

DATE: NOVEMBER 15, 2017

REQUIREMENTS FOR EXTERNAL RESEARCH COLLABORATION PROPOSALS INTENDING TO CONDUCT HUMAN SUBJECT RESEARCH AT LEGACY HEALTH OR UTILIZE LEGACY HEALTH DATA

Purpose: The purpose of this policy is to define the parameters and guidelines for Research Collaborations (RCs – clinical and non-clinical) with Legacy Health (LH) and establishes the conditions under which an External Research Collaborator (ERC) may have access to and utilize LH patients, data, resources, and facilities for research purposes. The policy requires that all factors pertaining to research conducted by ERC (non-employee, non-affiliated) investigators/researchers have been vetted and approved before the research is submitted for IRB review and approval.

Policy: All research at LH, or that uses LH patients, data, resources, or facilities must be overseen or directed by a LH researcher, either as the principal investigator, a co-investigator, or collaborator. Collaboration with ERCs may only be allowed when the proposal clearly aligns with LH's mission and when involvement in the proposed research and the research proposal has also been granted approval by a LH manager or administrator of the department in which the research is to be conducted. In all collaborations with ERCs, LH will either partner, collaborate or otherwise oversee the research, either by providing administrative oversight by LH management, or by providing ethical oversight via Legacy IRB. All collaborations with LH must provide benefit to Legacy patients, staff or providers, either in the form of advances in scientific and/or medical knowledge, direct treatment benefit to LH patients, sharing of data or results of the research, or by inclusion in publications and presentations of LH co-authors.

In special circumstances, research at LH may be conducted without a LH researcher participating as a principal investigator, a co-investigator, study staff, or collaborator, if the Legacy Research Institute (LRI) VP of Research and/or the LH Chief Medical Officer and the appropriate LH manager or administrator of the department in which the research is to be conducted, grants permission, and if the research has been vetted according to this policy, and adequate grounds exist for allowing the research to be conducted without LH investigator collaboration.

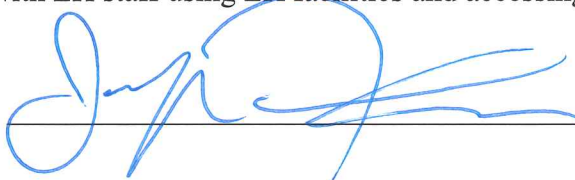
Research Consistent with LH Mission: The IRB will consider the relevance of the research to the mission of LH and the patient population that it serves. The research must be relevant to the health or welfare of the LH patient population.

Notification: External Researchers are required to notify LH IRB Administration of any plan to conduct research at LH.

External Research Collaborators (ERC): ERC are investigators/researchers of any kind that are non-employees, and non-affiliated with LH. ERC are expected to conduct research projects with LH via truly meaningful collaboration with LH investigators. This collaboration may utilize equipment, or other LH resources, that are otherwise unavailable to, or not easily accessible by, the ERC. ERC include medical professionals that have obtained medical privileges at LH but are not LH employed staff. Medical privileges do not permit ERCs to conduct research without evidence of an approved collaboration.

ERC include, but are not limited to, scientists, engineers, physicians and other scientific or health care providers who are engaged in research collaborations with LH and LH staff and are authorized and approved by LH to engage in scientific studies and investigations with LH staff using LH facilities and accessing LH patients and data.

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There are two kinds of ERC: (1) those who provide no direct services to LH; and (2) those who, as LH medical professionals with LH privileges and providers who provide some services to LH and function, in part, under the supervision and control of LH management. ERC agreements must be documented in writing and all ERC must provide evidence of collaboration with a LH staff.

The following individuals are not eligible to be ERC:

Scientists/Medical professionals at LH for the purpose of informal observation or discussions unrelated to an established research collaboration;

- Individuals under 18 years of age;
- Individuals who are not covered by a documented research collaboration with LH staff;
- Medical Professionals who have medical privileges at LH but have conducted research at LH without permission or approval and have not requested collaboration with LH.

Collaboration: Documentation of the collaboration and permission to conduct the research must be sought prior to submitting any proposal for IRB review. Evidence of collaboration includes, but is not limited to: inclusion of LH staff as co-investigators, sub-investigators, and/or study staff directly involved in the conduct of the research, documentation of permission to conduct the research by LH management or supervisory departmental staff, IRB approval (or exemption determination) or deferral, or an external IRB to conduct the research at LH, data use agreement, etc. It is expected that the collaboration between the ERC and LH staff will be real and material, such that the collaborating LH staff will meet accepted standard for inclusion as authors on disseminated materials.

Publications and Dissemination of Results: Dissemination of results originating from research conducted by ERC in LH facilities, through publications or other vehicles, should, where appropriate, include the LH collaborator as an author. If it is not appropriate to include the LH collaborator as an author, or if they do not wish to be included as an author, then the collaboration must acknowledge the collaborating LH investigator(s) and LH as an organization as well as the participating hospital and department. It is also understood that any results disseminated are consistent with the approved research project, especially in how any patient data is used and presented.

Intellectual Property: Intellectual property (IP) rights for inventions or discoveries developed by ERC are LH property, unless LH waives its rights in writing. ERC do not automatically obtain IP rights from LH if the IP is generated through interaction either with LH patients or LH data merely by permission to conduct research at LH.

Length of Assignment: The duration of the Research Collaboration will be set according to the approved proposal and does not extend beyond the specific project for collaboration.

Request from ERC: Requests from ERC to conduct human subject research at LH must be forwarded to the LRI Research Regulatory Specialist at pwnewton@lhs.org. The request must include the following:

- Protocol;
- Consent Document, if applicable;
- All documents subjects will receive or review; and
- Evidence of external IRB approval or an exemption determination, if any;

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- Evidence of collaboration with a LH collaborator and permission by LH administrator or manager to conduct the research;
- PI's CV and documentation of human subject research protection training;
- Study Staff documentation of human subject research protection training
- Information showing how the research is consistent with LH's Mission

Factors to Consider:

- Budget
- Costs/Budget for data capture and transmittal
- Time constraints and demands on LH employees to accommodate the research
- Access to patients
- Sensitivity of patient information
- Sensitivity of provider information
- Publishing and Authorship plans
- Affiliations
- Staff access to patient information
- Method of access to patient information

Determination: The LRI Research Regulatory Specialist will review the ERC request and associated documents and determine whether the research is acceptable, the consent process is adequate and the ERC's IRB has either approved the research or determined the research to be exempt. The LRI VP of Research, upon the advice and input of the LRI Research Regulatory Specialist, and the IRB Chair, will determine if the research is acceptable as proposed by the ERC. The LRI Research Regulatory Specialist will provide notification to the ERC of the determination of the LRI VP of Research.

Exceptions: Exceptions to this policy require the approval of the LRI VP of Research and/or the LH SVP Chief Medical Officer.

Name (External Research Collaborator)	Date
Address	
Phone	

Name (Legacy Principal/Co Investigator)	Date
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