

MULTICENTER REGISTRY for HYPERBARIC OXYGEN THERAPY

Requesting Shared Data for Member-Initiated Research

PURPOSE: To describe the procedure for use and publication of shared data for member-initiated research.

SCOPE: All members of the registry.

DEFINITIONS:

Member Data-means information regarding patient treatment with hyperbaric oxygen therapy submitted by a Member to the Registry, including but not limited to clinical, administrative, and financial information.

Member Database-means the database created by each Member to hold each such Member's own Member Data.

Member-Initiated Research-means research undertaken by a Member utilizing Shared Data.

Members-means the Parties to the Consortium Agreement, and other entities that are admitted to the Consortium by the Steering Committee that will provide data as described herein to the Registry and are signatories to this Agreement through the execution of a New Member Agreement.

Researcher – Individual at a Member center who is undertaking research with the registry.

Shared data – The data set held in the central registry that contains de-identified data from all participating centers.

PROCEDURE: Researcher who would like to use the Shared Data for research initiated by that member shall contact the Steering Committee representative at their center and submit the request to the Steering Committee.

A researcher who is not at a Member institution, may request to use shared data by teaming up with a researcher at a member institution. The Member center will request the use of the shared data on behalf of the non-member researcher.

The request shall include

- Title
- Researcher name
- Purpose of the research (no more than 1 page, single spaced, 12-point font, 1" margins)
- What registry data are needed
- How data will be used (one paragraph)
- How the data will be protected

The completed request will be circulated to the Steering Committee who will have 2 weeks to review and vote upon the request. Approval will be by majority vote as

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outlined in the Consortium Agreement. At the time of the vote the Steering Committee Representative from the center's hyperbaric program will have the option to serve as a co-author on the study provided they agree to meet the requirements for authorship outlined in the JAMA Article "Authorship and Team Science" (Fontanarosa P, Bauchner H, Flanagin A. Authorship and Team Science. *JAMA*. 2017;318(24):2433–2437. doi:10.1001/jama.2017.19341.

(Link - <https://jamanetwork.com/journals/jama/fullarticle/2667044>)

A steering committee representative can assign another person within their hyperbaric unit to serve as co-author instead, provided this individual also agrees to meet the authorship requirements.

The requestor will be informed of the decision of the Steering Committee by the Chairperson of the Steering Committee.

If the request is provisionally approved a letter to that effect will be issued to the researcher. The researcher must then provide documentation that the project has been reviewed and approved by a certified IRB (usually the Member institution's IRB) before final approval by the Steering Committee.

The requested Shared Data will be made available to the researcher by the programmer.

The researcher will agree to acknowledge the Multicenter Registry for Hyperbaric Oxygen Therapy in all publications by including the following items in any publication.

1. Cite the registry protocol paper *Harlan NP, Ptak JA, Rees JR, Cowan DR, Fellows AM, Kertis JA, Hannigan PM, Peacock JL, Buckley JC Development of an International, Multicenter, Hyperbaric Oxygen Treatment Registry and Research Consortium: Protocol for Outcome Data Collection and Analysis JMIR Res Protoc 2020;9(8):e18857 URL: <http://www.researchprotocols.org/2020/8/e18857/> doi: 10.2196/18857*
2. Include the International Registered Report Identifier for the registry (usually at the end of the abstract), which is RR2-10.2196/18857.
3. Include the following in the acknowledgments: "The Multicenter Registry for Hyperbaric Oxygen Therapy received support from the Dartmouth-Hitchcock Medical Center Department of Medicine Scholarship Enhancement in Academic Medicine (SEAM) Award Program. The Registry Consortium Centers include: [Steering committee rep A] [Institution A], [Steering Committee rep B] [Institution B],.....etc."

Authorship on publications will be listed as:

Researcher A [Proposing Researcher], Researcher B [optional],Steering Committee Rep A [optional], Steering Committee B [optional],for the Multicenter Registry for Hyperbaric Oxygen Therapy Consortium.

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The Researcher proposing the study can choose additional authors if needed.

RESPONSIBILITIES:

Researcher requesting Shared Data is responsible for submitting the request and IRB approval for the project.

Steering Committee will review and vote on the request.

RELATED DOCUMENTS:

Amended and Restated Hyperbaric Oxygen Treatment Registry Consortium Agreement

APPROVAL and REVIEW

Steering Committee - Approval: 8 December 2020