



Thank you for your interest in NCDR – the American College of Cardiology’s suite of data registries and programs, helping hospitals, health systems, centers and practices measure and improve the quality of cardiovascular care they provide.

When you take part in NCDR, you join a global community of cardiovascular professionals committed to using data-driven insights, analysis and research to inform clinical and operational decisions, allowing them and their cardiovascular care team members to perform at the highest level and to deliver optimal care to every patient, every time.

Get Started Today

Enrollment materials include:

- ☐ Master Agreement
- ☐ Contact Information Sheet
- ☐ Invoice to be sent separately

Please email your complete paperwork to ncdr@acc.org. We will return a customized invoice. Once we receive and process the participation dues, it will take approximately two weeks to process the paperwork and enroll your facility. Your Registry Site Manager will receive a welcome email with further instructions.

If you have any questions or need assistance with the enrollment process, please contact us at 800-257-4737 or ncdr@acc.org Monday through Friday, 9 a.m. – 5 p.m. ET.

Sincerely,

Christina Koutras, BSN, RN, CQH, AACC
Senior Director, Clinical Registry Services and System Solution

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The Mission of the American College of Cardiology and the American College of Cardiology Foundation is to transform cardiovascular care and improve heart health for all.

**NATIONAL CARDIOVASCULAR DATA REGISTRY PARTICIPANT MASTER AGREEMENT
BY AND BETWEEN THE AMERICAN COLLEGE OF CARDIOLOGY FOUNDATION
AND _____**

THIS NATIONAL CARDIOVASCULAR DATA REGISTRY PARTICIPANT MASTER AGREEMENT (the “Agreement”) is entered into made effective this _____, 20 ____ (“Effective Date”), by and between the American College of Cardiology Foundation (“ACCF”), a District of Columbia nonprofit corporation that is tax-exempt under Section 501(c)(3) of the Internal Revenue Code and located at 2400 N Street NW, Washington, DC 20037 and _____ (“Participant”), a _____ located at _____. ACCF and Participant may each be referred to herein as a “Party” and collectively as the “Parties.”

WHEREAS, ACCF has developed the National Cardiovascular Data Registry (“NCDR”), to collect and report on standardized national clinical cardiovascular data in connection with different cardiovascular procedures and conditions, as well as a suite of related product offerings;

WHEREAS, the NCDR provides a mechanism that permits medical facilities to make comparisons between performance in specific areas covered by the NCDR and similar national or regional summary data on performance in order to advance quality improvement initiatives of such medical facilities; and

WHEREAS, Participant desires to participate in the NCDR and the related product offerings provided by ACCF in order to improve the quality of Participant’s cardiovascular care and ACCF wishes to permit such participation pursuant to the terms and conditions set forth in this Agreement and all attachments hereto;

WHEREAS, the Parties understand that many of the NCDR offerings involve ACCF providing data aggregation services to Participant which qualifies ACCF as a “Business Associate” with respect to Participant pursuant to the Health Insurance Portability and Accountability Act of 1996 and its implementing regulations (45 CFR §160 and 164, as amended) (“HIPAA”); and

NOW, THEREFORE, in consideration of the mutual promises and agreements set forth, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged by ACCF and Participant, the Parties agree as follows:

IT IS AGREED:

1. Participation in ACCF NCDR Offerings.
 - a. Participant. For purposes of this Agreement, a Participant is defined as a single hospital or other medical facility located in a discrete geographic area that elects to participate in the NCDR pursuant to this Agreement.
 - b. Program Requirements. Participant hereby agrees to adhere to the offering specific program requirements which can be found at <https://cvquality.acc.org/NCDR-Home/program-requirements> and are hereby incorporated by reference in this Agreement (the “Program Requirements”). ACCF may modify the Program Requirements from time to time with notice to Participant. Upon receipt of such notification, Participant must review the changes to the Program Requirements. Participant’s continued participation in the NCDR and/or product offerings shall be deemed to constitute Participant’s agreement and consent to the updated Program Requirements.
 - c. Existing Programs. To the extent applicable, the Parties agree that this Agreement shall supersede and replace the terms and conditions of any previously executed NCDR Participant Master Agreement by and between ACCF and the Participant, and that any such previously executed NCDR Participant Master Agreement shall be terminated as of the Effective Date of

this Agreement. Notwithstanding, any previously executed Data Release Consent Form(s) under the previous NCDR Participant Master Agreement by and between the ACCF and Participant shall remain in force during the term of this Agreement.

