NONREIMBURSABLE SPACE ACT AGREEMENT PROGRAM LETTER OF AGREEMENT BETWEEN The Methodist Hospital Graduate Medical Education AND The National Aeronautics and Space Administration Johnson Space Center for Orthopaedic Surgery Sports Medicine Program Collaboration

AUTHORITY AND PARTIES

This Non-reimbursable Space Act Agreement/Program Letter of Agreement (hereinafter referred to as the "Agreement") is by and between The Methodist Hospital, dba Houston Methodist Hospital ("TMH") and NASA Johnson Space Center ("NASA") under its authority codified in the National Aeronautics and Space Act (51 U.S.C. § 20113(e)). TMH and NASA may be individually referred to as a "Party" and collectively referred to as the "Parties."

I. PURPOSE AND PROGRAM

The purpose of this Agreement is to facilitate collaboration between the Parties in order to promote astronaut health and enable humans to optimize physical performance while training for, participating in, and recovering from spaceflight missions and to improve orthopedic care for patients on Earth. Specifically, TMH seeks to expand upon its expertise in the field of orthopedic sports medicine through exposure to a unique population of space travelers. Through this collaboration, TMH will receive experience evaluating effects of living and working in microgravity on the musculoskeletal system, thereby broadening their knowledge base to benefit terrestrial medicine, while providing orthopedic expertise to NASA through participation in astronaut patient care.

This collaborative partnership directly aligns with several of NASA's Strategic Goals as outlined in its 2018 Strategic Plan. Per Strategic Objective 1.2, NASA seeks to better understand human responses of biological and physical systems to space flight in order to enable further space exploration while also pioneering uses to benefit life on Earth. Objective 2.2 focuses on NASA's need to understand and mitigate the highest risks to astronaut health and performance to ensure that crews remain healthy and productive during long-duration missions beyond low Earth orbit. This Agreement provides a training experience and will allow TMH Fellows to collaborate with NASA on a rotational basis to fulfill these Strategic Objectives by providing specialized expertise to NASA to prevent and address musculoskeletal challenges astronauts must overcome to succeed on long duration space missions. The Fellows are highly trained in orthopedics sports medicine and possess dedicated skills that are not available within the NASA physician cadre. In turn, TMH Fellows will participate in musculoskeletal ultrasound training offered to flight surgeons and astronauts, thereby increasing their skills in preparation for their certification examinations. The Fellows will not have access to the NASA Electronic Medical Records system or clinical privileges at JSC.

A. <u>Points of Contact.</u>

Management Points of Contact

NASA Lyndon B. Johnson Space Center

The Methodist Hospital

Gary Beven, MD Space and Occupational Medicine Branch, Chief Mail Stop: SD311 2101 NASA Parkway Houston, Texas 77058 Phone: (281)483-3091 gary.beven-1@nasa.gov

Technical Points of Contact

NASA Lyndon B. Johnson Space Center Richard Scheuring, MD Team Lead, Musculoskeletal and Sports Medicine, Flight Surgeon and Site Supervisor Mail Suite: SD311 2101 NASA Parkway Houston, Texas 77058 Phone: (281)483-9769 richard.a.scheuring@nasa.gov Orthopedic Surgery Sports Medicine Laura M. Colton, MD Designated Institutional Official 6565 Fannin St, MGJ9-024 Houston, TX 77030-2602 Phone: (713)441-1107 Fax: (713)441-1107 Imcolton@houstonmethodist.org

<u>The Methodist Hospital</u> <u>Orthopedic Surgery Sports Medicine</u> David Lintner, MD Program Director Orthopedic Surgery Sports Medicine 6565 Fannin St, MGJ9-024 Houston, TX 77030-2602 dmlintner@houstonmethodist.org

Trevor M. Burst, MS, EdD Vice President Education Administration tmburst@houstonmethodist.org

B. Educational Goals and Objectives.

The TMH educational purpose of this one-half (1/2) day per week experience for 8 weeks per Fellow in sports medicine program of the Space Medicine Division is to provide the Orthopaedic Surgery Sports Medicine Program Fellows with the instruction and experience necessary to acquire skills and proficiency in:

