THE SOCIETY FOR CARDIOVASCULAR MAGNETIC RESONANCE (SCMR) REGISTRY

PARTICIPATION AGREEMENT

THIS PARTICIPATION AGREEMENT (“Agreement” or “Participation Agreement”) is entered into and made effective the date of the last signature below (“Effective Date”), by and between (a) the Society for Cardiovascular Magnetic Resonance (“SCMR”) and (b) ____________________________________________, (“Participant”).

WHEREAS, SCMR (with the assistance of a third party contractor) has developed and maintains certain computerized databases containing information and images relating to patient treatment, the practice of medicine, and third party patient data and images submitted to these databases pursuant to rules developed by SCMR (said databases collectively referred to herein as the “the Registry”); and

WHEREAS, Participant has expressed an interest in participating in the Registry in accordance with this Agreement and SCMR requirements;

NOW, THEREFORE, in consideration of the foregoing recitals and the covenants contained herein, and for other good and valuable consideration, the parties hereto agree as follows:

1. Definitions.

1.1. “Local Data” shall be defined as information including images related to the practice of medicine created and maintained by Participant and physically stored in a data center owned and operated by Participant or Participant’s employer. Local Data will contain “Protected Health Information” (“PHI”) as that term is defined by the regulations promulgated under the Health Insurance Portability and Accountability Act of 1996, codified at 45 CFR Parts 160 and 164, as amended by the Privacy and Security provisions set forth in Section 13400 of the Health Information Technology for Economic and Clinical Health Act, Public Law 111-5 (the “HIPAA Regulations”).

1.2 “De-Identified Data” shall be defined as Local Data that has been de-identified in accordance with the HIPAA Regulations at 45 C.F.R. § 164.514.

1.3 “Synchronized Cloud Data” shall be defined as a set of De-Identified Data that is a de-identified copy of the Local Data that is automatically kept in synchrony with the Local Data by specialized computer software. Synchronized Cloud Data is stored in an Internet data center by SCMR, with the assistance of Heart Imaging Technologies, Inc. (“Heart IT”), SCMR’s third party contractor (“Contractor”).
1.4 “Project-Based Use” shall be defined as the use of Synchronized Cloud Data for a specific purpose defined by SCMR that may involve multiple participants, such as a multi-center research study.

2. Participation in the Registry.

2.1 Participant will participate in the Local Data collection conducted by the Registry by using software created by Contractor to automatically de-identify Local Data and upload such De-Identified Data to SCMR’s internet data center. SCMR and other participants shall be permitted to view and audit (but not use) Participant’s Synchronized Cloud Data through the software maintained by Contractor.

2.1.1 Participant agrees to comply with the rules, policies, and guidelines reasonably established by SCMR in connection therewith. Such rules, policies, and guidelines will be posted to SCMR’s website and may be updated from time to time. Participant will receive notification of all changes before they take effect.

2.1.2 Participant agrees and acknowledges that SCMR will not have access to Participant’s Local Data that contains PHI, and will only have access to De-Identified Data.

2.1.3 Participant agrees and acknowledges that Contractor will have access to Participant’s Local Data that contains PHI for the sole purpose of supporting and improving the software used by Participant to create and maintain Local Data. Consequently, Participant shall enter into a Business Associate Agreement (“BAA”) with Contractor in order to ensure compliance with the HIPAA Regulations.

2.1.4 To the extent that any other international, federal, or state law, including, but not limited to, the European Union’s General Data Protection Regulation (“GDPR”), applies to the Local Data submitted by Participant to the Registry, and such law requires that Participant enter into a written agreement with Contractor regarding the transfer and protection of Participant’s data, Participant shall enter into such agreement with Contractor.