2. Privacy and Security.

- a. Compliance with Laws. The Parties agree to abide by all federal, state, and local laws pertaining to confidentiality and disclosure with regard to all information or records obtained and reviewed hereunder. The Parties acknowledge that, pursuant to this Agreement, ACCF may provide data aggregation and/or quality assessment and improvement services to Participant, which involve the use, creation and/or access by ACCF to Individually Identifiable Health Information of Participant, which qualifies ACCF as a “Business Associate” with respect to Participant pursuant to the Health Insurance Portability and Accountability Act of 1996 and its implementing regulations (45 CFR §160 and 164, as amended) (“HIPAA”). Accordingly, ACCF shall take reasonable steps to comply with the requirements under HIPAA for Business Associates as set forth in the Business Associate Agreement herein attached as Appendix A to this Agreement (“Business Associate Agreement”). ACCF will have all rights, as well as all responsibilities, set forth in the Business Associate Agreement as if fully set forth herein.

3. Use of Names and Logos.

- a. Use of ACCF Name. Without the express prior written consent of ACCF, Participant shall not make any announcements concerning the matters set forth in this Agreement, use the word or symbol ACCF, the American College of Cardiology (“ACC”), NCDR® or any trademarks or service marks of ACCF, ACC, and ACCF business partners, or make any reference to ACCF, ACC, and ACCF business partners in any advertising or promotional material, letterhead, symbol or logo, or other communication that is not strictly internal to participant, or in any other manner, including, without limitation, press releases or lists.
- b. Use of Participant’s Logo/Trademarks. Without the express prior written consent of Participant, ACCF shall not use the logos, trademarks or service marks of Participant provided however that ACCF may list the name of Participant and State of Participant in a public list of participating facilities for each product offering.

4. Data and Copyright Ownership.

- a. Individual Patient Data. The data for individual patients submitted by Participant shall be the exclusive property of Participant, subject to the rights, if any, of the Participant’s patients in Individually Identifiable Health Information, and subject to the rights granted to ACCF in this Agreement and the Business Associate Agreement. Participant hereby agrees that the return of such data is infeasible as it has been integrated into the NCDR and related proprietary aggregate databases. Participant grants to ACCF a perpetual, enterprise-wide, royalty-free license, that is worldwide and in all forms and all media (including derivative works), to use the data of individual patients, including Individually Identifiable Health Information, submitted by Participant in such manner that is consistent with this Agreement. To the extent ACCF de-identifies Individually Identifiable Health Information from the information submitted by Participant for individual patients in accordance with the standards set forth in HIPAA, or to the extent the Participant submits information that is not Individually Identifiable Health Information from the data submitted by Participant for individual patients, ACCF shall exclusively own right, title and interest in and to such data, and any derivative works from it, and all Intellectual Property Rights, as defined in subsection (b) below therein.
- b. Intellectual Property; Aggregate Data. All Intellectual Property Rights, as defined herein, and title to all proprietary information in and rights to any software, provided by or used by the ACCF in connection with the NCDR, all ACCF databases and the information contained in

