |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | * For studies in which investigators are likely to elicit information about child or vulnerable adult abuse or neglect: There is a Mandated or permitted Reporter Language statement.
 |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | * A description of any other limitations on confidentiality based on possible legal issues (e.g. if the research team is likely to uncover drug use or other sensitive information, this information may be disclosed to appropriate authorities under Minnesota’s communicable disease reporting rule).
 |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | The statement that “You may be asked by the study team for your permission for an auditor to observe your consent meeting”, if applicable |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | An explanation of how to contact the research team for questions, concerns, or complaints about the research. |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | An explanation of 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 |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | The subject's responsibilities |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | A statement that participation is voluntary |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | No penalty for refusal: |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | * A statement that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled
 |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | The information given to the subject or the representative is in language understandable [readable] to the subject or the representative. |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | There is no exculpatory language through which the subject or LAR is made to waive or appear to waive the subject’s legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability from negligence. |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | Any additional costs to the subject that may result from participation in the research |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | Procedures for orderly termination of participation by the subject |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | Approximate number of subjects involved in the study |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | Amount and schedule of all payments  |
|  |  | If potential for injury: |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | * Whether any compensation is available if injury occurs and, if so, what it consists of, or where further information may be obtained
 |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | * Whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained
 |

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|  | Elements of Consent – Additional Informed Consent Disclosures |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | A statement that the particular treatment or procedure may involve risks to the subject, which are currently unforeseeable |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | A statement that if the subject is or becomes pregnant, the particular treatment or procedure may involve risks to the embryo or fetus, which are currently unforeseeable, if applicable |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | Anticipated circumstances under which the subject’s participation may be terminated by the investigator without regard to the subject’s consent, if applicable |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | The consequences of a subject’s decision to withdraw from the research, if applicable |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | A statement that 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, if applicable |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | For FDA-regulated studies, the data collected on the subject to the point of withdrawal remains part of the study database and may not be removed. |
|  |  |
|  | Elements of Consent - Required for Clinical Trials |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | The probability for random assignment to each treatment, if applicable |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | The reasonably foreseeable risks or inconveniences to an embryo, fetus, or nursing infant, if applicable |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | If the results of the trial are published, the subject’s identity will remain confidential. |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | For applicable trials (as identified in ETHOS): “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.”  |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | For clinical trials: “You and your insurance company will be charged for the health care services that you would ordinarily be responsible to pay. In some cases, insurance will not pay for services ordinarily covered because these services are performed in a research study. You should check with your insurance to see what services will be covered by your insurance and what you will be responsible to pay.” |
|  |  |  |
|  | Elements of Consent - Other |  |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | If a short form of consent documentation is used, there is a written summary of what is said to the subject or LAR. |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | The written summary includes signature lines for the witness and the individual obtaining consent. |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | For CMRR studies, language highlighted in HRP-592 TEMPLATE Consent Form Template for Medical Research, is included. |
|  |  | For research involving prisoners: |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | * The statement “Taking part in this research study will not improve your housing or correctional program assignments. Your taking part in this research study will not improve your chance of parole or release.”
 |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | * The statement “If you are a prisoner, your medical records may also be given to officials and agencies within the criminal justice system when necessary and permitted by law.”
 |
|  |  | For data or specimens collected: |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | * If data or specimens will be retained after the study for future research, an explanation of “where the data or specimens will be stored, who will have access to the data or specimens, and how long the date or specimens will be retained.”
 |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | * If identifiable private information or identifiable specimens will be collected during the research, the applicable statement appearing in the HRP-592 TEMPLATE Consent Form Template for Medical Research, is included.
 |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | * The statements “Your information and samples (both identifiable and de-identified) may be used to create products or to deliver services, including some that may be sold and/or make money for others. If this happens, there are no plans [or replace with plans when using identifiable information/samples] to tell you, or to pay you, or to give any compensation to you or your family,” if applicable.
 |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | For research involving genetic information the paragraph:A federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:* Health insurance companies and group health plans may not request your genetic information that we get from this research.
* Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
* Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Be aware that this federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. |
|  |  | [Additional requirements may apply depending upon the treatment under study] |

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| **C. Regulatory - General**  |
|  |  |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | Signed grant/agreements/contracts between parties |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | If there is a grant, annual progress reports for grant |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | Letters of support from collaborating institutions (e.g. schools) submitted to the IRB, as required |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | Most recent version of the IRB approved protocol |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | Previously IRB approved versions of the protocol |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | IRB approved amendments to the protocol |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | Most recent version of the IRB approved consent documents |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | Previous versions of the IRB approved consent documents |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | Most recent versions of IRB approved information provided to subjects |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | Previous versions of IRB approved information provided to subjects |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | Currently approved recruitment materials |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | Previous versions of approved recruitment materials |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | For ceded studies: IRB roster, FWA #, or Letter of Assurance associated with each approval letter or with the study |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | Correspondence with the IRB on file:  |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | * Initial IRB approval
 |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | * Continuing review approvals
 |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | * Modification approvals
 |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | * Interim and final reports (not IRB continuing review or closure reports)
 |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | * Notifications of IRB disapproval, deferral, modifications required to secure approval
 |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | * Responses to IRB actions
 |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | * IRB suspensions or terminations
 |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | Subject screening log **Number screened:**  |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | Subject enrollment log **Number enrolled:**  |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | Subject identification code list |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | Correspondence to and from the sponsor/CRO/monitor, including letters, meeting notes, notes of telephone calls |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | CVs or other relevant documents evidencing qualifications of PI, co-investigators, and all study personnel |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | CVs/other relevant information have been updated as requested by the sponsor, the IRB/EC and/or regulatory authority(ies) |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | Records of investigator and staff training required by the protocol |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | Records of investigator and staff training required by the institution |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | Staff signature log  |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | Staff working on the study are listed with the IRB |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | Delegation of responsibility (The investigator maintains a list of appropriately qualified persons to whom the investigator has delegated significant trial-related duties.) |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | Monitoring is conducted in accordance to the plan (e.g. monitoring log, monitoring visit reports submitted per protocol) |
|  |  |  |
|  | Regulatory General -Document Retention |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | Research records are to be retained for at least 3 years after the completion of the research. |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | HIPAA authorizations are to be retained for 6 years from the date of its creation or the date when it was last in effect, whichever is later. |
|  |  |  |
|  | Regulatory General -Other |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | The investigator or sponsor, upon request by the IRB, FDA or any other regulatory authority(ies) shall provide accurate, complete, and current information about any aspect of the investigation. |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | Monitoring visit reports are filed with the QA-CMR Central File. |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | If the research involves deception, there is a process to debrief the participant.  |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | If there is the transfer of tangible research materials between two organizations where the recipient intends to use the materials for research purposes, there is a material transfer agreement. |
|  | Other | [Additional requirements may apply depending upon the treatment under study] |

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| D. Regulatory – Clinical Trials |
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|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | Record of retained body fluids/ tissue samples |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | Instructions for handling of investigational product(s) and trial-related materials (if not in protocol or investigator’s brochure) |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | Decoding procedures for blinded trials |
|  |  | Laboratory items: |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | * Normal lab values
 |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | * Updates to normal lab values
 |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | * Lab certification (e.g. CLIA)
 |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | * Updates to lab certification (e.g. CLIA)
 |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | Site Initiation report/visit documentation |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | Study close-out report/visit documentation |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | DSMB reports |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | For marketed products, a package insert/product information |
|  |  |  |
|  | Other | [Additional requirements may apply depending upon the treatment under study] |

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| **E. Drugs & Devices**  |
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|  | Drugs & Devices - Both Drug & Device Studies |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | A signed current FDA 1572 (drug) or Investigator Statement (device) |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | Previous signed versions of FDA 1572 (drug) or Investigator Statements (device) |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | A current signed financial disclosure form submitted to the sponsor |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | Previous versions of signed financial disclosure forms submitted to the sponsor |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | Valid licensure for each investigator/staff member listed on the 1572 (drug) or in the Investigator Statement (device) |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | Current investigator brochure (drug) or Report of Prior Investigations (device) |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | Previous versions of or updates to the investigator brochure or Report of Prior Investigations |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | There is shipping log for each ~~drug~~ investigational product. These include: |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | * Date shipment received
 |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | * Shipment # from packing slip
 |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | * Batch#/lot #/code mark
 |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | * # of boxes, kits, or devices per lot #
 |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | * # of bottles, vials, inhalers, or devices per box or kit
 |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | * Condition of study drug/device shipment (Intact/damaged)
 |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | * Receiver’s name
 |
|  |  | Sponsor-investigators who file an IND or IDE with the FDA must submit copies of all documents relevant to the FDA pre-submission and INDE/IDE to the IND/IDE Central file. The required documentation copies include: |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | * The application
 |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | * Safety reports
 |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | * Amendments
 |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | * Communications, including transcriptions of calls with the FDA
 |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | * Annual report(s)
 |
|  |  |  |
|  | Drugs & Devices - Drug Studies (includes Biologics) |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | There is an accountability log for each drug under investigation. These include: |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | * Subject ID #, initials, or name
 |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | * Lot or kit number
 |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | * # Bottles, vials, etc.