Medical Knowledge

Fellows must demonstrate medical knowledge of established and evolving biomedical, clinical, epidemiological, and social behavioral sciences, as well as the application of this knowledge to patient care. Fellows are expected to:

- Develop knowledge of the field of Space Medicine, particularly:
 - The musculoskeletal challenges astronauts must overcome in order to succeed in their demanding occupation
 - The mechanism of injuries that result from donning and working in the Extravehicular Mobility Unit (EMU)
- Recognize the importance of coexisting diseases and their effects on caring for their orthopedic injuries
- Apply detailed principles of basic science (e.g., anatomy, biomechanics, pathology, and physiology specific to orthopedic surgery and sports medicine) in the use of non-operative techniques including therapy modalities, physical therapy exercises, bracing, and performance training

- Apply the basic and clinically supportive sciences appropriate to orthopedic surgery and sports medicine
- Demonstrate competence in describing the expectations for surgery, both physically and psychologically
- Develop and demonstrate detailed knowledge in the mechanisms of injury and apply this knowledge to:
 - o Chronic and acute injuries of the acromioclavicular and sternoclavicular joints
 - Disorders of the rotator cuff
 - Shoulder instability
 - $\circ \quad \text{Elbow instability and tendon disorders}$
 - Spinal disorders (i.e., disc herniation)
 - Meniscus tears
 - o Chondral injuries
 - o Patellofemoral disorders
 - o Isolated ACL injury
 - o Isolated PCL injury
 - Knee dislocations
 - Complications of knee surgery
 - o Stress fractures
- Recognize and apply appropriate indication for and interpretation of various imaging studies
- Demonstrate an investigatory and analytic thinking approach to clinical situations

Patient Care

Fellows must be able to provide patient care that is compassionate, appropriate, and effective for the treatment of health problems and the promotion of health. The following standards for patient care will be followed to:

- Coordinate referrals for testing outside of NASA and for prescriptions for medications outside of the NASA formulary and pharmacy by the NASA physician supervisor or the delegated authority before the referral is written
- Coordinate changes to ASCR standing orders through the NASA physician supervisor or the delegated authority
- If competent, perform and render a preliminary interpretation of ultrasound imagery to diagnose musculoskeletal conditions and injuries. (Final diagnosis and report of ultrasound scans by a Radiologist affiliated with NASA)
- Interview patients in an appropriate, respectful, and non-judgmental manner (e.g., use a translator when appropriate and use language that is socially and ethnically sensitive)
- Evaluate and provide care to injured astronauts in their training room and perform (if competent to perform) and interpret musculoskeletal ultrasound to make a preliminary diagnosis.
- Develop and demonstrate the necessary skills to take a complete orthopedic history and physical examination of patients in the office and athletic training rooms with a focus on occupationally related injuries
- Develop and implement plans for non-operative management, operative treatment, and postoperative rehabilitation of patients with injuries and disorders of the knee, shoulder, and elbow
- Develop appropriate non-operative care plans for occupational injuries of the hip, spine, hand, foot, and ankle
- Evaluate relevant imaging studies

Practice Based Learning and Improvement

Fellows must demonstrate the ability to investigate and evaluate their care of patients, to appraise and assimilate science evidence, and to continuously improve patient care based on consistent selfevaluation and life-long learning. Fellows electing to work on the NASA project to correlate injury data to anthropomorphic and biometric data gathered in astronauts, will be provided IT access at NASA/Johnson Space Center to the Lifetime Surveillance of Astronaut Health (LSAH) databases to gather data. Fellows are expected to:

- Participate in in-house musculoskeletal ultrasound training offered to flight surgeons and astronauts
- Provide orthopedic training to Flight Surgeons through clinical work, or, if available, informal training sessions at future forums
- Be able to apply and build on the basic concepts of orthopedics from experience gathered from one patient to the next
- Locate, appraise, and assimilate evidence from scientific studies related to their patients' health problems
- Apply knowledge of study designs and statistical methods to the appraisal of clinical studies and other information on diagnostic and therapeutic effectiveness
- Analyze and evaluate practice experiences and implement strategies to continually improve the quality of patient practice
- Participate in the education of patients, families, students, residents, and other health professionals