such databases, the NCDR, registries, any de-identified aggregated data submitted and accepted by ACCF for use in the NCDR and related product offerings or developed by ACCF from Individually Identifiable Health Information submitted by Participant pursuant to this Agreement, aggregate data and the compilation of the same with any other data received in connection with the NCDR or related product offering, and any derivative works using the deliverables prepared by or for ACCF including, without limitation, any reports, calculations and models based thereon, and any de-identified Individually Identifiable Health Information (“De-identified Data”), including, without limitation, all copyrights, patent rights, trademarks, trade secret rights, and any other rights and interest in any of the foregoing shall be and remain at all times for all purposes with ACCF. For purposes of this Agreement, “Intellectual Property Rights” means and includes all, or any intermediate version or portion, of any formulas, processes, outlines, algorithms, ideas, inventions, know how, techniques, intangible, proprietary and industrial property rights and all intangible and derivative works thereof, including, without limitation, any and all now known or hereafter existing, in and to (i) trademarks, trade name, service marks, slogans, domain names, uniform resource locators or logos; (ii) copyrights, moral rights, and other rights in works of authorship, including, but not limited to, compilations of data; (iii) patents and patent applications, patentable ideas, inventions and innovations; (iv) know-how and trade-secrets; and (v) registrations, applications, renewals, extensions, continuations, divisions or reissues of the foregoing. ACCF reserves the right to use De-identified Data and Protected Health Information (“PHI”) in electronic or other format whether or not contained in a Limited Data Set as discussed more fully in the Business Associate Agreement, including, without limitation, to support ongoing improvements and enhancements to the NCDR or product offerings. Once Participant data is accepted by ACCF into a registry for analysis and reporting, this data becomes part of the registry specific aggregate data and it cannot be retracted from the registry by Participant. Information to which ACCF has access or ownership under this Section 4 shall not be considered Confidential Information to be returned to Participant under Section 6.

5. Term, Enforcement and Termination. This Agreement shall be effective until the end of the then current calendar year, then renew automatically for additional one (1) year terms unless (a) the Participant provides ACCF with ninety (90) days’ advance written notice of its desire to terminate the Agreement at the end of the then-current term or (b) this Agreement is terminated earlier pursuant to the terms of this Agreement. The Parties agree that this Agreement may be enforced or terminated with respect to any particular NCDR product offering, without initiating or impairing any Party’s right to enforce any right with respect to any other NCDR product offering or this Agreement as a whole.
 - a. Termination for Breach. Either Party may terminate this Agreement upon the other Party’s material breach of this Agreement by providing the breaching Party with thirty (30) days written notice of its intention to terminate for a material breach. The breaching Party shall have thirty (30) days from the date of such notice to cure the breach. If, after thirty (30) days of the date of such notification, the breach is not cured to the satisfaction of the non-breaching Party, this Agreement will terminate automatically at the end of the foregoing thirty (30) day period. Notwithstanding the foregoing, the non-breaching Party may determine in its sole discretion that the breach cannot be reasonably cured within the foregoing thirty (30) day period and may extend the cure period by written notice to the breaching Party.
 - b. Termination for Insolvency. ACCF may terminate this Agreement effective immediately upon written notice to Participant in the event the Participant files for protection under bankruptcy laws, makes an assignment for the benefit of creditors, appoints or suffers appointment of a receiver or trustee over its property, files a petition under any bankruptcy or insolvency act, or has any such petition filed against it which is not discharged within sixty (60) days of the filing thereof.

