**UPLOAD COMPLETED FORM WITH ALL APPLICABLE SIGNATURES IN IMEDRIS
WITH PROTOCOL AND STUDY DOCUMENTS (**[**https://imedris.mlhs.org**](https://imedris.mlhs.org)**)**

Date: Click or tap to enter a date. Department/Group: Click or tap here to enter text.

Principal Investigator: Click or tap here to enter text.

Affiliation with Main Line Health Entity:\* Click or tap here to enter text.
 \*MLH Employed Physician, NON-MLH Physician with Medical Staff Privileges, Employee Resident, etc.

Phone: Click or tap here to enter text. Email: Click or tap here to enter text.

Co-Investigator(s): Click or tap here to enter text.

IRB Study Title: Click or tap here to enter text.

Proposed Project Period: Click or tap to enter a date. To Click or tap to enter a date.

Is this a Funded/Sponsored Research Project?
[ ]  YES – **Complete Sections I through IV**

[ ]  NO – **Proceed to Section II through IV**

**SECTION I – Funding Information**

Sponsor/Granting Agency: Click or tap here to enter text.

Contact Name and Address for IRB Fees\*: Click or tap here to enter text.
\*MLH IRB Fees for all industry sponsored studies are charged as follows: 1) new studies ($2400); 2) continuing reviews ($850); 3) industry-initiated amendments ($500); local context review for industry sponsored multicenter clinical trials using single IRB ($850). These fees should be negotiated in all Clinical Trial Agreements/Contracts. The IRB fee schedule can be found at: <https://www.mainlinehealth.org/research/office-of-research-protections/institutional-review-board>

Indicate Sponsor/Granting Agency Type:

[ ]  Industry: Sponsor Name Click or tap here to enter text.

[ ]  Federal Grant: Agency Click or tap here to enter text.

[ ]  Private/Foundation Grant: Agency Click or tap here to enter text.

[ ]  Other (explain): Click or tap here to enter text.

If part of Grant Subcontract, include Full Project Title and Name of Principal Investigator:
Click or tap here to enter text.

**SECTION II – Certifications and Signatures**

Principal Investigator:
As the Principal Investigator, I certify that the information in this form is accurate and complete as of this date and agree to accept responsibility for the regulatory, scientific, and technical conduct of this research project in accordance with the policies and procedures of the sponsor, Main Line Hospitals, Inc. the Main Line Hospitals Institutional Review Board and the Lankenau Institute for Medical Research.

As the Principal Investigator, I acknowledge that all industry sponsored new studies ($2400), continuing reviews ($850) and industry-initiated amendments ($500) are charged MLH IRB Fees. An $850 MLH IRB fee is charged for industry sponsored multicenter clinical trials with Central IRB review. In addition, studies which are reviewed by the MLH IRB at Investigators Option, by Independent Physicians with Staff Appointments are charged fees for which I am responsible and vary depending on the type of review conducted.[[1]](#footnote-1) For more information refer to the IRB fee schedule located at: <https://www.mainlinehealth.org/research/office-of-research-protections/institutional-review-board>

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**Principal Investigator Name Signature Date**

Department Chair or Clinical Division Chief:
As Department Chair or Clinical Division Chief, I approve the participation of staff members/resources in the research, approve of the scientific and scholarly validity of this research protocol, approve the research to be conducted the department/division, and certify that the institution has been informed of the research.

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**Name of Department Chair or Signature Date
Clinical Division Chief\***
 \*Refer to Current listing on MLH Intranet: <http://intranet/medicalstaff/page12.aspx>

Nursing Research ONLY:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_
**Name of Nursing Research and Signature Date
Innovation Council Chair**

**STOP! Only proceed to Sections III and IV once the applicable signatures above have been obtained**

**SECTION III – Supporting Hospital Departments (when applicable)**

**Supporting Hospital Departments may include, but are not limited to the following: Pharmacy, Radiology, Main Line Clinical Labs, and Emergency Department**

I have reviewed the sections of this research protocol that require the services of my department. Following the completion of any applicable Protocol In-service Training, the staff of my department can fulfill its responsibilities as defined in this protocol. I attest to this statement by signing as Authorized Person in the table below.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Authorized Person (Print Name)** | **Department** | **MLH Entity** | **Signature** | **Date** |
|  |  |  |  |  |
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**SECTION IV – ALL Research Requires the Signatures Below**

In order to obtain the signatures below, the following information **must accompany this form**:

1. One Completed IRB Submission Packet, including a copy of the Protocol and Data Collection Forms
2. Clinical Trial Agreement (sponsored/funded only)

**To obtain the signature below, provide this completed transmittal form with all applicable signatures above and required materials by inter-office, postal, or email to John Wellenbach, LIMR Clinical Business Manager or Tam Mai-Nguyen, LIMR Director of Finance at:**

|  |  |
| --- | --- |
| **Inter-office Mail or Postal** | **Email** |
| John Wellenbach, Clinical Business Manager | wellenbachj@mlhs.org |
| *OR* |  |
| Tam Mai-Nguyen, Director of Finance | nguyent@mlhs.org |
| Lankenau Institute for Medical Research (LIMR) |  |
| 100 Lancaster Avenue |  |
| Wynnewood, PA 19096 |  |

(TO BE COMPLETED BY John Wellenbach or Tam Mai-Nguyen)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| ***The Organization has a written agreement with the Sponsor that:*** | **YES** | **NO** | **PENDING** | **N/A** |
| 1. Addresses medical care for research participation with a related injury, when appropriate.
 |[ ] [ ] [ ] [ ]
| 1. That the Sponsor promptly reports to the Organization findings that could affect the safety of the participants or influence the conduct of the study.
 |[ ] [ ] [ ] [ ]
| 1. Addresses provisions for monitoring the data to ensure that safety of participants and for providing data and safety monitoring reports to the Organization.
 |[ ] [ ] [ ] [ ]
| 1. Describes plans for disseminating findings from the research and the roles that Researchers will play in the publication or disclosure of results.
 |[ ] [ ] [ ] [ ]
| 1. The Researcher or Organization will be notified of the results in order to consider informing participants.
 |[ ] [ ] [ ] [ ]
| Charge IRB Fee? |[ ] [ ] [ ] [ ]

Lankenau Institute for Medical Research Finance Signature:

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**John Wellenbach Signature Date
Clinical Business Manager**Or
**Tam Mai-Nguyen
Director of Finance**

**Signed Transmittal Forms are returned directly to the Principal Investigator**

1. This group is further defined in Category B of the MLH Administrative Policy 1.50: [IRB Jurisdiction over Research Involving Human Subjects Research](https://mainlinehealth.ellucid.com/documents/view/11263) available at: <https://www.mainlinehealth.org/research/office-of-research-protections/policies-procedures> [↑](#footnote-ref-1)