Interpersonal and Communication Skills

Fellows must acquire and demonstrate interpersonal and communication skills that result in the effective exchange of information and collaboration with patients, their families, and health professionals. Fellows are expected to:

- Publish medical information pertaining to the astronaut corps is only allowed after NASA review and with written consent from NASA
- Work with the Astronaut Strength, Conditioning and Rehabilitation (ASCR) athletic trainers in the crew gymnasium
- Work as part of a team of providers who care for a specialized patient population in that of NASA's astronauts
- Effectively and appropriately communicate physical findings pertinent for orthopedic care to members of the health care team
- Communicate effectively with physical therapists and athletic trainers in the care of athletes
- Communicate effectively and respectfully with operating room personnel
- Demonstrate a bedside manner that improves patient confidence and reduces patient anxiety regarding their orthopedic injuries
- Provide effective professional consultation to other physicians at NASA/JSC and the Hospital and health care professionals at NASA/JSC and the Hospital and sustain therapeutic ethically sound professional relationships.
- Use effective listening, questioning, and narrative skills to communicate with patients and families
- Interact with consultants in a respectful and appropriate manner
- Maintain comprehensive, timely, and legible medical records

Professionalism

Fellows must demonstrate a commitment to carrying out professional responsibilities and an adherence to ethical principles. Fellows are expected to demonstrate:

- Sensitivity to medical records regarding the small cadre of people that comprise the astronaut corps
- Relate to a high demand professional patient population (astronauts) in a respectful and caring manner
- Compassion, integrity, and respect for others

- Responsiveness to patient needs that supersedes self-interest
- Respect for patient privacy and autonomy, including the patient's medical information
- Accountability to patients, society, and the profession
- Sensitivity and responsiveness to a diverse patient population, including but not limited to diversity in gender, age, culture, race, religion, disabilities, and sexual orientation
- Commitment to excellence and ongoing professional development
- Commitment to ethical principles pertaining to provision or withholding of clinical care, confidentiality of patient information, informed consent, and business practices
- Sensitivity and responsiveness to fellow health care professionals' culture, age, gender, and disabilities
- Adherence to principles of confidentiality, scientific/ academic integrity, patient privacy and informed consent

C. <u>Period of Assignment of Fellows, Financial Support and Benefits</u>.

Fellows will rotate one-half day per week for 8 weeks per Fellow (total of 4 days), as scheduled by the TMH Program Director and NASA on site coordinator. Prior notice, when possible, will be made for any changes in these Rotations. Only one (1) PGY6 Fellow will rotate at any given time.

TMH will provide NASA with a written list of the names of Fellows assigned to NASA, the level of academic preparation, and the length and dates of assignment at NASA at least thirty (30) days prior to the beginning of each Rotation, unless otherwise agreed by the parties. Due to the lengthy duration required to obtain security badging and other access requirements, TMH will provide Fellow information well in advance of the rotation so that NASA can contact the Fellows directly.

The first one-half day rotation for each Fellow will be used for an orientation session and to complete paperwork required to work in a Federal facility.

Financial arrangements (e.g., Fellow salary, benefits, and professional liability insurance) will be provided by TMH. Fellow(s) will be under the general direction of NASA Medical Staff Bylaws and TMH Fellow Policies and Procedures, including policies related to benefits and leave time. TMH shall provide evidence to NASA of professional liability coverage for TMH Fellows.

This training will be in compliance with the Accreditation Council for Graduate Medical Education Common Program Requirements, VI. Fellow Duty Hours and Working and Learning Environment, effective July 1, 2017.

D. <u>Responsibility for Teaching, Supervision, and Evaluation of Fellows</u>.

TMH has the responsibility for the Fellows' educational program. NASA will, at all times, have sole authority and control over all aspects of patient care and will designate those patients to whom Fellows may be exposed during the Rotation. Appropriately qualified TMH Medical Staff members will be responsible for providing supervision of the Fellow(s) during the course of their educational experience at NASA. Fellows will be expected to behave as peers to NASA's medical staff members but must be supervised in all their activities commensurate with the complexity of care being given and the Fellow's own abilities and experience. Fellows will not replace NASA staff or provide service to patients except as identified for educational value and delineated in the Program.