- c. Termination Rights for Non-Payment. ACCF may, in ACCF's sole discretion, (a) terminate this Agreement effective immediately and upon written notice to Participant or (b) limit Participant's access to NCDR programs and products, in the event the Participant fails to pay the applicable participation fees when due, and such failure continues for a period of sixty (60) days after payment is due.
 - d. Termination Without Cause. Either Party may terminate this Agreement without cause by providing the other with at least ninety (90) days written notice.
 - e. Termination Due to Acquisition. In the event that Participant is acquired by, merged into, or otherwise becomes subject to the control and oversight of an entity that is a party to a Corporate Level NCDR Master Agreement with ACCF (a "Controlling Entity"), and the Controlling Entity has contracting authority on behalf of the Participant, the Participant or ACCF may terminate this Agreement upon written notice to the other Party. Such termination shall not be effective until: (i) all actions required to terminate this Agreement and to carry out wind down procedures consistent with applicable program offerings have been fulfilled; and (ii) Participant is included as an affiliate Participant pursuant to the agreement between the Controlling Entity and ACCF, such that there is no lapse in the provision of applicable program offerings provided to the Participant hereunder.
6. Confidentiality.
- a. Confidentiality. For the purposes of this Agreement, "Confidential Information" means any software, material, data, or business, financial, operational, customer, vendor and other information disclosed by one Party to the other and not generally known by or disclosed to the public or known to the receiving Party solely by reason of the negotiation or performance of this Agreement, and shall include, without limitation, the terms of this Agreement. Each Party shall maintain all of the other Party's Confidential Information in strict confidence and will protect such information with the same degree of care that such Party exercises with its own Confidential Information, but in no event with less than a reasonable degree of care. Except as provided in this Agreement, a Party shall not use or disclose any Confidential Information of the other Party in any manner without the express prior written consent of such Party, with the exception that ACCF may share a Participant's identification number ("Participant ID") with that Participant's software vendor so long as such vendor is approved as provided in this Agreement. Access to and use of any Confidential Information shall be restricted to those employees and persons within a Party's organization with known discretion and with a need to use the information to perform such Party's obligations under this Agreement. A Party's consultants, subcontractors, and business partners shall be included within the meaning of "persons within a Party's organization," provided that such consultants, subcontractors, and business partners have executed a non-disclosure or confidentiality agreement with provisions no less stringent than those applicable to such Party under this Agreement, and such Party shall make such signed agreements available to the other Party upon request. Notwithstanding anything herein to the contrary, Confidential Information shall not include information that is: (a) already known to or otherwise in the possession of a Party at the time of receipt from the other Party, and that was not known or received as the result of violation of any obligation of confidentiality; (b) publicly available or otherwise in the public domain prior to disclosure by a Party; (c) rightfully obtained by a Party from any third party having a right to disclose such information without restriction and without breach of any confidentiality obligation by such third party; (d) developed by a Party independent of any disclosure hereunder, as evidenced by detailed written records made in the normal course of Participant's business during the development process; or (e) disclosed pursuant to the order of a court or administrative body of competent jurisdiction or a government agency, provided that the Party receiving such order shall notify the other

prior to such disclosure, and shall cooperate with the other Party in the event such Party elects to legally contest, request confidential treatment, or otherwise avoid such disclosure.