 |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | * Total amount dispensed
 |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | * Date dispensed
 |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | * Total amount returned
 |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | * Balance: number dispensed less number returned
 |
|  |  |  |
|  | Drugs & Devices - Drug Studies - Reporting |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | The investigator furnishes all reports to the sponsor of the drug. |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | 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 [ ]  N/A [ ]  N/R** | An investigator shall provide the sponsor with an adequate report shortly after completion of the investigator’s participation in the investigation. |
|  |  |  |
|  | Drugs & Devices - Drug Studies - Labeling |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | Investigational Product Label sample is available in study file. |
|  |  |  |
|  | Drugs & Devices - Drug Studies - Product Management |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | Ensure that only a licensed practitioner or pharmacist is authorized to compound or dispense legend drugs.  |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | Ensure that all drugs dispensed to or for a patient to self-administer, unless dispensed in unit dose, must be labeled with specific information: name, address, and telephone number of clinic or physician's office. |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | Only a person licensed within the state of Minnesota and so authorized by their professional scope of practice must administer a legend or investigational new drug to a subject. A principal investigator may designate the responsibility of administering the drug only after the designee has been given and has demonstrated an understanding of basic pharmacologic information about the drug.  |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | Any clinical research project performed by an investigator involving the use of a legend or investigational new drug in an inpatient setting will require involvement of the University of Minnesota Medical Center, Fairview Department of Pharmaceutical Services' Investigational Drug Service (Fairview IDS). |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | For all inpatient studies at a Fairview Health Services site, Fairview IDS serves as the coordinator and control center for all investigational drugs. |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | For all outpatient studies at a Fairview Health Services site or a non-Fairview Health Services site, the Investigational Drug Studies Registration form outlines the information that must be provided to Fairview IDS and the study must be registered with Fairview IDS. |
|  |  |  |
|  | Drugs & Devices - Device Studies |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | There is an accountability log for each device under investigation. Items include: |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | * Subject ID #, initials, or name
 |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | * Study device lot #, batch #, or code mark
 |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | * Date dispensed
 |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | * Device disposition (returned, repaired or disposed)
 |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | * Comments, such as malfunctions, device failure, or any other pertinent information concerning the device
 |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | * Person who dispensed the device
 |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | Correspondence with an IRB, the sponsor, a monitor, or FDA, including required reports |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | If a FDA-regulated study, correspondence with another investigator |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | 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 [ ]  N/A [ ]  N/R** | Instructions for handling of investigational product(s) and trial-related materials (if not in protocol or investigator’s brochure) |
|  |  |  |
|  | Drugs & Devices - Device Studies - Reporting |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | An investigator shall report to the sponsor and to the reviewing IRB a report of any unanticipated adverse device effect occurring during an investigation no later than 10 working days after the investigator first learns off the effect.  |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | An investigator shall submit progress reports on the investigation to the sponsor, the monitor, and the reviewing IRB at regular intervals (e.g. “continuing review”), but in no event less often than yearly. In the case of a significant risk device, a sponsor shall also submit progress reports to FDA. |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | An investigator shall notify 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 shall be given as soon as possible, but in no event later than 5 working days after the emergency occurred.  |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | An investigator, within 3 months after termination or completion of the investigation or the investigator's part of the investigation, shall submit a final report to the sponsor and the reviewing IRB. |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | An investigator shall notify the sponsor, within 5 working days, a withdrawal of approval by the reviewing IRB of the investigator’s part of an investigation. |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | 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 [ ]  N/A [ ]  N/R** | If the study is a sponsor-investigator study, the sponsor shall also notify FDA of the device use. |
|  |  |  |
