**Study Administrative File**

**Device Study**

**Table of Contents**

**CORRESPONDENCE**

* **IRB Correspondence**
* **Institutional Reviewing Committees**
* **Sponsor/CRO Correspondence**
* **CMS-NGS Correspondence**
* **General Correspondence**

**STUDY DOCUMENTS**

* **Protocol**
* **Informed Consent & HIPAA Authorization**
* **Case Report Form Sample**
* **Device Information**
* **FDA Investigator Agreement (CFR 812.43)**
* **Laboratory Documents**

**STUDY TRACKING LOGS**

* **Subject Logs**
* **Adverse Events & Unanticipated Adverse Device Effects**
* **Investigational Product Accountability**
* **Monitoring**

**RESEARCH PERSONNEL**

* **Curriculum Vitae & Licenses**
* **Signature and Delegation of Responsibility Log**

**IRB CORRESPONDENCE**

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| * **IRB Correspondence**   + Include copy of and documentation of initial submission form   + Include all approval/acknowledgement letters   + Correspondence between the research site and the IRB regarding the conduct of the study and the research subjects   + IRB correspondence may include: approval letters, protocol amendments, changes to the consent form, study updates, protocol violations, adverse event reporting, continuing review reports, and notification of study termination * **IRB Membership/Assurance**   + The IRB of record issues a letter with a DHHS assurance number that documents the IRB is in conformance to federal regulations. If this number or letter is centrally available on an institutional webpage, a reference can be made to the webpage location. Both [OHRP’s online FWA database](https://ohrp.cit.nih.gov/search/fwasearch.aspx?styp=bsc) and NYU Langone Health’s [Resources for Sponsors webpage](https://med.nyu.edu/research/office-science-research/clinical-research/resources-sponsors) contain information regarding NYU Langone Health’s Federal Wide Assurance numbers * **Federal Agencies that may review/approve the study** * **BRANY:** If BRANY is the IRB of record, the items below should all apply to correspondence with BRANY |

* IRB Initial Submission Form
* IRB Approval Letter
* IRB Letter of Assurance
* IRB Correspondence
* IRB Amendment Submission Form
* Continuing Review
* Final Study Closure Letter
* Final Study Report

Institutional REVIEW COMMITTEES

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| * **Letters of Approval or Receipt of Submission** from the NYU reviewing committees relevant to the study * **Copies of any correspondence** * Emails can be accepted as a source of communication |

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| **Copy of Submission** | | **Approval Letter** | | **N/A** |  | |
|  |  | |  | | | **Device Review Committees:**   * ICB: Inventory Control Board - Tisch * New Product Committee – HJD * Value Analysis - EP LAB |
|  |  | |  | | | **Bellevue** |
|  |  | |  | | | **Radiation Safety** |
|  |  | |  | | | **CMS/NGS –** (Center for Medicare and Medicaid/National Government Services |
|  |  | |  | | | **CTSI**: Clinical & Translational Research Center |
|  |  | |  | | | **ESCRO**: Embryonic Stem Cell Research Oversight Committee |
|  |  | |  | | | **IBC:** Institutional Biosafety Committee (Environmental Health and Radiation Safety) |
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SPONSOR / CRO

CORRESPONDENCE

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| * Includes relevant communication between investigative sites, the CRO or study sponsor, regarding study administration, study conduct, subject management, protocol violations, and adverse events * Correspondence may take the form of letters, facsimiles, telephone discussions, and emails   1. *Document correspondence in such a manner that the date, persons involved, and relevance to the study is apparent* * Facsimile confirmations and shipping receipts should be saved and filed with the corresponding documents as proof (receipt) of communication * If the sponsor is the Department or another internal source, this section is not applicable |

**Correspondence to/from:**

* Sponsor
* CRO
* Other Investigative Sites

CMS CORRESPONDENCE

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| * All device studies that involve a device with the categorization of an IDE or 510K must be approved by Center for Medicare and Medicaid Services (CMS) through Local Medicare Beneficiary. National Government Services (NGS) is the entity for New York State. * The process involves sending the Device Submission Form to NGS. Response from NGS will indicate whether or not they will reimburse for the costs of the trial. * NGS will respond to an email inquiring whether or not they have reviewed the trial for another site. If you are the first site to ask for a review, the process is slightly different than if they have made a decision prior to your review request. * Correspondences will be either hard copy letters or electronic communications. |

* NGS Submission for Review
* NGS Coverage Response

GENERAL CORRESPONDENCE

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| * Includes relevant communication within NYU between clinical personnel, and additional service providers such as radiology etc. regarding study administration, study conduct, subject management, protocol violations, and adverse events. * Correspondence may take the form of letters, facsimiles, telephone discussions, and emails   1. *Document correspondence in such a manner that the date, persons involved, and relevance to the study is apparent* * Facsimile confirmations and shipping receipts should be saved and filed with the corresponding documents as verification (receipt) of communication |

