

POLICY FOR REGISTRY DATABASE ACCESS BY EXTERNAL RESEARCHERS

Philosophy

The North American Malignant Hyperthermia Registry encourages qualified medical scientists to work with the Registry staff to obtain epidemiologic and other data from the database, without learning individual patients' names.

Registry Policy

1. An external researcher is defined as a researcher who is not a member of a MH diagnostic center, a member of the North American Malignant Hyperthermia Registry (NAMHR) staff, or a volunteer Hotline Consultant, Registry Advisory Committee member or MHAUS Board member.
2. An external researcher will be permitted access to Registry data only after meeting the following requirements:
 - a) His or her application for research access to the Registry data has been approved by a majority of the Registry Advisory Committee.
 - b) The researcher has examined a list of Registry tables and fields, and selected specific fields needed in accordance with HIPAA guidelines.

During the approval process, preference will be given to applications, which do not overlap with research in progress, by the NAMHR staff or its member centers.
3. Approval of a data access application does not guarantee access to an individual MH biopsy center's patients.
4. The Registry will not reveal the names of patients registered in the Registry to researchers.

5. If researchers need to contact individual patients (e.g. to draw blood samples), then the following procedure will be available:
 - a) Registry personnel working with the researcher will identify (anonymously to the researcher) patients appropriate for study.
 - b) The Registry will notify individual MH biopsy center directors that a researcher would like to obtain specimens from the identified patients.
 - c) If the MH biopsy center director wishes to collaborate with the researcher, then the Registry will give the names of the appropriate biopsy center directors to the external researcher and furnish each biopsy center director with the lists of identified patients.
 - d) The NAMHR will contact the patient with information about the study, including contact information for the researcher conducting the study.

6. The external researcher will reimburse the Registry for all costs incurred by the Registry to:
 - a) Search the Registry database for appropriate patients.
 - b) Contact MH biopsy center directors with information about external researcher's project.
 - c) Contact patients on behalf of the investigator.

7. The external researcher will reimburse the Registry for an additional research utilization fee of no less than \$500 in addition to the above costs. The Registry Advisory Committee will specify the research utilization fee when it has reviewed and approved the application and anticipated costs forwarded from the Registry.

8. The NAMHR library of papers will be made available to researchers when they have paid the initial fee, as subject to copyright laws.

9. Any publications resulting from use of Registry data will cite the North American Malignant Hyperthermia Registry as a source of the data.