|  | Drugs & Devices - Device Studies - Labeling |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | The device is labeled with the name and place of business of the manufacturer.  |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | The device is labeled with the following statement: “CAUTION-Investigational device. Limited by Federal (or United States) law to investigational use.” |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | The labeling describes all relevant contraindications, hazards, adverse effects, interfering substances or devices, warnings, and precautions.  |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | The labeling does not contain any false or misleading statements or imply that the device is safe or effective for the purposes being investigated. |
|  |  |  |
|  | Drugs & Devices - Fetal Tissue Studies |
|  |  | Researchers conducting research on the transplantation of human fetal tissue or cell lines derived from human fetal tissue for therapeutic purposes must: |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | * Submit a fetal tissue acquisition form to the Anatomy Bequest Program (ABP) or obtain approval from ABP for the source of human fetal tissue supplied by a research sponsor
 |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | * Register the research with the Research Compliance Office (RCO) in the Office of the Vice President for Research
 |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | * Retain the tissue only for the amount of time necessary to complete the research
 |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | * Notify ABP when the research is complete to arrange for disposition of any remaining human fetal tissue
 |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | All personnel, including students, using human fetal issue in research must complete the training provided by ABP. |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | Personnel who performs human fetal tissue transplantation research must be separate from the attending physician treating the person undergoing an induced abortion. |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | University personnel (personnel) may accept and/or use human fetal tissue for transplantation into a relative of the donor or other individual designated by the donor (i.e., donor-designated recipient) only if the tissue is obtained from a spontaneous abortion or stillbirth.  |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | Human fetal tissue from a spontaneous abortion or stillbirth may be used for human fetal tissue transplantation research only with the informed consent of both parents of the fetus. If either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, it is sufficient to obtain the informed consent of one parent to donate the tissue for human fetal transplantation research. |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | Informed consent must be obtained for the transplantation procedure from the recipient of the transplant or the recipient's parent/legal guardian. |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | Researchers conducting research for therapeutic purposes using human embryos or human stem cells must obtain approval from the Stem Cell Research Oversight (SCRO) Panel. |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | When required by other University policies and federal regulations, researchers also must also obtain approval from the Institutional Animal Care and Use Committee (IACUC) and/or the Institutional Biosafety Committee (IBC). |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | Federal funds are allowable only for research using federally approved human embryonic stem cell (hESC) lines or for research that involves no more than minimal risk to embryos. |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | No federal or state of Minnesota funding may be used to support the derivation of new hESC lines or research using hESC lines derived from any source other than excess in vitro fertilization embryos created for reproductive purposes. |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | Units must register studies involving human embryos or human embryonic stem cell lines ineligible for federal or state funding with the Office of Biotechnology Activities (OBAO) in the OVPR.  |
|  |  |  |
|  | Other | [Additional requirements may apply depending upon the treatment under study] |

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| **F. SI IND Requirements**  |
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|  | SI IND Requirements - Responsibilities |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | The sponsor-investigator submits a completed Form FDA 3454 attesting to the absence of financial interests and arrangements for all participating clinical investigators. |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | For any participating clinical investigator for whom the sponsor-investigator does not submit a completed Form FDA 3454, the sponsor-investigator submits a completed Form FDA 3455 (Disclosure Statement). |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | The sponsor-investigator selects investigators qualified by training and experience. |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | The sponsor-investigator provides participating investigators with the information they need to conduct an investigation properly. |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | The sponsor-investigator maintains an effective IND with respect to the investigations.  |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | The sponsor-investigator ensures that FDA is promptly informed of significant new adverse effects or risks with respect to the drug.  |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | The sponsor-investigator ensures that all participating investigators are promptly informed of significant new adverse effects or risks with respect to the drug. |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | The sponsor-investigator ships investigational new drugs only to investigators participating in the investigation. |
