Annual Report
Clinical Trials of Investigational Stem Cell Treatment

NOTICE: THE INFORMATION IS PUBLICLY AVAILABLE

Report Year September 1, 2024 to August 31, 2025

1. NAME AND ADDRESS OF THE INSTITUTIONAL REVIEW BOARD (IRB)

Name of IRB			
University of Texas Health Science Center at Houston Committee for the Protection of Human Subjects (CPHS)			
Address 1	Address 2		
6410 Fannin Street	Suite 1100		
City	State	ZIP or Postal Code	
Houston	TX	77030	
Email Address	Phone		
charles.s.cox@uth.tmc.edu	(713) 500-7943		

2. NAME AND ADDRESS OF ALL MEDICAL SCHOOLS AND HOSPITALS AFFILIATED WITH THE IRB

Note: The IRB must be affiliated with a medical school as defined by Section 61.501 of the Education Code or a hospital licensed under Chapter 241 of the Texas Health and Safety Code that has at least 150 beds.

Name of Medical School or Hospital			
UTHealth Houston McGovern Medical School			
Address 1	Address 2		
6431 Fannin Street	Department of Pediatric Surgery, MSB 5.246		
City	State	ZIP or Postal Code	
Houston	TX	77030	

3. NAME AND ADDRESS OF PATIENT TREATMENT LOCATION(S) (Attach TMB-MD-0002-A if more space is necessary)

Treatment Location 1			
Memorial Hermann Hospital - Clinical Research Unit (MHH-CRU)			
Address	City	State	Zip
6411 Fannin Street	Houston	TX	77030
Treatment Location 2			
The University of Texas Health Science Center at San Antonio			
Address	City	State	Zip
8403 Floyd Curl Drive	San Antonio	TX	78229
Treatment Location 3			
Address	City	State	Zip
Treatment Location 4			
Address	City	State	Zip

4. PHYSICIAN NAMES CERTIFIED BY THE IRB OR AFFILIATED ENTITY (Attach TMB-MD-0003-A if more space is necessary)

Name (Last, First)	TX License Number	Certification Dates	
		From	To
Cox, Charles S.	H6136	12/06/1989	05/31/2026
Prossin, Alan R.	S6018	04/03/2020	05/31/2026
Ashley, Janet Rose	BP10074708	06/24/2021	06/23/2026
Fox, Peter T.	J0491	12/04/1991	11/30/2025
Fajemisin, Mokunfayo Oluwatosin	U5396	07/07/2023	08/31/2026
Covell, Jared	V2462	07/03/2024	08/31/2026
Alam, Tabrez	W0107	07/25/2025	08/31/2027

5. Provide a summary below containing the following information.

1. Sets forth the study's current findings.
2. Specifies the total number of patients participating in the stem cell clinical trials(s).
3. Includes the treatment results of all patients treated with investigational stem cell treatments.
4. Generally describes the effects of the treatments and all adverse events.

Do not include any patient identifying information

Autologous Adipose Derived Mesenchymal Stem Cells for Chronic Traumatic Brain Injury
NCT# 05951777

UTHealth in Houston began study enrollment in April 2024. A total of 24 subjects have been consented and 20 subjects have been enrolled and randomized. Fifteen subjects were randomized to investigational stem cell treatment and five subjects were randomized to placebo. Thirteen subjects have completed all three infusions. Seven subjects have completed the 6-month follow up visits. The first one year visit is due on August 2025. Minor AEs have been reported, such as headaches, irritability, fatigue, increased stress, nausea, and concentration intolerance. Only the headache and fatigue AEs were determined to be related to the study intervention after review of the Investigator's Brochure. Only one SAE, aspiration pnemonia, has recently been reported and detemined it was not related to study intervention as this occurred after the 6-month visit. No study analysis available at this time.

UTHealth in San Antonio is not actively screening and enrolling subjects. Training is ongoing. Expected to start enrollment in 1-2 months.

Houston Methodist Research Institute, located on 6670 Bertner Ave., Ste., R1-301, Houston, Texas 77030, is where imaging takes place.

Fat extractions are completed at:
Nikko Dermatology & Cosmetic Surgery Center 4707 Eigel Street, Suite 100, Housto, Texas 77007
and
Hamilton Clinic Houston 6624 Fannin Street, Suite 1650, Houston, Texas 77030

6. Indicate the top three treatment areas of the study.

1. Confirm the safety of HB-adMSC's as determined by the infusional toxicity of the cell product.
2. Microstructural metrics in brain MRI and PET images.
3. Develop a potency assay matrix.

7. SIGNATURE - I certify that the contents of and attachments to this document are complete and accurate.

SIGNATURE OF IRB CHAIRPERSON	DATE (mm/dd/yyyy)
Sujatha Sridhar, AVP Research Compliance -	12/16/2025