- b. Return of Confidential Information. Except as otherwise provided herein, all of a Party's Confidential Information disclosed to the other Party, and all copies thereof, shall be and remain the property of the disclosing Party. All such Confidential Information, and any and all copies and reproductions thereof, shall, upon the expiration or termination of this Agreement for any reason, or within fifteen (15) days of written request by the disclosing Party, be promptly returned to it, or destroyed, at the disclosing Party's direction. In the event of such requested destruction, the Party receiving such request shall provide to the other Party written certification of compliance therewith within fifteen (15) days of such written request. Notwithstanding the provisions of this Section 6, any information governed by Section 6.a. or 6.b. or the provisions of the Business Associate Agreement shall be governed, respectively, by those Sections of this Agreement, as applicable.
7. Indemnification.
 - a. ACCF Indemnity. To the fullest extent allowed under applicable law, ACCF will indemnify, defend, and hold Participant harmless from any third-party claim, demand, cause of action, lawsuit, or proceeding brought against Participant based upon any gross negligence or willful misconduct on the part of ACCF, provided, however, that any such liability for any such indemnification shall be limited to and not exceed the amount of any fees paid by Participant in the year the liability arose. Such indemnification may include: (1) reasonable attorneys' fees and costs associated with defense of such claim; (2) damages and costs finally awarded; and (3) the cost of any settlement entered into by ACCF. Such indemnification obligation is contingent on Participant: (i) notifying ACCF of any such claim within thirty (30) days of Participant's notice of such claim; (ii) providing ACCF with reasonable information, assistance, and cooperation in defending the lawsuit or proceeding (to the extent requested by ACCF); and (iii) giving ACCF full control and sole authority over the defense and settlement of such claim. ACCF will not enter into any settlement or compromise of any such claim without Participant's prior consent, which shall not be unreasonably withheld.
 - b. Participant's Indemnities. To the fullest extent allowed under applicable law, Participant will indemnify, defend, and hold ACCF and ACCF's employees, officers, directors, agents, contractors, and business partners (collectively as the "ACCF Indemnitees") harmless from any third-party claim, demand, cause of action lawsuit, or proceeding brought against one or more ACCF Indemnitees based upon: (1) any errors or inaccuracies contained in the data as delivered by Participant to ACCF; (2) any medical treatment, diagnosis or prescription rendered by Participant or its agents (including physicians and healthcare professionals); (3) Participant failing to have all rights in the data necessary to use the NCDR product offerings and to disclose such information to ACCF; and (4) the use of ACCF provided reports in connection with any quality assurance, peer review, or similar administrative or judicial proceeding; and (5) any claim that is based, in whole or in part, on a breach of any warranty, representation or covenant made by Participant under this Agreement, including, but not limited to, any third-party lawsuit or proceeding brought against ACCF or any of ACCF Indemnitees based upon a claim that any data submitted by Participant infringe any third-party rights. Participant's indemnification will include: (i) all attorneys' fees and costs associated with defense of such claim; (ii) all damages and costs finally awarded; and (iii) the full cost of any settlement entered into by Participant.
8. Limitation of Liability. To the fullest extent allowed under applicable law, the aggregate liability of ACCF Indemnitees under this Agreement for any and all claims and causes of action, including, without limitation, any action predicated on indemnification as set forth in Section 7.a. above, shall

NATIONAL CARDIOVASCULAR DATA REGISTRY PARTICIPANT MASTER AGREEMENT

be limited to and not exceed the amount of any fees paid by Participant in the year the liability arose, regardless of whether ACCF has been advised of the possibility of such damages, or any remedy set forth herein fails of its essential purpose or otherwise. ACCF Indemnitees shall not be liable for any other damages or costs, including costs of procurement of substitutes, loss of profits, loss of activity data or other information, inability to access the services or software, interruption of business, or for any other special, consequential, or incidental damages, however caused, whether, without limitation, for breach of warranty, contract, tort, infringement, negligence, strict liability or otherwise. Participant acknowledges that the fees and business model reflect this allocation of risk. Participant agrees it will take no legal action against ACCF, ACCF subcontractors, ACCF business partners, software or other Participants.

9. Notices. All notices and demands of any kind or nature which either 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, or by overnight courier (e.g., Federal Express, DHL, or UPS) or electronic mail to the following addresses:

If to the Participant:

E-mail: _____

With a copy to:

E-mail: _____

If to ACCF:

American College of Cardiology Foundation
2400 N Street NW, Washington, DC 20037
Attn: General Counsel
E-mail: ACCLegal@acc.org

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.

10. Headings. The headings of the various paragraphs hereof are intended solely for the convenience of reference and are not intended for any purpose whatsoever to explain, modify, or place any construction upon any of the provisions of this Agreement.
11. Assignment. Neither this Agreement nor either Parties' rights and obligations hereunder may be assigned to a third party without the prior written consent of the non-assigning Party; provided, however, that ACCF may assign this Agreement and its rights and obligations to a parent or an entity controlled by or under common control with ACCF, or a venture or entity in which ACCF has a majority ownership interest, or upon a change of control of ACCF, without the consent of the Participant.