|  |  | Before permitting an investigator to begin participation in an investigation, the sponsor-investigator obtains the following:  |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | * A signed investigator statement (Form FDA-1572)
 |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | * A curriculum vitae or other statement of qualifications of the investigator
 |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | * Sufficient accurate financial information to allow the sponsor-investigator to submit complete and accurate certification or disclosure statements
 |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | * If more than one protocol is being followed, an outline of the protocol
 |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | The sponsor-investigator provides each participating clinical investigator an investigator brochure. |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | The sponsor-investigator ensures that all participating investigators are promptly informed of significant new adverse effects or risks with respect to the drug and are informed of new observations discovered by or reported to the sponsor-investigator. |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | If the study is registered at http://www.ClinicalTrials.gov, the sponsor-investigator updates the information, as required. |
|  |  |  |
|  | SI IND Requirements - Monitoring |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | The sponsor-investigator selects a monitor qualified by training and experience to monitor the progress of the investigation. |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | The sponsor-investigator monitors the progress of all clinical investigations being conducted under the IND.  |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | If the sponsor-investigator discovers that an investigator is not complying with the signed agreement (Form FDA-1572), the general investigational plan, or other applicable requirements; the sponsor-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 [ ]  N/A [ ]  N/R** | If the investigator’s participation in the investigation is ended, the sponsor-investigator ensures that the investigator disposes of or returns the investigational drug and notifies the FDA. |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | The sponsor-investigator reviews and evaluates the evidence relating to the safety and effectiveness of the drug as it is obtained from the investigator(s). |
|  |  | If the sponsor-investigator determines that the investigational drug presents an unreasonable and significant risk to subjects, the sponsor-investigator: |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | * Ensures discontinuation of those investigations that present the risk
 |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | * Notifies the FDA, all institutional review boards, and all investigators who have at any time participated in the investigation of the discontinuance
 |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | * Ensures the disposition of all stocks of the drug outstanding
 |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | * Furnishes the FDA with a full report of the sponsor-investigator’s actions
 |
|  |  | * Discontinues the investigation as soon as possible, and in no event later than 5 working days after making the determination that the investigation should be discontinued
 |
|  |  |  |
|  | SI IND Requirements - Reporting |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | The sponsor-investigator notifies FDA and all participating investigators in an IND safety report of potential serious risks as soon as possible, but in no case later than 15 calendar days after the sponsor-investigator determines that the information qualifies for reporting. |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | The sponsor-investigator shall submit annual reports on the progress of the investigation to FDA.  |
|  |  |  |
|  | SI IND Requirements – Product Management |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | The sponsor-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 [ ]  N/A [ ]  N/R** | The sponsor-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 [ ]  N/A [ ]  N/R** | The sponsor-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 [ ]  N/A [ ]  N/R** | The sponsor-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 sponsor-investigator ensures: |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | * 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 [ ]  N/A [ ]  N/R** | * 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 [ ]  N/A [ ]  N/R** | The sponsor-investigator ensures the return or authorizes a safe alternative disposition of all unused supplies of the investigational drug from each individual investigator whose participation in the investigation is discontinued or terminated. |
|  |  |  |
|  | Other | [Additional requirements may apply depending upon the treatment under study] |

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| G. Abbrev. SI IDE & SI IDE Requirements  |
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|  | Abbrev. SI IDE & SI IDE Requirements - Monitoring |
|  | [ ]  Yes [ ]  No [ ]  N/A [ ]  N/R | A sponsor-investigator shall immediately conduct an evaluation of any unanticipated adverse device effect.  |
|  | [ ]  Yes [ ]  No [ ]  N/A [ ]  N/R  | The sponsor determines whether an unanticipated adverse device effect presents an unreasonable risk to subjects. |
|  | [ ]  Yes [ ]  No [ ]  N/A [ ]  N/R | The sponsor shall terminate all investigations or parts of investigations presenting that risk not later than 5 working days after making this determination and not later than 15 working days after first receiving notice of the effect.  |
|  | [ ]  Yes [ ]  No [ ]  N/A [ ]  N/R | * If the device is a significant risk device, a sponsor may not resume a terminated investigation without IRB and FDA approval.
 |
|  | [ ]  Yes [ ]  No [ ]  N/A [ ]  N/R | * If the device is not a significant risk device, a sponsor may not resume a terminated investigation without IRB approval.
