**How to Initiate Research at MossRehab:**

**A Resource for MossRehab Clinicians, Residents, and Staff**

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*This is a companion document to an* [*explanatory video*](https://youtu.be/9Qh2dP79K_Y) *that provides (1) an introduction to the Moss Rehabilitation Research Institute Research Registry; and (2) outlines administrative steps that are required prior to initiation of research at MossRehab.*

This document is for clinicians, residents, and other staff who are considering engaging in research at Moss Rehab. It outlines the administrative steps that must be in place prior to initiation of any research project at Moss Rehab. It also describes the [Moss Rehabilitation Research Institute **(MRRI)** Research Registry](http://mrri.org/patient-research-registry/) and how it can be used to support research at Moss Rehab.

**Three types of administrative approval must be in place prior to engaging in any research with human subjects at MossRehab, and they must be in place prior to using the MRRI Research Registry.**

**(1) a review of the institutional resources needed to conduct the research**

**(2) a review of scientific merit of the project**

**(3) a review of human subjects ethical issues by the IRB**

Each of these steps is described in turn, below.

**(1) Review/Approval of the Use of Institutional Resources**.

As a first step for planning any study, a [**Research Resource Utilization form**](http://mrri.org/wp-content/uploads/2018/07/FORM-MossRehab-Research-Resources-Utilization.pdf)is submitted to MRRI. The Research Resource Utilization form covers the study’s need for a range of institutional resources (such as space needs and staff impact) as well as need for specific kinds of patients.

The Research Resource Utilization form should be submitted for all proposed projects at MossRehab, regardless of intended funding source or intent to use the Research Registry. If the proposal will be submitted as an application for funding at an outside agency, the **Research Resource Utilization form must be submitted prior to the time of application to the granting agency**. This is to assure the project is feasible prior to submission.

**A request to use the MRRI Research Registry for participant recruitment is made with submission of the Research Resource Utilization form**. Registry administrators use the Research Resource Utilization form to determine whether the MRRI Research Registry can support recruitment for the project. Do note, in some cases, Registry administrators may determine the Registry cannot support study recruitment.

Studies that do not aim to use the MRRI Research Registry still require submission of the Research Resource Utilization form to confirm the study’s targeted population is not available in the registry, and so study staff can obtain approval to recruit by alternative means.

The [**Research Resource Utilization form**](http://mrri.org/wp-content/uploads/2018/07/FORM-MossRehab-Research-Resources-Utilization.pdf) is submitted to **Kevin Whelihan, Administrator of MRRI**, whose contact information can be found in **Outlook**.

(2) **Review of Scientific Merit**.

All proposed research at MossRehab must undergo a review of scientific merit. This can include the following kinds of review:

1. If the study is funded by the Albert Einstein Society or a government funding agency such as the National Institutes of Health, which conducts its own peer review, this suffices for review of scientific merit.
2. If the study is a FDA-approved trial or peer-reviewed clinical trial solicited by an industry sponsor, this can suffice for review of scientific merit.
3. If the study has none of these types of review, the study needs to be submitted for review by the **Moss Peer Review Committee (PRC)**. If applying for PRC scientific review, the Research Resource Utlization form will be submitted as part of PRC review. Thus, the PRC evaluates the project’s resource requirements and its scientific merit. Note, the PRC also has limited funds available to support pilot research. For questions about the PRC review process, contact **Mary Ferraro** whose information can be found in **Outlook**.

(3) **IRB Review**

Lastly, prior to initiation of research, the study must be approved by the Einstein Healthcare Network Institutional Review Board at the [**Office of Research and Technology Development**](https://www.einstein.edu/healthcare-professionals/researchers/development/research-clinical-trials). For studies that require PRC review for scientific merit, approval from the PRC must be obtained before submitting the IRB application. If your study can be supported by the MRRI Research Registry, you should **list the Research Registry as a recruitment source in your IRB protocol**. **Beth Lynch** at the **Office of Research and Technology Development** is the point of contact for the IRB. Her contact information can be found in **Outlook.**

**Introduction to the MRRI Research Registry**

The MRRI Research Registry supports neurorehabilitation research in the MossRehab community and contains information for over 2000 research volunteers. These volunteers include adults who have a neurological condition like stroke or traumatic brain injury. The Registry also includes individuals who have no existing or prior neurological condition and are willing to serve as control participants. Although MossRehab is fortunate to have a rich program of research, this comes with the need to prevent patients from being overburdened by recruitment approaches and the need to fairly manage access to MossRehab’s finite population of patients. The MRRI Research Registry serves to facilitate access to potential research participants with specific characteristics. It also helps manage the demand and competition for particular kinds of participants across studies that may have similar inclusion and exclusion criteria.

Research staff who are approved to access the Registry use the Registry database to identify research volunteers who meet the criteria and scientific goals of their study. The registry contains demographic and contact information for all research volunteers. For volunteers with a neurological condition, the Registry also includes medical history information relating to their condition including findings from neurological, neuroimaging and clinical tests.

To support the Research Registry, MRRI employs multiple full-time research registry recruiters who approach eligible individuals when they are inpatients or outpatients at MossRehab, both at Elkins Park and other MossRehab locations. If you encounter inpatients or outpatients at MossRehab that are interested in research and may be appropriate for the Registry, please see the [MRRI Research Registry webpage](http://mrri.org/patient-research-registry/) on the MRRI website for contact information.

The MRRI Research Registry is approved by the Institutional Review Board of Einstein Healthcare Network. The Registry’s IRB protocol specifies the details of the Registry consent process, how information is maintained in the database, and how participants are approached for studies that use the Registry. All research projects that use the Registry are conducted with IRB oversight to maintain the highest standards of research ethics and confidentiality.

**Using the MRRI Research Registry**

Before using the Registry to support a research project, the three administrative steps described earlier must be in place. This includes submission and **approval of the Research Resource Utilization form** to use the Registry, a **review of scientific merit**, and **IRB approval**.

**Once all the requisite approvals are in place, a staff member on the project is designated to be added to the Registry IRB protocol**. When that individual is added to the Registry IRB protocol, they will be trained by Registry administrators on Registry procedures and how to use the Registry database to recruit participants. Keep in mind that **the designated staff member will be required to attend weekly Registry meetings either remotely or in person at Elkins Park**. At these meetings, Registry staff discuss recruitment needs and equitable access to patients. The designated staff member will also be required to attend monthly Registry meetings where current and new operating procedures are reviewed, and staff can receive support from administrators to help meet recruitment goals.

For more information, please see the [Research Registry section](http://mrri.org/patient-research-registry/) on the MRRI website.