Fellow evaluations will be both formal and informal. At the conclusion of the Fellow's NASA Rotation, TMH will provide an evaluation form to NASA medical staff members who have had significant contact with TMH's Fellows. Fellows will also be expected to complete evaluations for the NASA Rotation and the teaching faculty.

The NASA on-site coordinator shall have the right to deny access to a Fellow, in accordance with NASA policy.

E. Policies and Procedures that Govern Fellows' Education.

TMH is ultimately responsible for the Program per the ACGME Institutional Requirements and retains responsibility for the quality of graduate medical education, even when resident education occurs in other institutions. TMH GME policies and procedures will apply to Fellows. NASA's rules, regulations, policies, procedures, and medical staff bylaws will also govern the Fellow's educational experience at NASA.

II. NASA Responsibilities

NASA JSC will use reasonable efforts to:

- A. Accommodate three (3) Methodist Fellows per year, one (1) at a time for one-half day per week every other week, with each Fellow rotating every two (2) months twice per year, and accompanied by the Attending Orthopedic Surgeon monthly, as scheduled by the Methodist Program Director and NASA on-site coordinator;
- B. Provide Fellows with security badges and physical access to JSC, including buildings Fellows may need to access that require additional permission to enter (i.e. crew gymnasium);
- C. Provide an orientation for Fellows to inform them of JSC facilities, policies, procedures, rules, and regulations;
- D. Allow Fellows, at their own expense, to utilize JSC dining facilities.
- E. Provide Fellows with access to astronaut patients to facilitate orthopedic sports medicine education through evaluation of a diverse group of individuals;
- F. Provide the Fellows musculoskeletal ultrasound training similar to that offered to NASA flight surgeons and astronauts;
- G. Provide input to Methodist regarding NASA's experience with the Fellows in a mutually agreed upon format and participate in collaborative reviews to enable continuous improvement of the partnership.

III. <u>TMH's Responsibilities</u>

TMH will use reasonable efforts to:

- A. Assign Fellows in Sports Medicine to provide specialized orthopedic expertise to assist with injury prevention and treatment of astronauts;
- B. Provide NASA a written list of the names of the Fellows assigned to NASA, the level of academic preparation, and the length and dates of assignment at NASA at least thirty (30) days prior to the beginning of each rotation, unless otherwise agreed by the Parties;

- C. Provide evidence to NASA of professional liability coverage for the rotational Methodist Fellows;
- D. If applicable, ensure that each Fellow has secured and maintains all documentation required for Fellow to enter and stay in the United States to allow Fellow to participate in the Rotation;
- E. Provide NASA with documentation that Fellows assigned to NASA are authorized by the Texas Medical Board to provide patient care services;
- F. Provide information regarding Fellows participating in the Program as requested by NASA, unless prohibited by Federal or State Law;
- G. Meet with NASA virtually as necessary to provide for adequate communication and planning and/or evaluate progress of Fellows and value of the experience received, including participation in collaborative reviews to enable continuous improvement of the partnership;
- Promote adherence by the Fellows to JSC and other Federal policies, procedures, rules, and regulations, including but not limited to Health Information Management System (HIMS), 1974
 Privacy Act as Amended, and Health Insurance Portability and Accountability Act of 1996 (HIPAA) Compliance, in accordance with the NASA-provided orientation, in order to maintain participation in the Rotation.
- I. Ensure that each Fellow assumes responsibility for his/her own uniforms, transportation, parking, housing, meals, laundry needs, and health care in the performance of activities under this Program, when such things not provided for by NASA.

IV. Milestones

The planned major milestones for the activities defined in the "Responsibilities" above are as follows:

Methodist Assignment of Fellows	No Later Than (NLT) 30 days prior to each Rotation
NASA JSC physical access provisioning	Start of each Rotation
NASA evaluation of experience with Fellows	Quarterly
Methodist Fellow evaluation of experience at NASA	NLT 30 days following the end of the final Rotation for each Fellow
NASA and Methodist Collaborative Review to enable continuous improvement of the partnership	Yearly

V. <u>General Provisions</u>

A. <u>Term of Agreement.</u> This Agreement becomes effective on Tuesday, July 5, 2022 and shall remain in effect until the completion of all obligations of both Parties hereto, or five years from the Effective Date, whichever comes first.

