MEMORANDUM OF UNDERSTANDING

Between

European Academy for Molecular Hydrogen Research in Biomedicine n.o., Institute for Heart Research, Center of Experimental Medicine, Slovak Academy of Sciences Bratislava, Dubravska cesta 9, Slovak Republic

Represented by director: **Prof. Jan Slezak, PhD**, DSc., FIACS

And

MOLECULAR HYDROGEN INSTITUTE (MHI)
Represented by: CEO **Tyler LeBaron**, PhD, Founder / Executive Director
(hereinafter **"MHI"**)

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1. PURPOSE AND OBJECTIVES

1.1 The Parties wish to establish a formal framework for collaboration in **molecular hydrogen (H_2) biomedical research, education, and scientific translation**, with particular emphasis on:

- **Cardiovascular applications**: ischemia-reperfusion injury, heart failure, atherosclerosis, hypertension, cardiometabolic syndromes and radiation injury.
- **Nanobubble delivery systems**: characterization, stability, dosing standardization, and pharmacokinetic profiling of H_2 nanobubbles in preclinical and clinical settings;
- **Regulatory pathways**: alignment of preclinical evidence packages with EU (EMA, SÚKL) and US (FDA) requirements for hydrogen-based medical devices and investigational medicinal products.

1.2 This MoU sets out the principles, governance, and operational modalities for joint activities without creating legally binding financial obligations. Specific projects shall be implemented through **Annexes** (Work Packages) signed by both Parties.

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2. SCOPE OF COLLABORATION

The Parties agree to cooperate in the following **Core Activity Areas**:

Area	Description	Lead / Coordinator
A. Joint Research & Preclinical Development	Collaborative grant applications (Horizon Europe, MSCA, NIH, national agencies); shared preclinical models (rodent/large-animal I/R, heart failure); nanobubble formulation optimization; biomarker	Institution/EUH2ACAD: Prof. Slezak / MHI: Designated Science LeadDr.Tyler LeBaron

Area	Description	Lead / Coordinator
	discovery (oxidative stress, mitochondrial function, inflammatory signatures).	
B. Clinical Translation & Regulatory Strategy	Design of investigator-initiated trials (IITs) for H_2 in cardiovascular indications; regulatory roadmap documents (EMA Scientific Advice, FDA Pre-IND, SÚKL national pathway); harmonization of H_2 dosing, purity, and administration standards.	Joint Regulatory Working Group
C. Education, Training & Scientific Literacy	Co-developed curricula (micro-credentials, summer schools); plain-language summaries for patients/public; mentorship/exchange for PhD students and postdocs (3–6 month visits).	Institution: Education Officer / MHI: Outreach Director
D. Knowledge Dissemination & Open Science	Joint publications (open access); shared data repositories (FAIR principles); co-branded "Collaboration Hub" on both websites; consensus statements / position papers.	Joint Communications Committee
E. Standards & Quality Assurance	Cross-validation of H_2 measurement methods (gas chromatography, electrochemical sensors, nanobubble tracking analysis); contribution to ISO/TC 197 / CEN standards for medical hydrogen.	Joint Technical Committee

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3. GOVERNANCE STRUCTURE

3.1 Steering Committee

- **Composition**: 2 representatives per Party (1 senior scientist, 1 administrative/legal).
- **Chair**: Rotating annually.
- **Meetings**: Quarterly (virtual); ad hoc as needed.
- **Decisions**: Consensus; disputes → Section 12.

3.2 Working Groups (WGs)

Established by Steering Committee for each Core Activity Area. Each WG has a **Lead** from each Party and meets monthly.

3.3 Designated Liaisons

- **EUH2ACAD&Institution**: Prof. Jan Slezak, DSc (scientific) + [Admin Contact] (administrative)
- **MHI**: Dr.Tyler LeBaron PhD (scientific) + [Admin Contact] (administrative)

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4. INTELLECTUAL PROPERTY (IP)

Category	Ownership	Rights
Pre-existing IP	Remains with originating Party	Non-exclusive, royalty-free license for collaboration purposes only
Jointly Generated IP (co-invented, co-authored)	Joint ownership	Each Party may exploit freely with accounting to the other; patent filing costs shared 50/50 unless otherwise agreed in Annex
Educational / Outreach Materials	Joint copyright	Licensed **CC-BY 4.0** (attribution to both Parties)
Data & Databases	Party generating data	Shared under **CC-BY 4.0** or **ODbL** for research use; commercial use requires separate agreement

Publication Policy: Joint review 30 days prior to submission; neither Party unreasonably withholds consent. Authorship follows ICMJE criteria.