 |
|  | [ ]  Yes [ ]  No [ ]  N/A [ ]  N/R  | A sponsor shall select monitors qualified by training and experience to monitor the investigational study. |
|  |  |  |
|  | Abbrev. SI IDE & SI IDE Requirements - Records |
|  |  | The sponsor maintains the following records consolidated in one location and available for FDA inspection and copying: |
|  | [ ]  Yes [ ]  No [ ]  N/A [ ]  N/R | * A statement of the extent to which the good manufacturing practice regulation in part 820 will be followed in manufacturing the device
 |
|  | [ ]  Yes [ ]  No [ ]  N/A [ ]  N/R | * The name and intended use of the device and the objectives of the investigation
 |
|  |  | * A brief explanation of why the device is not a significant risk device
 |
|  | [ ]  Yes [ ]  No [ ]  N/A [ ]  N/R  | * The name and address of each investigator
 |
|  | [ ]  Yes [ ]  No [ ]  N/A [ ]  N/R  | * The name and address of each IRB that has reviewed the investigation
 |
|  | [ ]  Yes [ ]  No [ ]  N/A [ ]  N/R | * Records concerning adverse device effects (whether anticipated or unanticipated) and complaints.
 |
|  |  | A sponsor-investigator shall maintain: |
|  | [ ]  Yes [ ]  No [ ]  N/A [ ]  N/R  | * All correspondence with another sponsor, a monitor, an investigator, or FDA, including required reports
 |
|  | [ ]  Yes [ ]  No [ ]  N/A [ ]  N/R  | * Records of shipment and dispositions, including name and address of consignee, type and quantity of device, date of shipment, and batch numbers or code marks of any devices returned to the sponsor-investigator, repaired, or disposed and the reasons for and method of disposal
 |
|  | [ ]  Yes [ ]  No [ ]  N/A [ ]  N/R  | * Signed investigator agreements including the financial disclosure information
 |
|  | [ ]  Yes [ ]  No [ ]  N/A [ ]  N/R  | * Records concerning adverse device effects (whether anticipated or unanticipated) and complaints
 |
|  |  |  |
|  | Abbrev. SI IDE & SI IDE Requirements - Reports |
|  | [ ]  Yes [ ]  No [ ]  N/A [ ]  N/R  | A sponsor-investigator who conducts an evaluation of an unanticipated adverse device effect shall report the results to FDA, all reviewing IRBs and participating investigators within 10 working days after the sponsor-investigator first receives notice of the effect. Thereafter, the sponsor-investigator shall submit such additional reports concerning the effect as requested. |
|  | [ ]  Yes [ ]  No [ ]  N/A [ ]  N/R  | A sponsor-investigator shall notify FDA, all reviewing IRB's and participating investigators of any withdrawal of approval of an investigation or a part of an investigation by a reviewing IRB within 5 working days after receipt of the withdrawal of approval. |
|  | [ ]  Yes [ ]  No [ ]  N/A [ ]  N/R  | A sponsor-investigator shall notify all reviewing IRB's and participating investigators of any withdrawal of FDA approval of the investigation, and shall do so within 5 working days after receipt of notice of the withdrawal of approval. |
|  | [ ]  Yes [ ]  No [ ]  N/A [ ]  N/R  | At regular intervals, and at least yearly, the investigator submitted progress reports to the monitor and all reviewing IRBs.  |
|  | [ ]  Yes [ ]  No [ ]  N/A [ ]  N/R  | If the device is a significant risk device, a sponsor-investigator shall also notify FDA. |
|  | [ ]  Yes [ ]  No [ ]  N/A [ ]  N/R  | A sponsor-investigator shall notify FDA and all reviewing IRB's 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.  |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | The sponsor-investigator reports significant new information about the investigation to the reviewing IRBs. |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | If the device is a significant risk device, the sponsor-investigator shall also notify the FDA. |
|  |  | If the device is a significant risk device: |
|  | [ ]  Yes [ ]  No [ ]  N/A [ ]  N/R | * The sponsor-investigator shall notify FDA within 30 working days of the completion or termination of the investigation.
 |
|  | [ ]  Yes [ ]  No [ ]  N/A [ ]  N/R | * The sponsor-investigator shall submit a final report to FDA and all reviewing IRBs within 6 months after termination or completion.