**Correspondence to/from:**

* Investigator
* Other Research Personnel
* Additional service providers

**PROTOCOL**

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| * **Protocol**   + The document that describes the objective(s), design, methodology, statistical considerations, and organization of a research study   + Maintain all versions in file * **Protocol Amendments**    + A written description of a change(s) to or formal clarification of a protocol   + Each amendment should indicate a date of revision and version number     - * **NOTE**: Protocol amendments must be IRB-approved **before** being implemented |

**INFORMED CONSENT**

**& HIPAA AUTHORIZATION**

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| * **Informed Consent Form**    + A copy of the IRB-approved Informed Consent Form must be kept on file   + A consent form is not valid for subject use at NYU without an affixed IRB approval stamp on the first page   + All versions of the approved consent are kept in the regulatory files: the original version and all revisions     - * *indicate dates of approval and expiration for each version*   + Include where applicable Assent Form, Translated Consent Form, Short Form   + Consent should indicate which costs will be the responsibility of the subject and his/her insurance as well as which costs will be covered by the study sponsor (ie- the investigational drug, device, etc) * **IRB Approved Educational Materials and Advertisements**    + Information describing the study that is to be presented to subjects in verbal or written form, including recorded audiovisual media   + These materials help substantiate that subjects were given appropriate information to support their ability to fully give informed consent |

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| * **HIPAA Authorization Form** *(if not incorporated into the consent form):*   + A copy of the HIPAA Authorization Form or copy of IRB Waiver of HIPAA Authorization Form. Include acknowledgement of receipt by the IRB. * **Disclosures of PHI**    + When disclosures of PHI are reported, include documentation of this reporting here |

**CASE REPORT FORM**

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| * **Clean Copy of the Case Report Form packet (if paper CRF’s are available)**   + All versions of the CRF should be maintained * **Case Report Form Completion Guidelines** * **For electronic Case Report Forms, it is not necessary to print out hard copies as long as they are maintained in the online database** |

* Case Report Form (clean copy)
* Case Report Form Completion Guidelines
* All Case Report forms are electronic

**Device Information**

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| * **Device Manual**   + Provides relevant and current scientific information about the investigational product   + Maintain most current brochure including updates and revisions * **Product Labeling and Handling Instructions**   + For approved products, include the package insert and/or approved labeling   + Maintain a sample of the label(s) attached to the containers   + Include instructions for handling the investigational product   + If applicable, include procedures for un-blinding * **Radiation Safety Manual**   + Required only for studies involving use of radioactive products |

* Device Manual
* Product Labeling and Handling Instructions
* Radiation Safety Manual

**INVESTIGATOR AGREEMENT – CFR 812.43**

**Investigator’s Agreement**

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| * The Investigator’s Agreement declares the Principal Investigator's commitment to:   + conduct the investigation in accordance with the agreement, the investigational plan, applicable FDA regulations, and conditions of approval imposed by the reviewing IRB or FDA   + supervise all testing of the device involving human subjects   + ensure that the requirements for obtaining informed consent are met * The original, signed Investigator’s Agreement is be filed with the sponsor prior to study initiation and a copy will be placed in the Study Administrative File * FDA regulations do not require a 1572 to be filed for device trials |

**Confirm presence of Investigator’s Agreement and any updates by initialing and dating below:** (🞎 Not Applicable)

Initial / date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Update / date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Update / date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Update / date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Update / date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**LABORATORY DOCUMENTS**

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| * **Laboratory Certifications and Licenses**    + Required for studies utilizing laboratory data or results   + Provides evidence of the competence of the facility to perform the required test(s) and supports the reliability of the lab results   + NYU or Bellevue certifications may include: the state laboratory license/permit, an accreditation by The College of American Pathologists ( CAP ), Clinical Laboratory Improvement Amendment Accreditation (CLIA), and the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO), CV of laboratory license holder   + For NYU Lab certificates, go to the following link:   https://central.nyumc.org/research/site/ore/Pages/Updated-Laboratory-Certification.aspx   * **Normal Reference Ranges**    + Laboratory reference ranges may vary from laboratory to laboratory; therefore, it is necessary to include documentation of the laboratory's normal range values. All updates to the laboratory ranges must also be maintained.   + For NYU lab normal reference ranges, go to the following link: https://central.nyumc.org/research/site/ore/Pages/Updated-Laboratory-Certification.aspxand Click Normal Value Card * **Lab Manual(s), if applicable** |

* Current Lab Certification
* Lab Manual
* Current Normal Lab Ranges
* CV of Lab Director (local)
* Record of Retained Samples

**SUBJECT LOGS**

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| * **Screening Log**    + Identifies who was evaluated for the study and documents the criteria that excluded them from study participation   + Generally, subjects who were reviewed or consented for study participation, but were then found to be ineligible are considered screen failures * **Enrollment Log**    + Confidential list with identifiable information (e.g. name, date of birth, date of hospital admission)   + Identifies subject enrollment in chronological order   + Subjects who enrolled in the study and who withdrew or have been withdrawn   **These two types of logs can be maintained as one combined document or as two separate documents, depending on the need of the study** |

