Hebrew SeniorLife

Care • Community • Innovation

Procedure for Access to Patient Related Data for Quality Improvement and/or Research (for Hebrew SeniorLife Investigators)

1. What to information the Investigator will need to provide:
    - IRB approval notice
    - HIPAA waiver or approval notice (may be part of IRB approval notice)
    - Project Sponsor (funder)
    - Project Investigator
    - Project Summary and/or Protocol
    - Involvement of HSL residents (including access to their data)
    - Involvement of HSL staff (including access to their data)
    - Use of HSL facilities

2. Which HSL departments to contact if the research includes any of the following for HSL:
    - Research with HSL residents/patients and/or resident, patient data – HSL IRB
    - Use of HSL resident and/or patient data – HSL IT and HSL Privacy Officer
    - Sponsored Research Funding – Marcus Institute Research Administration
    - Research Contracts or Agreements – Marcus Institute Research Administration or the HSL Legal Department

3. To know whether HSL is Engaged in the Research (determines if IRB review is required), complete the HSL Engagement Checklist on page 2.

4. To request approval for the research to be conducted within HSL departments and/or with HSL resources, complete the HSL Department Authorization Form on page 3. Appropriate Department signatories are listed on page 4. In general, unless otherwise noted, the person signing the Department Authorization Form should be a member of the HSL Senior Leadership Team.

If you have any questions, please contact HSL IRB Director: Sherry Felchlin

Hebrew SeniorLife
Care • Community • Innovation

HSL Engagement Checklist

Instructions: Check √ all that apply for HSL.

- If one or more item is checked, HSL is engaged in the research and the HSL IRB Director, Sherry Felchlin, should be contacted for further information and instruction.
- If HSL is *not* engaged in the research, the appropriate HSL department heads (see page 4) may determine whether it is appropriate for HSL and/or its residents to participate in the research.

HSL is Engaged in Research when…

	HSL receives a grant, contract or cooperative agreement directly from HHS for non-exempt human subjects research (even if no human subjects research activities are carried out by HSL/HSL employees)
	HSL employees intervene for research purposes with any human subjects of the research by performing invasive or non-invasive procedures (e.g. blood draws, buccal swabs, administration or drugs or other treatments, individual or group therapy, etc.)
	HSL employees intervene for research purposes with any human subject of the research by manipulating the environment (e.g. controlling light, sound, temperature, sensory stimuli, environmental or social events/interactions)
	HSL employees interact for research purposes with any human subject of the research (e.g. engaging in protocol dictated communication/contact; asking someone to provide a specimen, conducting research interviews/questionnaires, etc.)
	HSL employees obtain the informed consent of the human subjects for the research.
	HSL employees obtain for research purposes identifiable private information or identifiable biospecimens from any source for the research. This includes: (a) Observing or recording private behavior; (b) Using, studying or analyzing for research purposes identifiable private information or identifiable specimens provided by another institution; and (c) Using, studying or analyzing for research purposes identifiable private information or identifiable specimens already in the possession of the investigators.

NOTE: HSL is <u>not</u> engaged when its role is limited to the following activities:

- Performing services it would normally provide for non-research purposes if the services do not merit professional recognition or publication privileges, and do not involve administration of study intervention;
- Providing recruitment information or Investigator contact information to prospective subjects, or seeking or obtaining the prospective participant's permission for Investigators to contact them;
- Permitting the use of HSL facilities for interactions/interventions with research participants by Investigators from another institution;
- Obtaining de-identified or coded private information/biological specimens if the identities of the subjects to whom the information/data/biological specimens pertains is not readily ascertainable.

Hebrew SeniorLife
Care • Community • Innovation

HSL Department Authorization for Non-Marcus Institute HSL Investigators

Note – use one form per department. Retain all paperwork for dept records & send copies to:

IRB: Sherry Felchlin and the HSL Research Compliance Committee.

1. General Information	
Date	
Project Title	
Principal Investigator Name	
Principal Investigator Contact Information	
Principal Investigator Primary Institution	
Reviewing IRB	
HSL Site Investigator Name (if any)	

2. Project Summary (include the purpose of the research, the procedures for participants, and participant inclusion/exclusion criteria)

3. Impact (benefits and risks) to HSL Residents, Families and/or Staff

4. HSL Departments Involved and Research Activities to take place in each Department

5. HSL Department Resources Needed (e.g.: staffing, IT, facility space, financial support, etc. Confirm if department personnel will need to take human subjects protection training)

6. Required Signature		
HSL Department Head Name	**Signature**	**Date**

HSL Department Head Contacts:

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, Center for Memory Health
apleone@hsl.harvard.edu

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

If the research involves additional departments not listed above, please contact
HSL IRB Director: Sherry Felchlin