12. Relationship of Parties. 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.
13. 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.
14. Waiver. A waiver by either Party to this Agreement of any of its items 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.
15. Governing Law. Unless otherwise predicated by Participant's status as a local, state, or federal government agency, this Agreement will be governed by and construed exclusively in accordance with the laws of the District of Columbia, without regard to any conflicts of law principles applied. The Parties agree that United Nations Convention on Contracts for the International Sale of Goods does not apply to this Agreement. Unless otherwise predicated by Participant's status as a local, state, or federal government agency, any suit or proceeding relating to this Agreement shall be brought only in the District of Columbia. Unless otherwise predicated by Participant's status as a local, state, or federal government agency, each Party consents to the exclusive personal jurisdiction and venue of the courts located in the District of Columbia.
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 the Agreement shall remain in full effect, provided that its general purposes remain reasonably capable of being effected.
17. Entire Agreement. This Agreement and the attached Appendices: (a) constitute the entire Agreement between the Parties with respect to the subject matter; (b) supersede and replace all prior agreements, oral or written, between the Parties relating to the subject matter; and (c) except as otherwise indicated, may not be modified or otherwise changed in any manner except by a written instrument executed by both Parties.
18. Survival. The following sections of this Agreement survive its termination as to any NCDR product offering or in its entirety, for any reason: Sections 4, 6, 7, 8, 15 and the Business Associate Agreement.
19. No Third-Party Beneficiaries. The Parties agree there are no third-party beneficiaries, intended or otherwise, to this Agreement, including, without limitation, patients of any Participant.

[SIGNATURE PAGE TO FOLLOW]

NATIONAL CARDIOVASCULAR DATA REGISTRY PARTICIPANT MASTER AGREEMENT

IN WITNESS WHEREOF, each of the Parties hereto has caused this Agreement to be executed as of the Effective Date:

PARTICIPANT	ACCF
PID#: _____	Signature: _____
Signature: _____	Name: _____
Name: _____	Title: _____
Title: _____	Date: _____
Date: _____	
E-Mail Address: _____	
Phone: _____	

APPENDIX A
BUSINESS ASSOCIATE AGREEMENT AND DATA USE AGREEMENT

In the course of satisfying its contractual obligations to Participant pursuant to the Participant's engagement of ACCF through the National Cardiovascular Data Registry Participant Master Agreement ("Agreement"), ACCF is performing a function or activity on behalf of Participant that constitutes ACCF a "Business Associate" of Participant within the meaning of the Health Insurance Portability and Accountability Act of 1996 and its implementing regulations (45 CFR §160 and 164, as amended) as amended by the Health Information Technology for Economic and Clinical Health Act, enacted as Title XIII, Subtitle D of the American Recovery and Reinvestment Act of 2009, including regulations published as the Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules (the "Omnibus HITECH Regulations"), Vol. 78 Federal Register No. 17 (January 25, 2013) and as any further amendments, modification, or renumbering which occurs or takes effect during the term of the Agreement (collectively, "HIPAA"). The purpose of this Appendix is to provide the Participant with satisfactory assurance that, as Participant's Business Associate, ACCF shall comply with the privacy and security requirements concerning Business Associates imposed by HIPAA. Accordingly, ACCF and Participant agree as follows:

I. GENERAL PROVISIONS

1. **Effect.** The terms and provisions of this Appendix shall supersede any other conflicting or inconsistent terms and provisions in the Agreement to which this Appendix is attached, including all exhibits or other attachments thereto and all documents incorporated therein by reference, with respect to information which constitutes Participant's PHI.
2. **Amendment.** ACCF and Participant agree to amend this Appendix to the extent necessary to allow Participant and the ACCF to comply with HIPAA. ACCF agrees to develop amendments to this Appendix to incorporate any material provisions required by HIPAA, and to distribute the same to Participant for adoption. Any amendment distributed by ACCF shall be deemed to be accepted by Participant unless ACCF is notified by Participant of any objections within thirty (30) days of its receipt of such amendment. Each Party is responsible for determining the adequacy of the amendment for its compliance with HIPAA.
3. **Definitions.** Capitalized terms used herein without definition shall have the respective meanings assigned to such terms in the Agreement, Part V of this Appendix, or HIPAA.