* Screening Log
* Enrollment Log
* Specimen Shipping Log
* Study Subject Contact Information (optional)

**ADVERSE EVENTS**

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| * An **Adverse Event** is defined by the US Department of Health and Human Services as: any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject’s participation in the research, whether or not considered related to the subject’s participation in the research * **Unanticipated Problems** (UAP) as defined by the NYU IRB are events (including internal or external events, deaths, life-threatening experiences, injuries, breaches of confidentiality, or other problems) that occur any time during or after the research study, which in the opinion of the Monitoring Entity or the PI are:  1. Unanticipated - not in the consent form, investigator brochure, protocol, package insert, or label; or unanticipated in its frequency, severity, or specificity 2. AND Related to the research procedures - caused by, or probably caused by research activity, or, if a device is involved, probably caused by, or associated with the device 3. AND Harmful - caused harm to participants or others, or placed them at increased risk of harm  * You should be familiar with the local regulatory board, the sponsor’s and the FDA’s reporting requirements for your study. * Adverse Events (AE) and Serious Adverse Events (SAEs) Tracking Log * Unanticipated Adverse Device Effects (including MedWatch forms) * Documents tracking AE Reporting (e.g. IRB, sponsor, federal agencies, etc.) * SAE Reports from participating sites **NOTE**: It may be beneficial to keep onsite AE reports separate from off-site AE reports within this section |

* AE Tracking Logs
* AE Reports sent to Sponsor
* SAE Reports from sponsor/participating sites
* SAE Report Form

**INVESTIGATIONAL PRODUCT ACCOUNTABILITY**

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| * Drugs and devices must be inventoried via a tracking or accountability form * Documentation may include shipments, receipt, dispensation, return and destruction of the investigational product * Include shipment receipts and supply correspondence |

* Investigational Product Accountability Log
* Shipment Receipts
* Investigational Product Supply Correspondence

**MONITORING**

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| * **Monitor Signature Log and Visit Record**   + Tracking document that records the visits made by the monitor throughout the course of the study * **Study Initiation Reports**   + Letter documenting that the procedures were reviewed prior to study initiation and the site was determined to be suitable for enrollment * **Interim Monitoring Reports**   + Letter documenting the findings after each monitoring visit * **Close-Out Report**   + A report or letter documenting that the study had a final monitoring visit after the conclusion of the study to ensure any outstanding issues have been resolved |

* Monitor Signature Log and Visit Record
* Study Initiation Report
* Interim Monitoring Reports

Report from visit date: \_\_\_\_\_\_\_\_\_\_\_

Report from visit date: \_\_\_\_\_\_\_\_\_\_\_

Report from visit date: \_\_\_\_\_\_\_\_\_\_\_

Report from visit date: \_\_\_\_\_\_\_\_\_\_\_

Report from visit date: \_\_\_\_\_\_\_\_\_\_\_

Report from visit date: \_\_\_\_\_\_\_\_\_\_\_

* Close-Out Report

**CURRICULUM VITAE & LICENSES**

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| **The utilization of a Central File is highly recommended for CVs & Licenses. If a central file is used a clear reference should be made on this page as to where that Central File can be located.**   * **Curriculum Vitae (CV)**    + A summary of the educational and academic backgrounds, teaching and research experience, publications, presentations, awards, honors, affiliations of each research staff   + CVs should be maintained for the PI, Sub-Investigators and Research Coordinators   + CVs should be signed, dated and recent (within 2 years) * **Medical Licenses**   + Professional licensure should be present for physicians and other licensed personnel   + The CV and license documents the qualifications and eligibility of staff to provide medical supervision and to conduct the study * **Training Certificates**   + May include copies of relevant training certificates (e.g. Human Subjects Protection training such as the Patient Oriented Research (POR) training certificate or CITI training, Environmental Health and Radiation Safety (EHRS) training, HIPAA training, etc.)   + Specimen Handling/Shipping * **Contact list for Personnel at other sites**   + For studies involving non-NYU Langone sites, include a listing of those personnel andtheir contact information.This allows for quick access to that information when needing to interact with personnel at those sites |

**Investigator**

□ CV

* Medical License
* Human Subjects Protections Training Certificate

**Co/Sub-Investigator(s)**

□ CV

* Medical License
* Human Subjects Protections Training Certificate

**Study Coordinator(s)**

* CV
* Clinical License (🞎 Not Applicable)
* Human Subjects Protections Training Certificate

**Contact list for Personnel at other sites**

**SIGNATURE AND DELEGATION OF RESPONSIBILITY LOG**

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| * **Signature and Delegation of Authority Log**   + The signature log contains examples of the signatures and initials of research staff   + Any provision of signature authorities approved by the PI should be included   + Identifies the study-related tasks that the PI has delegated to other research staff   + The delegation log and signature form may be combined into a single document   + May include a clear description of activities conducted by key staff at collaborating sites |