2.2 Participant agrees and acknowledges that SCMR may request Project-Based Use of Participant’s Synchronized Cloud Data. Such request will be made in writing from SCMR to the medical director of the clinical service responsible for creating and maintaining Participant’s Local Data. Upon such request, Participant’s medical director may approve or deny use of its Synchronized Cloud Data for the requested Project-Based Use. Once granted, Participant shall not revoke use of its Synchronized Cloud Data by SCMR for the approved Project-Based Use, except as described in Section 8.2 upon breach by SCMR, or Section 8.4. Participant’s approval of the use of its Synchronized Cloud Data for one Project-Based Use shall not imply approval for any other purpose.

2.2.1 Participant hereby states that to the best of its knowledge, all De-identified Data submitted for inclusion in the Registry will be accurate and complete. Participant will use reasonable efforts to address any data or related deficiencies identified by SCMR.
or Contractor. SCMR will work with Contractor to convert the Participant’s Local Data to the data format of SCMR. Participant agrees to inform SCMR of any change to its Local Data format.

Participant further promises to take reasonable steps to avoid the submission of duplicative data for inclusion in the Registry, and agrees to assist and cooperate with SCMR in its efforts to conduct the Registry.

2.2.2. Participant understands that SCMR provides the Registry “as is” and makes no warranties regarding the Registry, either express or implied, including no warranty of merchantability or fitness for a particular purpose.

2.3 Participant acknowledges that its failure to submit De-identified Data to the Registry, or its submission of De-identified Data to the Registry that does not comply with SCMR requirements, or failure to reasonably allow Project-Based Use of Participant’s Synchronized Cloud Data may result in Participant’s removal from the Registry and termination of this Participation Agreement as outlined in Section 8.

2.4 Participant agrees that it is Participant’s responsibility to obtain any permissions from its institutional review board (“IRB”) or other relevant regulators that may be required in order to submit such data for inclusion in the Registry.

3. **Benefit to Participants.** Participants will receive the following benefits from agreeing to Project-Based Use as defined in Section 1.4 above:

3.1 Participant will be informed in writing by SCMR of any research project approved by SCMR that will potentially involve usage of Participant’s data.

3.2 In the event that Participant approves use of its Synchronized Cloud Data for a requested Project-Based Use (as outlined in Section 2.2 above), Participant will have the option, on terms mutually agreeable to the parties, of participation, recognition and/or authorship in any research or work product resulting from the Project-Based Use. Such participation, recognition, and/or authorship shall be subject to the due consideration by the parties based on the scientific merits, potential authorships, time and effort provided to the research, sources of funding used in support of the project, and such other factors as may be determined by the parties from time to time, in accordance with academic standards and ICJME guidelines.

4. **Registry Funding.** Participant acknowledges that SCMR may from time to time seek sponsorships or other forms of commercial funding to help sustain the Registry, which funding opportunities may include allowing commercial entities to propose Project-Based Use of Synchronized Cloud Data submitted by participants (subject to Participant approval as described in Section 2.2 above).
5. **Compliance with Laws.** The parties hereby agree to comply with all applicable statutes and regulations, under federal and state laws, including but not limited to the HIPAA Regulations and any other applicable statutes or regulations concerning patient privacy and data security.

6. **Intellectual Property.**

   6.1 It is agreed and acknowledged that all Local Data submitted for inclusion in the Registry by Participant, including subsets thereof, are and shall remain Participant’s proprietary information. Participant hereby grants SCMR a royalty-free, non-exclusive, limited license to SCMR to use and allow other third party researchers approved by SCMR to use De-Identified Data to facilitate Participant’s participation in the Registry and for research purposes subject to the terms of this Agreement, including but not limited to Participant’s prior approval of Project-Based Use of Participant’s Synchronized Cloud Data under Section 2.2 herein. Unless otherwise stated in this Agreement, SCMR agrees that nothing herein shall be deemed to be a grant of any intellectual property rights to SCMR or any third party researchers with respect to Participant’s Local Data.