- B. <u>Termination upon Notice</u>. This agreement may be terminated by either party upon written notice to other party sixty (60) calendar days prior to termination.
- C. <u>Notice</u>. Any notice, request or other communication required or permitted under this Agreement shall be in writing and addressed to:

The Methodist Hospital	NASA Johnson Space Center
Academic Institute	Human Health and Performance
6670 Bertner Avenue	2101 NASA Parkway
Houston, TX 77030	Houston, TX 77058
Attn: Trevor M. Burt, MS, EdD	Attn: John T. Sims

- D. <u>Non-discrimination</u>. The Program and all related Rotation activities will be conducted in a manner that does not discriminate against any person on a basis prohibited by applicable law, including but not limited to race, color, national origin, religion, sex, age, veteran status, or disability.
- E. <u>Fellows' Status</u>. Fellows participating in this Program will not be employees of NASA and have no claim against NASA for any employment benefits including but not limited to wages, workers' compensation benefits, disability benefits, or health insurance. At no time will Fellows or TMH personnel be considered or represent themselves as agents, either express or apparent, officers, servants, or employees of NASA. Fellows will wear TMH-defined nametags identifying their status.
- F. <u>Entire Agreement/Modification</u>. This Agreement constitutes the entire understanding between the parties with respect to the identified subject matter, and no prior or contemporaneous agreement, written or oral, will be effective to vary the terms of this Agreement. Any modification(s) to this Agreement shall be executed, in writing, and signed by an authorized representative of NASA and TMH.
- G. <u>Use of TMH Name and Emblems</u>. Except as otherwise required by law or regulation, neither party will use, release, or distribute any materials or information containing the name or logo or any of its employees without the prior written approval of an authorized representative of the non-releasing party, such approval not to be unreasonably withheld. For purposes of this section, the authorized representative of TMH is Lara Colton, MD, DIO.
- H. <u>Use of NASA Name and Emblems.</u>

1. NASA Name and Initials. TMH shall not use "National Aeronautics and Space Administration" or "NASA" in a way that creates the impression that a product or service has the authorization, support, sponsorship, or endorsement of NASA, which does not, in fact, exist. Except for releases under the "Release of General Information to the Public and Media" Article, TMH must submit any proposed public use of the NASA name or initials (including press releases and all promotional and advertising use) to the NASA Associate Administrator for the Office of Communications or designee ("NASA Communications") for review and approval. Approval by NASA Office of Communications shall be based on applicable law and policy governing the use of the NASA name and initials.

2. NASA Emblems. Use of NASA emblems (i.e., NASA Seal, NASA Insignia, NASA logotype, NASA Program Identifiers, and the NASA Flag) is governed by 14 C.F.R. Part 1221. TMH must submit any proposed use of the emblems to NASA Communications for review and approval.

- I. <u>Release of General Information to the Public and Media.</u> NASA or TMH may, consistent with Federal law and this Agreement, release general information regarding its own participation in this Agreement as desired. Pursuant to Section 841(d) of the NASA Transition Authorization Act of 2017, Public Law 115-10 (the "NTAA"), NASA is obligated to publicly disclose copies of all agreements conducted pursuant to NASA's 51 U.S.C. §20113(e) authority in a searchable format on the NASA website within 60 days after the agreement is signed by the Parties. The Parties acknowledge that a copy of this Agreement will be disclosed, without redactions, in accordance with the NTAA.
- J. <u>Representative's authority to contract</u>. By signing this Agreement, each representative thereby represents that such person is duly authorized to execute this Agreement.
- K. <u>Assignment.</u> Neither this Agreement nor any interest arising under it will be assigned by TMH or NASA without the express written consent of the officials executing, or successors, or higher-level officials possessing original or delegated authority to execute this Agreement.
- L. <u>Applicable Law.</u> U.S. Federal law governs this Agreement for all purposes, including, but not limited to, determining the validity of the Agreement, the meaning of its provisions, and the rights, obligations, and remedies of the Parties.