 |
|  | [ ]  Yes [ ]  No [ ]  N/A [ ]  N/R | If the device is not a significant risk device, the sponsor-investigator shall submit a final report to all reviewing IRB's within 6 months after termination or completion. |
|  |  |  |
|  | Abbrev. SI IDE & SI IDE Requirements - Responsibilities |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | A sponsor-investigator shall select investigators qualified by training and experience to investigate the device. |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | A sponsor-investigator shall ship investigational devices only to qualified investigators participating in the investigation. |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | A sponsor-investigator shall obtain from each participating investigator a signed agreement. The agreement is to include: |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | * Investigator's curriculum vitae
 |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | * Statement of investigator's relevant experience, including dates, location, extent, and type of experience
 |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | * If an investigator was involved in an investigation or other research that was terminated, an explanation of the circumstances that led to the termination
 |
|  | [ ]  Yes [ ]  No [ ]  N/A [ ]  N/R  | * Statement of the investigator's commitment to:
 |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | * Conduct the investigation in accordance with the agreement, the investigational plan, this part and other applicable FDA regulations, and conditions of approval imposed by the reviewing IRB or FDA
 |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | * Supervise all testing of the device involving human subjects
 |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | * Ensure requirements for obtaining informed consent are met
 |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | * Sufficient accurate financial disclosure information to allow the sponsor-investigator to submit a complete and accurate certification or disclosure statement
 |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | * The sponsor-investigator shall obtain a commitment from the clinical investigator to promptly update this information if any relevant changes occur during the course of the investigation and for 1 year following completion of the study.
 |
|  | [ ]  Yes [ ]  No [ ]  N/A [ ]  N/R  | A sponsor-investigator shall supply all investigators participating in the investigation with copies of the investigational plan and the report of prior investigations of the device. |
|  |  | A sponsor-investigator who discovers that an investigator is not in compliance shall: |
|  | [ ]  Yes [ ]  No [ ]  N/A [ ]  N/R  | * promptly either secure compliance, or discontinue shipments of the device to the investigator and terminate the investigator's participation in the investigation
 |
|  | [ ]  Yes [ ]  No [ ]  N/A [ ]  N/R  | * require such an investigator to dispose of or return the device, unless this action would jeopardize the rights, safety, or welfare of a subject
 |
|  | [ ]  Yes [ ]  No [ ]  N/A [ ]  N/R  | If the study is registered at http://www.ClinicalTrials.gov, the sponsor-investigator updates the information, as required. |
|  |  |
|  | Abbrev. SI IDE & SI IDE Requirements - Device Promotion |
|  | [ ]  Yes [ ]  No [ ]  N/A [ ]  N/R | * Unduly prolong an investigation
 |
|  | [ ]  Yes [ ]  No [ ]  N/A [ ]  N/R | * Represent that an investigational device is safe or effective
 |
|  |  |  |
|  | Other | [Additional requirements may apply depending upon the treatment under study] |

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| H. Abbreviated SI IDE Requirements |
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|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | The protocol/sponsor-investigator includes a brief explanation of why the device is not a significant risk device. |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | If an IRB determines that a device is a significant risk device, and the sponsor-investigator had proposed that the IRB consider the device not to be a significant risk device, the sponsor-investigator shall submit to FDA a report of the IRB’s determination within 5 working days after first learning of the IRB’s determination. |
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|  | Other | [Additional requirements may apply depending upon the treatment under study] |

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| I. SI IDE Requirements |