II. OBLIGATIONS OF ACCF

1. **Use and Disclosure of Participant's PHI.**
 - a. ACCF agrees to not use or further disclose Participant's PHI other than as permitted or required by the Agreement, this Appendix, or as Required By Law and to otherwise comply with the provisions of the Privacy Standards and the Security Standards applicable to the ACCF as a Business Associate.
 - b. ACCF may use or disclose Participant's PHI to perform functions, activities, or services for, or on behalf of, Participant to the extent specified in the Agreement, provided that such use or disclosure would not violate the Privacy Standards if done by Participant. Notwithstanding the foregoing, ACCF may use and disclose Participant's PHI: (i) for ACCF's proper management and administration to carry out ACCF's legal obligations if the disclosure is Required By Law or ACCF enters into a written agreement with a party to whom it discloses Participant's PHI and uses reasonable measures to require such party to hold such Participant's PHI confidentially, to further use or disclose it only as Required By Law or for the purpose for which it was disclosed, and to notify ACCF of any instances of which it becomes aware in which the confidentiality of the Participant's PHI is breached; (ii) to provide Data Aggregation services relating to the Health Care Operations of Participant and other providers or health

- systems with which ACCF contracts; (iii) to de-identify PHI it receives from Participant, if any, pursuant to 45 CFR §164.514, which De-identified Data, and any derivative works from such data, shall be owned by ACCF, in all forms and media worldwide, and may be used by ACCF for any lawful purpose; or (iv) to create and disclose a Limited Data Set, provided that the conditions set forth in Section II. 8. of this Appendix are satisfied.
- c. ACCF may disclose Participant's PHI to a Subcontractor, provided that the Subcontractor agrees, in a form meeting the requirements of 45 CFR §§ 164.314(a) and 164.504(e)(1)(i), to substantially the same restrictions and obligations that apply through this Appendix to ACCF with respect to such Protected Health Information, including those obligations relating to ePHI. Upon ACCF's knowledge of a pattern of activity or practice of a Subcontractor in violation of the requirements of the foregoing agreement, ACCF will provide notice and an opportunity, not longer than thirty (30) business days after the notice, for the Subcontractor to end the violation. ACCF may terminate the agreement with the Subcontractor if the Subcontractor does not end the violation within the time specified by the ACCF in the notice.
 - d. ACCF shall request, and Participant shall provide, no more than the "Minimum Necessary" of Participant's PHI required to fulfill the purposes of the Agreement. At such time as the Secretary issues Guidance or the equivalent regulation on what constitutes the "Minimum Necessary" for purposes of the Privacy Standards, ACCF shall provide Participant with an amendment to this Section II. 1.d. which complies with the Guidance, which shall replace this Section II. 1.d. as of the date upon which compliance is required with Guidance of the Secretary or with applicable regulations relating to the Minimum Necessary requirements of HIPAA is required. Subject to the foregoing, the Parties agree that the information contained in a Limited Data Set, as defined in 45 CFR §164.514(e)(2) is not sufficient to meet the requirements of the Agreement and that the amount of Participant's PHI requested by the ACCF and provided by the Participant under the Agreement is the Minimum Necessary in order to accomplish the intended purpose of the use, disclosure, or request, consistent with the terms of the Agreement, other than those uses, disclosures or requests that are exempt from the Minimum Necessary requirement specified in 45 CFR §164.502(b)(2), if any.
 - e. ACCF shall not engage in the Sale of Participant's PHI or the use of Participant's PHI for Marketing unless the Participant has obtained an authorization from the subject Individual(s) which complies with all applicable requirements or unless an exception specified in the Omnibus HITECH Regulations applies.
2. **Safeguards.** ACCF agrees that it shall use appropriate safeguards to prevent the use or disclosure of Participant's PHI other than as otherwise provided for in this Appendix and the Agreement. Such safeguards shall include the implementation and maintenance of reasonable and appropriate administrative, technical, and physical safeguards to protect the security, integrity, confidentiality, and availability of Participant's PHI created, maintained, received, or transmitted by ACCF. As to ePHI, ACCF shall fulfill the foregoing responsibilities by being in compliance with the provisions of the Security Standards set forth at 45 CFR §164.308 (Administrative Safeguards); 45 CFR §164.310 (Physical Safeguards); 45 CFR §164.312 (Technical Safeguards) and 45 CFR §164.316 (Policies and Procedures and Documentation Requirements). ACCF agrees to use reasonable efforts to mitigate, at its expense, any harmful effect that is known to ACCF that results from a use or disclosure of Participant's PHI by ACCF in violation of the requirements of the Agreement and/or this Appendix, including without limitation a Breach. ACCF will use reasonable efforts to coordinate and/or inform Participant of any mitigation efforts.
 3. **Reporting.**
 - a. ACCF agrees to report promptly to Participant any use or disclosure of Participant's PHI which is not provided for by this Agreement of which ACCF becomes aware.