M. <u>Compliance with Laws and Regulations.</u>

1. The Parties shall comply with all applicable laws and regulations including, but not limited to, safety; security; export control; environmental; and suspension and debarment laws and regulations. Access by a Partner to NASA facilities or property, or to a NASA Information Technology (IT) system or application, is contingent upon compliance with NASA security and safety policies and guidelines including, but not limited to, standards on badging, credentials, and facility and IT system/application access, including use of Interconnection Security Agreements (ISAs), when applicable.

2. With respect to any export control requirements:

a. The Parties will comply with all U.S. export control laws and regulations, including the International Traffic in Arms Regulations (ITAR), 22 C.F.R. Parts 120 through 130, and the Export Administration Regulations (EAR), 15 C.F.R. Parts 730 through 799, in performing work under this Agreement or any Annex to this Agreement. In the absence of available license exemptions or exceptions, the TMH shall be responsible for obtaining the appropriate licenses or other approvals, if required, for exports of hardware, technical data, and software, or for the provision of technical assistance.

b. TMH shall be responsible for obtaining export licenses, if required, before utilizing foreign persons in the performance of work under this Agreement or any Annex under this Agreement, including instances where the work is to be performed on-site at NASA and where the foreign person will have access to export-controlled technical data or software.

c. TMH will be responsible for all regulatory record-keeping requirements associated with the use of licenses and license exemptions or exceptions.

d. TMH will be responsible for ensuring that the provisions of this Article apply to its Related Entities.

3. With respect to suspension and debarment requirements:

a. TMH hereby certifies, to the best of its knowledge and belief, that it has complied, and shall comply, with 2 C.F.R. Part 180, Subpart C, as supplemented by 2 C.F.R. Part 1880, Subpart C.

b. TMH shall include language and requirements equivalent to those set forth in subparagraph C.1., above, in any lower tier covered transaction entered into under this Agreement.

4. With respect to the requirements in Section 889 of the National Defense Authorization Act (NDAA) for Fiscal Year 2019, Public Law 115-232:

a. In performing this Agreement, TMH will not use, integrate with a NASA system, or procure with NASA funds (if applicable), "covered telecommunications equipment or services" (as defined in Section 889(f)(3) of the NDAA).

b. The TMH will ensure that the provisions of this Article apply to its Related Entities.

- N. <u>Independent Relationship.</u> This Agreement is not intended to constitute, create, give effect to or otherwise recognize a joint venture, partnership, or formal business organization, or agency agreement of any kind, and the rights and obligations of the Parties shall be only those expressly set forth herein.
- O. <u>Confidentiality.</u> TMH and its Fellows and faculty participating in the Program under this Agreement agree to keep confidential all confidential information of NASA and not disclose or reveal any such information to any third party without the express prior written consent of NASA and if applicable, the patient or the patient's legal guardian or parent(s), consistent with applicable local, state, or federal law or regulation.

<u>Health Information Management System (HIMS) compliance and 1974 Privacy Act, as Amended</u> <u>compliance</u>. Compliance education will be completed during the orientation visit to NASA/JSC.

HIPAA Compliance. Each party and the Fellows and faculty of TMH participating in the Program under this Agreement agrees to comply, to the extent required, with the applicable provisions of the Administrative Simplification Section of the Health Insurance Portability and Accountability Act of 1996, as codified at 42 U.S.C. § 1320d through d-8 ("HIPAA"), and the requirements of any applicable regulations promulgated there under including without limitation the Privacy Act codified at 5 U.S.C. § 552a and federal privacy regulations as contained in 45 CFR Part 164 (the "Federal Privacy Regulations") and the federal security standards as contained in 45 CFR Part 142 (the "Federal Security Regulations"). Each party and the Fellows and faculty participating in the Program under this Agreement agrees not to use or disclose any protected health information, as defined in 45 CFR 164.504, or individually identifiable health information, as defined in 42 U.S.C. § 1320d (collectively, the "Protected Health Information"), concerning a patient other than as permitted by this Agreement and the requirements of HIPAA or regulations promulgated under HIPAA including without limitation the Federal Privacy Regulations and the Federal Security Regulations. Each party will promptly report to the other party upon knowledge and verification, any use or disclosure of a patient's Protected Health Information not provided for by this Agreement or in violation of any applicable local, state, or federal law, including HIPAA, the Privacy Act, the Federal Privacy Regulations, or the Federal Security Regulations of which that party becomes aware. Notwithstanding the foregoing, TMH and NASA agree that under HIPAA, healthcare training and educational Programs for provider trainees or Fellows are considered a facet of healthcare operations and as such, Protected Health Information may be disclosed in the performance of such functions without patient authorization. Notwithstanding the foregoing, no