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|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | The sponsor-investigator obtains FDA approval for the investigation. |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | The sponsor-investigator obtains FDA approval for a supplemental application before beginning that portion of the investigation. |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | The sponsor-investigator obtains maintains the FDA application. |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | A sponsor-investigator shall submit to FDA, at 6-month intervals, a current list of the names and addresses of all investigators participating in the investigation. The sponsor-investigator shall submit the first such list 6 months after FDA approval*.* |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | The sponsor-investigator reports to the FDA of any deviation from the investigational plan to protect the life or physical well-being of a subject in an emergency, no later than 5 working days after the emergency occurs.  |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | An investigator or sponsor-investigator may withdraw from the responsibility to maintain records and transfer custody of the records to any other person who will accept responsibility for them. Notice of a transfer shall be given to FDA not later than 10 working days after transfer occurs. |
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|  | Other | [Additional requirements may apply depending upon the treatment under study] |

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| J. Case Histories |
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|  | Case Histories - Subject Selection |
|  | [ ]  Yes [ ]  No [ ]  N/A [ ]  N/R | There is documentation that eligibility has been met (e.g. checklist). |
|  | [ ]  Yes [ ]  No [ ]  N/A [ ]  N/R | The documentation is dated and signed/initialed by the person obtaining the information, if applicable. |
|  | [ ]  Yes [ ]  No [ ]  N/A [ ]  N/R | If the study includes the use of medical records, there is documentation that subject did not opt out of the use of their medical record for research. |
|  | [ ]  Yes [ ]  No [ ]  N/A [ ]  N/R | The recruitment plan was followed in accordance with the protocol. |
|  |  |
|  | Case Histories - Consent |
|  | [ ]  Yes [ ]  No [ ]  N/A [ ]  N/R | *Original* copies of all consent forms signed and dated by subjects are on file (not a photocopy). |
|  | [ ]  Yes [ ]  No [ ]  N/A [ ]  N/R | There is a current consent form on file. |
|  | [ ]  Yes [ ]  No [ ]  N/A [ ]  N/R | All previous consent forms are on file.  |
|  | [ ]  Yes [ ]  No [ ]  N/A [ ]  N/R | Valid IRB-approved consent forms were used. |
|  | [ ]  Yes [ ]  No [ ]  N/A [ ]  N/R | All pages of the consent forms are on file for each subject. |
|  | [ ]  Yes [ ]  No [ ]  N/A [ ]  N/R | All yes/no or similar options on the consent forms are completed/initialed. |
|  | [ ]  Yes [ ]  No [ ]  N/A [ ]  N/R | Consent forms are free of any handwritten changes/corrections. |
|  | [ ]  Yes [ ]  No [ ]  N/A [ ]  N/R | There are appropriately signed consent documents.  |
|  | [ ]  Yes [ ]  No [ ]  N/A [ ]  N/R | It is documented that the subject (if long form) or person signing (short form) was given a copy of the consent form. |
|  | [ ]  Yes [ ]  No [ ]  N/A [ ]  N/R | 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. |
|  | [ ]  Yes [ ]  No [ ]  N/A [ ]  N/R | Documentation that informed consent was obtained prior to participation in the study.  |
|  | [ ]  Yes [ ]  No [ ]  N/A [ ]  N/R | The consent process was followed in accordance with the protocol. |
|  | [ ]  Yes [ ]  No [ ]  N/A [ ]  N/R | The HIPAA form was completed properly.  |
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|  | Case Histories - Data Collection Source Documents |
|  | [ ]  Yes [ ]  No [ ]  N/A [ ]  N/R | Data collection is complete/accurate for each subject. (e.g. no blank fields/missing data). |
|  | [ ]  Yes [ ]  No [ ]  N/A [ ]  N/R | Source documentation is available to support clinical data reported (e.g. medical records, progress notes of the physician, the individual’s hospital chart(s), and the nurses’ notes).  |
|  | [ ]  Yes [ ]  No [ ]  N/A [ ]  N/R | The source documentation/CRF for each subject includes dated signature/initials of the person obtaining the information for each subject.  |
|  | [ ]  Yes [ ]  No [ ]  N/A [ ]  N/R | Changes/cross-outs, additional comments (if any) in subject files routinely initialed and dated. |
|  | [ ]  Yes [ ]  No [ ]  N/A [ ]  N/R | 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). |
|  | [ ]  Yes [ ]  No [ ]  N/A [ ]  N/R | Participant compensation is made according to the protocol and/or consent form (e.g. OnCore, EPIC). |
|  | [ ]  Yes [ ]  No [ ]  N/A [ ]  N/R | Billing for research-related procedures is in compliance with the protocol and/or consent form. |
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|  | Case Histories - Other |
|  | **[ ]  Yes [ ]  No [ ]  N/A [ ]  N/R** | If the research involves deception, the participant was debriefed.  |
|  |  | [Additional requirements may apply depending upon the treatment under study] |