**Study Administrative File**

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\*As applicableIRB CORRESPONDENCE

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| * **IRB Correspondence**
* Include copy of and documentation of initial submission
* 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, reportable unanticipated problems posing risks to subjects or others, continuing review reports, and notification of study termination
* **IRB Membership/Assurance**
* NYU's IRB issues a letter with a DHHS assurance number (FWA00004028) that documents the IRB is in conformance to federal regulations
* **Federal Agencies that may review/approve the study**
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* IRB Initial Submission
* IRB Approval Letter
* IRB Letter of Assurance
* IRB Correspondence
* IRB Amendment Submission Forms
* Continuing Review
* Final Report

NYU REVIEWING ENTITIES

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| * **Letters of Approval or Receipt of Submission** from any of the other reviewing entities at NYU relevant to the study
* **Copies of initial submission and any correspondence**
* Emails can be accepted as a source of communication
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Letters of approval from other Relevant NYUentities

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| **Copy of Submission** | **Approval Letter** | **N/A** |  |
|  |  |  | **PRMC:** Protocol Review Monitoring Committee (NYU Cancer Institute) |
|  |  |  | **CTSI:** Clinical Translational Science Unit  |
|  |  |  | **Radiation Safety** |
|  |  |  | **Bellevue Hospital** |
|  |  |  | **BRC**: Biorepository Committee |
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\*\*These additions may not be relevant to this type of study but can be used in the other forms

SPONSOR/ CRO CORRESPONDENCE

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| * Includes relevant communication with the study sponsor/CRO regarding study administration, study conduct, subject management, protocol violations, and reportable unanticipated problems posing risks to subjects or others.
* 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
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**Correspondence to/from:**

* Sponsor
* CRO
* Other Investigative Sites

GENERAL CORRESPONDENCE

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| * Includes relevant communication within NYU between clinical personnel, research administrative offices, etc. regarding study administration, study conduct, subject management, protocol violations, and reportable unanticipated problems posing risks to subjects or others.
* 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
* NYU Research Administrative Office(s)

SITE CORRESPONDENCE

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| * This section is intended for multi-site research and includes relevant communication with investigative sites regarding study administration, study conduct, subject management, protocol violations, and reportable unanticipated problems posing risks to subjects or others.
* 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 this is a single-center study, this section is not applicable
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**Correspondence to/from:**

* Investigator
* Other Research Personnel
* Other Investigative Sites

**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 NYUwithout 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 expiry for each version*
* *Include where applicable Assent Form, Translated Consent Form, Short Form*
* **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
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 **CASE REPORT FORM**

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| * **Clean Copy of the Case Report Form**
	+ 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**
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* Case Report Form (clean copy)
* Case Report Form Completion Guidelines (🞎 Not Applicable)
* All Case Reports Forms are electronic

**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**
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* Screening Log
* Enrollment Log
* Specimen Shipping Log (🞎 Not Applicable)
* Study Subject Contact Information (optional)

**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 Curriculum Vitae (CV)**
	+ If monitor is hired by the PI, a copy of the monitor's CV
* **Monitor Curriculum Vitae (CV)**
* If monitor is hired by the PI, a copy of the monitor's CV
* **If no monitor is involved in this study check Not applicable**
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* 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: \_\_\_\_\_\_\_\_\_\_\_

* Close-Out Report
* Monitor’s CV (🞎 Not Applicable)
* Not applicable – There are no monitoring services being performed for this research

**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-NYULMC 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
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**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**

**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
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