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| --- | --- |
| **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 | | |
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|  | **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** | | |
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|  | **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) |
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|  | 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) |
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|  | 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. |
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|  | 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. |
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|  | 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. |
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|  | 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. |
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|  | 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 |
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|  | 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. |
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|  | 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. |
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|  | 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. |
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|  | 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 |
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|  | 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. |
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|  | 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. |
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|  | 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 |
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|  | 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. |
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|  | 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] |