   6.2. Participant acknowledges that SCMR is and shall be deemed the owner of all rights to the Registry, including without limitation the aggregate De-Identified Data, all databases, data elements, data fields, data dictionaries, reports or analyses derived from the De-Identified Data; and all trademarks associated with SCMR or the Registry (including, without limitation, “SCMR”, “Society for Cardiovascular Magnetic Resonance”, and the “SCMR Registry” and all variations thereon and graphic representations thereof), (collectively, “SCMR Intellectual Property”) with the exception of Participant’s Local Data, including subsets thereof.

   6.3 Participant may not use SCMR Intellectual Property without first obtaining the express written consent of SCMR, provided that Participant may use aggregated data from the Registry that have been included in SCMR reports to Participant or previously released to the public by SCMR (e.g., in published reports and slide sets) without first obtaining such written consent so long as Participant does not make any statements about such data that are false or misleading.

   6.4 Neither party shall use the name, trademark, or logo of the other party or its employees for promotional purposes without prior written consent of the other party.

7. **Limitation of Liability; Indemnity.** Each party to this Agreement agrees that it will be responsible for its own acts and omissions; and, shall not be responsible for the acts and omissions of the other party. Each party agrees that it will assume all risk and liability to itself, its agents, or its employees for any injury to persons or property resulting in any manner from conduct of its own operations and the operations of its agents or employees in the performance of
this Agreement. Under no circumstances will either party be liable to the other for any indirect or consequential damages of any kind, including lost profits (whether or not the Parties have been advised of such loss or damage) arising in any way in connection with this Agreement.

Each party (the “Indemnifying Party”) hereto shall indemnify, defend and hold the other party hereto (the “Indemnified Party”) and its directors, partners, officers, employees, representatives, agents, and affiliates, harmless from and against any and all liabilities, suits, damages, taxes and all other withholdings and charges, including reasonable attorneys’ fees, arising from (a) the negligence or willful misconduct of Indemnifying Party, (b) Indemnifying Party's violation of any applicable law, rule or regulation, or (c) the performance, failure to perform, or breach by Indemnifying Party of any of Indemnifying Party’s covenants, warranties, agreements, duties, or obligations under or pursuant to this Agreement. This indemnity obligation shall survive the expiration or termination of this Agreement by either party.

8. **Term and Termination.**

8.1 Subject to the terms of this Section, this Agreement shall be effective for a period of one year and shall be automatically renewed on an annual basis thereafter unless any party provides the other(s) with a written notice of termination at least 30 days prior to the expiration of any term.

8.2 This Agreement may be terminated upon any party’s material breach of this Agreement, provided, however, that if said breach is cured to the non-breaching party’s reasonable satisfaction within thirty (30) days after the provision of such notice, said termination notice shall be of no further force or effect and this Agreement shall be fully reinstated.

8.3 Additionally, this Agreement may be terminated by either party without cause upon thirty (30) days written notice to the other Party.

8.4. Upon termination of this Agreement, Participant shall have the option of asking that its Synchronized Cloud Data in the Registry be removed at the later of either the date of termination or the conclusion of any pending research projects using the Synchronized Cloud Data.

9. **Equitable Relief.** The parties understand and agree that money damages may not be a sufficient remedy for the breach of the provisions of this Agreement, and that each party shall be entitled to seek emergency injunctive relief as a remedy for any such breach by any other party. Such remedy shall not be deemed to be the exclusive remedy for a breach of this Agreement, but shall be in addition to all other remedies at law or in equity to the non-breaching party.

10. **Independent Contractors.** The relationship of the parties to this Agreement is that of independent contractors, and not that of master and servant, principal and agent, employer and employee, or partners or joint venturers.
11.  **Inadvertent disclosure of PHI.** In the event that PHI is inadvertently included in the Synchronized Cloud Data provided by Participant, then SCMR will immediately notify Participant and will return or destroy such PHI, in accordance with the Participant’s written instructions.

