



Procedure for Review of external requests to conduct research or gather data from Hebrew SeniorLife Business Lines

All inquiries and requests for conducting research by external researchers must be routed to the Human Subject Protection Office (HSPO)

Before any research involving staff, patients, residents or data can be conducted at HSL, the External Researcher Request Form must be completed by the requesting Researcher and sent to the HSPO with the applicable study materials such as: Protocol, consent form, participant-facing documents etc.

The HSPO will manage the contact with the External Researcher and collect all relevant documentation for HSL. Once documents are received, the HSL HSPO will then work with the appropriate individual from Senior Leadership to obtain review and approval.

Each person from Senior Leadership who is responsible for the business line, is expected to respond with an affirmative or with questions that will be directed to the Researcher by the HSL HSPO.

Approval will **not** be communicated to the External Researcher until all issues have been resolved to the satisfaction of Leadership.

The External Researcher must obtain and IRB determination from the IRB with jurisdiction over the researcher and provide this documentation to the HSL HSPO.

Research cannot commence at any HSL business line until all documents and approvals are in place.

When all documents and approvals are in place, the approval will be communicated by the HSPO either to the External Researcher or to the HSL applicable Senior Leadership who is approving the request.

HSL reserves the right to rescind approval based on institutional policies or any unanticipated problems that may occur that impact patients, residents or resources of the institution.

- For Data requests, or research involving patients and resident data, the Chief Information Officer will need to be included at the onset of processing the request to determine if IT will require additional resources to provide the requested data. HSPO will ask for written approval of the request.
- The HSPO will communicate the name of the PI, Title of the project to the CIO before IT may distribute data to an external researcher. No data can be provided to an external researcher without approval from Senior Leadership which will be communicated through the HSPO.
- IT is not the source of approval for any data sharing.
- HSPO will also contact the Privacy Officer to alert this Department of the request. The Privacy Officer will be responsible for corresponding with the External Researcher about any HIPAA requirements such as accounting disclosures.



HSL Senior Leadership responsible for final External Research Approval:

Kimberly Brooks, Chief Operating Officer, Senior Living
KimBrooks@hsl.harvard.edu

Ernest Mandel, MD, Chief Medical Officer
ErnestMandel@hsl.harvard.edu

Alvaro Pascual-Leone, MD, PhD, Medical Director, Wolk Center for Memory Health
APLeone@hsl.harvard.edu

Tammy Retalic, Chief Nursing Officer and Vice President of Patient Care Services
TammyRetalic@hsl.harvard.edu

To be consulted by HSPO as applicable:

Eric Rogers, Chief Information Officer
EricRogers@hsl.harvard.edu

Jamie Curtis, Assistant General Counsel and Director of Compliance and Privacy, Legal & Compliance
JamieCurtis@hsl.harvard.edu



External Researcher Form

1. GENERAL INFORMATION	
Date	
Project Title	
Principal Investigator Name	
Principal Investigator Contact Information	
Principal Investigator Primary Institution	
Reviewing IRB and IRB approval documentation	
HSL Site Investigator Name (if any)	
HSL Manager or contact who is aware of study:	

Please submit this page with Protocol, consent, plans for IRB review and any recruitment or participant materials to:
IRB@hsl.harvard.edu