



Annual Report

Clinical Trials of Investigational Stem Cell Treatments

Report Year September 1, 2018 to August 31, 2019

NOTICE: THE INFORMATION IS PUBLICLY AVAILABLE

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

Name of IRB Advarra			
Address 1 6940 Columbia Gateway Drive		Address 2 #110	
City Columbia	State MD	ZIP or Postal Code 21046	
Email Address sara.harnish@advarra.com		Phone (410) 884-2900	

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 Memorial Hermann Healthcare System-UT Health, McGovern Medical School			
Address 1 6410 Fannin Street		Address 2	
City Houston, TX	State	ZIP or Postal Code 77C30	

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

Treatment Location 1 Austin Sports Medicine				
Address 900 W. 38th		City Austin	State TX	Zip 78705
Treatment Location 2 Athletic Orthopedics & Knee Center				
Address 9180 Katy Fwy		City Houston	State	Zip 77055
Treatment Location 3 Regional Pain Care Center				
Address 1111 Raintree Circle, Suite 170		City Allen	State	Zip 75013
Treatment Location 4 Central Park Surgery Center				
Address 900 W. 38th		City Austin	State	Zip 78705

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 trial(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

Within the reporting period a total of eleven (11) patients have received investigational stem cell treatments. All patients have experienced some level of improvement when a comparison is drawn between the pre-injection (baseline) joint examination and the scheduled follow-up examinations. The time period of physician assessment for the reporting period ranges from (1C) ten days post injection up to six (6) months for one patient. There were no adverse events reported (anticipated or unanticipated) during the reporting period. No patients have self-selected out of the study.

Patient ID/ Gender/ Age /Joint/ Physician/ Patient Assessment from Baseline/ Patient Evaluation of Pain Reduction Post Injection

1	M	69	Knee	Greatly Improved	No Pain Post Injection
2	F	60	Hip	Greatly Improved	Pain Reduced
3	M	69	Knee	Slightly/ Somewhat Improved	Minimal Pain Reduction
4	F	60	Knee	Slightly/ Somewhat Improved	Significant Pain Reduction
5	F	87	Knee	Slightly/ Somewhat Improved	Minimal Pain Reduction
6	M	82	Shoulder	Greatly Improved	Significant Pain Reduction
7	M	46	Knee	Greatly Improved	Significant Pain Reduction
8	F	69	Thumb	Slightly/ Somewhat Improved	No Pain Reduction
9	F	69	Knee	Greatly Improved	Significant Pain Reduction
10	M	67	Knee	Greatly Improved	Significant Pain Reduction
11	F	77	Knee	Slightly/ Somewhat Improved	Minimal Pain Reduction

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

1. Osteoarthritis
- 2.
- 3.

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

SIGNATURE OF IRB CHAIRPERSON

Sara Harnish

DATE (mm/dd/yyyy)

10/24/2019



Additional Treatment Locations Page
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3. ADDITIONAL NAME AND ADDRESS OF PATIENT TREATMENT LOCATIONS

Treatment Location 5

Soni Medical Centers

Address	City	State	Zip
2519 AVE O	Brooklyn	NY	11210

Treatment Location 6

Orthopedic Associates of Central Texas

Address	City	State	Zip
1015 E. 32nd Street, Suite 101	Austin	TX	78705

Treatment Location 7

Address	City	State	Zip
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Treatment Location 8

Address	City	State	Zip
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Treatment Location 9

Address	City	State	Zip
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Treatment Location 10

Address	City	State	Zip
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Treatment Location 11

Address	City	State	Zip
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Treatment Location 12

Address	City	State	Zip
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