attorney-client, accountant-client, physician-patient or other legal privilege shall be deemed waived by NASA or TMH by virtue of this Subsection.

- P. <u>Non-Exclusion</u>. Each party represents and warrants that as of the Effective Date of this agreement, neither it nor any of its employees, Fellows, or medical staff members involved in this Program is excluded from a federal or state health care program or from participation in any federal or state procurement or non-procurement programs. Each party also represents that if it or any of its employees, Fellows, or medical staff members involved in this Program becomes so excluded from a federal or state health care program or from participation in any federal or state procurement or non-procurement program or from participation in any federal or state procurement or non-procurement program or from participation in any federal or state procurement or non-procurement programs, it will promptly notify the other party.
- Q. <u>Access to Records</u>. In the event that a request for NASA records pertaining to the subject matter of this Agreement and the provision of service under it is received, is received, NASA will respond in accordance with the Privacy Act of 1974, as amended, and/or the Freedom of Information Act (5 U.S.C. § 552,)
- R. <u>Deficit Reduction Act of 2005</u>. The DRA requires TMH to inform all employees, contractors, and their agents of the following: TMH receives reimbursement for many of its services from the Medicare and Medicaid programs. Under the federal False Claims Act and Texas laws, any person who knowingly submits, or causes someone else to submit illegal claims for payment of government funds is subject to government fines and penalties. Reports of suspected illegal claim activity may be made through (a) anonymously through TMH's Hotline service (1-800-500-0333); (b) by contacting the person indicated in the Notice Section of this Agreement; or (c) by contacting TMH's Business Practice Officer but may also be made to the Department of Health and Human Services Office of Inspector General or the Texas Health and Human Services are protected by TMH policy and by federal and state laws from retaliation for reports made in good faith.
- S. <u>Financial Obligations.</u> There will be no transfer of funds between the Parties under this Agreement and each Party will fund its own participation. All activities under or pursuant to this Agreement are subject to the availability of funds, and no provision of this Agreement shall be interpreted to require obligation or payment of funds in violation of the Anti-Deficiency Act, (31 U.S.C. § 1341).
- T. <u>Priority of Use.</u> Any schedule or milestone in this Agreement is estimated based upon the Parties' current understanding of the projected availability of NASA goods, services, facilities, or equipment. In the event that NASA's projected availability changes, TMH shall be given reasonable notice of that change, so that the schedule and milestones may be adjusted accordingly. The Parties agree that NASA's use of the goods, services, facilities, or equipment shall have priority over the use planned in this Agreement. Should a conflict arise, NASA in its sole discretion shall determine whether to exercise that priority. Likewise, should a conflict arise as between two or more non-NASA TMHs, NASA, in its sole discretion, shall determine the priority as between those TMHs. This Agreement does not obligate NASA to seek alternative government property or services under the jurisdiction of NASA at other locations.
- U. <u>Non-exclusivity.</u> This Agreement is not exclusive; accordingly, NASA may enter into similar agreements for the same or similar purpose with other private or public entities.
- V. <u>Liability and Risk of Loss.</u>

1. Each Party hereby waives any claim against the other Party or one or more of its Related Entities (defined below) for any injury to, or death of, the waiving Party or one or more of its Related Entities, or for damage to, or loss of, the waiving Party's property or the property of its Related Entities arising from or related to activities conducted under this Agreement, whether such injury, death, damage, or loss arises through negligence or otherwise, except in the case of willful misconduct.