12.  **Notices.** All notices and demands of any kind or nature which any party to this Agreement may be required or may desire to serve upon the other in connection with this Agreement shall be in writing, and may be served personally, by registered or certified United States mail, by fax transmission, by overnight courier or by e-mail to the following addressees:

If to Participant:  

__________________________________________________________

__________________________________________________________

__________________________________________________________

Email: _______________________________

(fax #) ______________________________

Attn: ________________________________

If to SCMR:  

Society for Cardiovascular Magnetic Resonance
19 Mantua Rd
Mt. Royal, NJ 08061
Email: hq@scmr.org
(fax #) 856-423-3420
Attn: Lauren Small

Service of such notice or demand so made shall be deemed complete on the day of actual delivery. Any party hereto may, from time to time, by notice in writing served upon the other party as aforesaid, designate a different mailing address or a different person to which all further notices or demands shall thereafter be addressed.
13. **Assignment.** This Agreement may not be assigned by either party without the prior express written approval of the other party.

14. **Counterparts.** This Agreement may be executed in one or more counterparts, each of which shall be deemed an original, and all of which taken together shall constitute one and the same instrument. Electronic signatures shall have the same effect as originals.

15. **Waiver.** A waiver by any party to this Agreement of any of its terms or conditions in any one instance shall not be deemed or construed to be a general waiver of such term or condition or a waiver of any subsequent breach.

16. **Severability.** All provisions of this Agreement are severable. If any provision or portion hereof is determined to be unenforceable by a court of competent jurisdiction, then the rest of this Agreement shall remain in full effect, provided that its general purposes remain reasonably capable of being effected.

17. **Entire Agreement.** This Agreement: (a) constitutes the entire agreement between the parties hereto with respect to the subject matter hereof; (b) supersedes and replaces all prior agreements, oral or written, between the parties relating to the subject matter hereof; and (c) except as otherwise indicated herein, may not be modified, amended or otherwise changed in any manner except by a written instrument executed by the party against whom enforcement is sought.

18. **Confidentiality.**

18.1 SCMR acknowledges that, in the course of providing services to Participant and/or in the course of Participant utilizing the Registry, SCMR may become aware of or come into possession of certain Confidential Information. “Participant Confidential Information” means all written and oral information, documents and data previously or hereafter obtained by SCMR from Participant in connection with this Agreement, including negotiated contract rates, technical data, programs, marketing plans, operating procedures and confidential medical information, but excluding the De-Identified Data that Participant submits to the Registry. SCMR agrees to hold all Participant Confidential Information in confidence and protect such Participant Confidential Information with the same protection it affords its own, but in no event less than reasonable protection. At the expiration or termination of this Agreement, SCMR shall return and/or destroy all Participant Confidential Information as specified by Participant. This provision shall survive the termination or expiration of this Agreement.

18.2 Participant acknowledges that, in the course of providing data to SCMR and/or in the course of SCMR utilizing the Registry, Participant may become aware of or come into possession of certain Confidential Information. “SCMR
Confidential Information” means all written and oral information, documents and data previously or hereafter obtained by Participant from SCMR in connection with this Agreement, including negotiated contract rates, technical data, programs, marketing plans, operating procedures and confidential medical information. Participant agrees to hold all SCMR Confidential Information in confidence and protect such SCMR Confidential Information with the same protection it affords its own, but in no event less than reasonable protection. At the expiration or termination of this Agreement, Participant shall return and/or destroy all SCMR Confidential Information as specified in writing by SCMR, provided however, that Participant will be entitled to retain one copy of the SCMR Confidential Information in a secure location for its legal and regulatory obligations hereunder and any electronic back-up or archival storage copies made in accordance with Participant’s standard procedures solely for purposes of disaster recovery and compliance with records retention policies. This provision shall survive the termination or expiration of this Agreement.
IN WITNESS WHEREOF, the parties hereto have duly executed this Agreement, as of the Effective Date.

SOCIETY FOR CARDIOVASCULAR MAGNETIC RESONANCE

By: ________________________________  By: ________________________________
Its: ________________________________  Its: ________________________________
Date: ________________________________  Date: ________________________________

PARTICIPANT