

HYPERBARIC OXYGEN TREATMENT REGISTRY CONSORTIUM NEW MEMBER AGREEMENT

This Hyperbaric Oxygen Treatment Registry Consortium New Member Agreement (this "New Member Agreement"), effective as of _____ ("Effective Date"), is by and among _____, an institution commissioned by NHS organized under the laws of England and Wales and located in _____, and the parties to the Amended and Restated Hyperbaric Oxygen Treatment Registry Consortium Agreement, dated as of November 15, 2016, as it may be amended from time to time (the "Consortium Agreement").

New Member wishes to participate in the Hyperbaric Oxygen Treatment Registry Consortium (the "Consortium"). In consideration for its participation in the Consortium, and except as set out below, New Member agrees to be bound by all of the covenants, obligations, terms and conditions applicable to Members contained in the Consortium Agreement.

Notwithstanding the foregoing, with respect only to New Member's participation in the Consortium, the Consortium Agreement shall be amended as follows:

1. For this purposes of this New Member Agreement, the terms below shall have the meanings given to them as follows:

"Anonymised Member Data" means De-identified Member Data which has been further anonymised in accordance with GDPR (as defined below), such that any personal data included therein has been rendered anonymous in such a manner that the data subject is not or no longer identifiable;

"De-identify", "De-identified", or "De-identification" means removal of Protected Health Information, or data from which Protected Health Information has been removed, in accordance with HIPAA at 45 C.F.R. Section 164.514;

"KCL National Database" means the database created and maintained by King's College London to hold New Member's Member Data in the UK, and from which Anonymised Member Data shall be exported pursuant to the terms of the Consortium Agreement to the Registry;

"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; and

"Registry" means the registry of Shared Data developed and managed by Geisel/D-H on behalf of the Consortium;

2. GDPR. For the avoidance of doubt, the definition of "Data Security Regulations" as set out in the Consortium Agreement shall include Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (the "GDPR"). The parties agree that any data submitted to the Registry by or on behalf of New Member shall be in accordance with the requirements of the GDPR, and therefore shall not constitute "personal data" thereunder. As between it and the other Members and/or Geisel/D-H, New Member shall remain responsible for ensuring that only Anonymised Member Data is provided to the Registry and agrees that the indemnification obligation set forth in Section 9.1.1 of the Consortium Agreement shall include the obligation of New Member to indemnify, defend and hold harmless Geisel/D-H and any other Member, as applicable, for any Losses resulting from any Claim related to the submission of any Member Data by or on behalf of New Member which has not been anonymised as such term is defined in the GDPR.

3. Research Ethics Committee. The definition of “IRB” as set out in the Consortium Agreement shall include a Research Ethics Committee or similar provided through the National Health Service’s Health Research Authority.
4. KCL National Database. New Member’s obligations under Section 2.2.3 to obtain and maintain for the duration of the Term its status as an end user of any software or other database management system or platform as required by the Steering Committee to access the Shared Data and to meet its obligations related to submission of De-identified Member Data to the Registry shall be met by maintenance of access to the KCL National Database maintained by Kings College London for providers of Hyperbaric Oxygen Therapy services to NHS England.
5. Data Submission. New Member will submit data to the KCL National Database at its own expense such that Anonymised Member Data can be exported to the Registry as required by the Steering Committee from time to time as further set out in Section 4.1 of the Consortium Agreement.
6. Dispute Resolution. Notwithstanding the provisions of Section 12.14.2 of the Consortium Agreement (Non-Binding Mediation), Members agree to enter into mediation in good faith to settle any dispute in connection with the Consortium Agreement which involves the New Member in accordance with the Centre for Effective Dispute (CEDR) Model Mediation Procedure. In such case, unless otherwise agreed by the disputing Members within fourteen (14) days of notice of the dispute, the mediator will be nominated by CEDR. The remaining provisions of Section 14.12.2 shall remain in effect with respect to any such mediation conducted under this Section.
7. Conflict. In the event of a conflict between the Consortium Agreement and this New Member Agreement, the terms of this New Member Agreement shall control.

For purposes of this New Member Agreement, the parties intend and agree that a signed copy delivered by facsimile or electronically shall be treated by the parties as an original of this New Member Agreement and shall be given the same force and effect.

In witness whereof, New Member has caused this New Member Agreement to be executed by its authorized agent:

[_____]

Signature: _____

Name: _____

Title: _____

Date: _____

Address
for Notice: _____

Acknowledgement of New Member Admission:

Signatures of Steering Committee Co-Chair
(or Designee):

Signature of Steering Committee Co-Chair
(or Designee):

Printed Name: _____

Printed Name: _____

Date: _____

Date: _____