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5. CONFIDENTIALITY

5.1 **"Confidential Information"**: Non-public information disclosed in writing (or orally confirmed in writing within 10 days) marked "Confidential" or reasonably understood as such.

5.2 **Obligations**: Hold in confidence ≥ **5 years** from disclosure; use solely for MoU purposes; disclose only to personnel with need-to-know bound by equivalent obligations.

5.3 **Exceptions**: Public domain; independently developed; lawfully received from third party; required by law (prompt notice to disclosing Party).

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6. DATA PROTECTION & ETHICS

- Personal data processed under **GDPR (EU 2016/679)** and Slovak Act No. 18/2018.
- Each Party acts as **independent controller** unless a Data Processing Agreement (DPA) is executed for specific shared datasets.
- Human research: Ethics Committee/IRB approval at performing site; compliance with **Declaration of Helsinki**, **ICH-GCP**, and national regulations.

- Animal research: Compliance with **EU Directive 2010/63/EU** and Slovak Act No. 39/2007; ARRIVE 2.0 reporting.

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7. FINANCIAL PROVISIONS

7.1 This MoU creates **no financial obligation**. Each Party bears its own costs (personnel, travel, consumables, publication fees) unless an Annex specifies otherwise.

7.2 **Grant Applications**: Joint submissions encouraged; budget allocation defined per Annex. Overhead rates per each Party's institutional policy.

7.3 **Commercial Exploitation**: Revenue-sharing for jointly owned IP negotiated in good faith per Annex (default 50/50 net revenue).

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8. BRANDING & PUBLIC COMMUNICATION

- **Joint Logo Lockup**: Co-branded mark for collaboration outputs (provided by MHI / Institution design office).
- **Press Releases / Social Media**: Pre-approval by both Liaisons (24-hr turnaround).
- **Website**: Each Party maintains a **Partner Page** and a shared **Collaboration Hub** (see Annex 1: Digital Presence Guidelines).

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9. TERM AND TERMINATION

Provision	Detail
Effective Date	Date of last signature
Initial Term	**3 years**
Renewal	Automatic 2-year renewals unless either Party gives **90 days' written notice**
Termination for Convenience	Either Party: **60 days' written notice**
Termination for Cause	Material breach uncured after **30 days' notice**
Effect of Termination	Surviving clauses: 4 (IP), 5 (Confidentiality), 6 (Data/Ethics), 12 (Disputes), 13 (Governing Law). Ongoing Annexes continue unless jointly wound down.

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10. LIABILITY & INDEMNIFICATION

- **No Consequential Damages**: Neither Party liable for indirect, consequential, or punitive damages.

- **Cap**: Liability limited to **direct damages up to €50,000** (or equivalent) per incident, except for: (a) breach of confidentiality; (b) IP infringement; (c) gross negligence/willful misconduct.
- **Indemnification**: Each Party indemnifies the other against third-party claims arising from its negligent acts/omissions under this MoU.

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11. DISPUTE RESOLUTION

1. **Good-faith negotiation** between Liaisons (15 days).
2. **Escalation** to Steering Committee (15 days).
3. **Mediation** under **Meditation Rules of the Slovak Arbitration Centre / [MHI's preferred body]** (60 days).
4. **Binding Arbitration**: **Slovak Arbitration Act (Act No. 244/2002)**, seat **Bratislava**, language **English**, **3 arbitrators** (1 each Party, 1 chair). Award enforceable in any jurisdiction where assets held.

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12. GENERAL PROVISIONS

Clause	Summary
14.1 Entire Agreement	This MoU + Annexes = complete understanding; supersedes prior discussions.
14.2 Amendments	Writing only, signed by both Parties' authorized signatories.
14.3 Assignment	Not permitted without prior written consent (except to affiliates with notice).
14.4 Notices	Email + registered mail to Liaisons; deemed received on email acknowledgment or 3 business days post-mailing.
14.5 Severability	Invalid provisions severed; remainder enforced.
14.6 Counterparts	May be executed in counterparts (electronic signatures valid).
14.7 No Agency	No partnership, joint venture, or employment relationship created.

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13. SIGNATORIES

FOR European Academy for Molecular Hydrogen Research in Biomedicine n.o., Institute for Heart Research, Center of Experimental Medicine, Slovak Academy of Sciences Bratislava, Dubravska cesta 9, Slovak Republic

Represented by director: **Prof. Jan Slezak, PhD**, DSc., FIACS

For: Molecular Hydrogen Institute
Date: _

Mgr. Tyler Le BaronPhD