2. TMH further agrees to extend this waiver to its related entities by requiring them, by contract or otherwise, to waive all claims against NASA and its Related Entities for injury, death, damage, or loss arising from or related to activities conducted under this Agreement. For purposes of this Agreement, "Related Entities" shall mean contractors and subcontractors of a Party at any tier; grantees, investigators, customers, and users of a Party at any tier and their contractors or subcontractor at any tier; or employees of the Party or any of the foregoing.

- W. <u>Intellectual Property Rights Data Rights.</u> Information and data exchanged under this Agreement is exchanged without restrictions unless required by national security regulations (e.g., classified information) or as otherwise provided in this Agreement or agreed to by the Parties for specifically identified information or data (e.g., information or data specifically marked with a restrictive notice).
- X. Intellectual Property Rights Invention and Patent Rights.

1. "Related Entity" as used in this Invention and Patent Rights Article means a contractor, subcontractor, grantee, or other entity having a legal relationship with NASA or TMH assigned, tasked, or contracted with to perform activities under this Agreement.

2. The invention and patent rights herein apply to employees and Related Entities of TMH. TMH shall ensure that its employees and Related Entity employees know about and are bound by the obligations under this Article.

3. NASA has determined that 51 U.S.C. § 20135(b) does not apply to this Agreement. Therefore, title to inventions made (conceived or first actually reduced to practice) under this Agreement remain with the respective inventing party(ies). No invention or patent rights are exchanged or granted under this Agreement. NASA and TMH will use reasonable efforts to report inventions made jointly by their employees (including employees of their Related Entities). The Parties will consult and agree on the responsibilities and actions to establish and maintain patent protection for joint invention, and on the terms and conditions of any license or other rights exchanged or granted between them.

- Y. <u>Continuing Obligations.</u> The rights and obligations of the Parties that, by their nature, would continue beyond the expiration or termination of this Agreement, e.g., "Liability and Risk of Loss" and "Intellectual Property Rights"-related clauses shall survive such expiration or termination of this Agreement.
- Z. <u>Dispute Resolution.</u> Except as otherwise provided in the Article entitled "Priority of Use," the Article entitled "Intellectual Property Rights Invention and Patent Rights" (for those activities governed by 37 C.F.R. Part 404), and those situations where a pre-existing statutory or regulatory system exists (e.g., under the Freedom of Information Act, 5 U.S.C. § 552), all disputes concerning questions of fact or law arising under this Agreement shall be referred by the claimant in writing to the appropriate person identified in this Agreement as the "Points of Contact." The persons identified as the "Points of Contact" for NASA and TMH will consult and attempt to resolve all issues arising from the implementation of this Agreement. If they are unable to come to agreement on any issue, the dispute will be referred to the signatories to this Agreement, or their designees, for joint resolution. If the Parties remain unable to resolve the dispute, then the NASA signatory or that person's designee, as applicable, will issue a written decision that will be the final agency

decision for the purpose of judicial review. Nothing in this Article limits or prevents either Party from pursuing any other right or remedy available by law upon the issuance of the final agency decision.

- AA. <u>Disclaimer of Endorsement.</u> NASA does not endorse or sponsor any commercial product, service, or activity. NASA's participation in this Agreement or provision of goods, services, facilities, or equipment under this Agreement does not constitute endorsement by NASA. Partner agrees that nothing in this Agreement will be construed to imply that NASA authorizes, supports, endorses, or sponsors any product or service of Partner resulting from activities conducted under this Agreement, regardless of the fact that such product or service may employ NASA-developed technology.
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By: ______Gary Beven, M.D. Chief, Space Medicine Operations Division

DocuSigned by: David Lintner, MD By:

David Lintner, M.D. Program Director Orthopaedic Surgery Sports Medicine Program

Jogel By:

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Joseph LaVan, M.D. Medical Director, Clinical Services *for* Richard A. Scheuring, M.D. Team Lead, Musculoskeletal and Sports Medicine Flight Surgeon and Site Supervisor

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