- b. ACCF shall report to Participant a Breach of Participant's PHI that is Unsecured within thirty (30) business days of ACCF's discovery of such Breach. The notice shall include the identification of each Individual or Individuals whose Unsecured Protected Health Information was, or is reasonably believed to have been, subject to the Breach and the circumstances of the Breach, as both are known to ACCF at that time. The notice shall be given via email to Participant's Privacy Officer, as stated by Participant. The Parties agree that notice in accordance with the foregoing satisfies the notice requirements of this Section II. 3. Following the notice, ACCF shall conduct such further investigation and analysis as is reasonably required and shall promptly advise Participant of additional information pertinent to the Breach which ACCF obtains. Participant is responsible for the provision of any required notices to impacted Individuals, the Secretary, and, if applicable, the media in a timely manner, provided that Participant shall consult with ACCF in good faith regarding the details of the notice.
 - c. ACCF shall also, promptly on becoming aware of it, report any Security Incident involving Participant's PHI to Participant, unless the Security Incident was the subject of a notice under Section II. 3.b. The Parties agree, however, that this Section II. 3.c. constitutes notice by ACCF to Participant of the ongoing existence and occurrence of Unsuccessful Security Incidents for which no additional notice to Participant shall be required. For purposes of this Agreement, such Unsuccessful Security Incidents include, without limitation, activity such as pings and other broadcast attacks on ACCF's firewall, port scans, unsuccessful log-on attempts, denial of service and any combination of the above, so long as no such Unsuccessful Security Incident results in unauthorized access, use, disclosure, modification or destruction of Participant's PHI or interference with information system operations related to Participant's PHI, provided that, upon written request from Participant, ACCF will provide a log or similar documentation of Unsuccessful Security Incidents for the period of time reasonably specified in Participant's request.
- 4. **Access to Participant's PHI.** Within twenty (20) days of receipt of a request by Participant for access to Participant's PHI maintained by ACCF in a Designated Record Set so that it may respond to an Individual's request for such information, ACCF shall make available to Participant such Participant's PHI. In the event any Individual requests access to Participant's PHI directly from ACCF, ACCF shall within twenty (20) days forward such request to Participant. Any denials of access to the Participant's PHI requested shall be the responsibility of Participant. Furthermore, Participant will determine and apply any appropriate limitations on such access and be responsible for providing such access (including, if appropriate) transmission to a third party.
- 5. **Availability of Participant's PHI for Amendment.** Within twenty (20) business days of receipt of a request by Participant for the amendment of Participant's PHI maintained by ACCF in a Designated Record Set so that it may respond to an Individual's request for such amendment, ACCF shall make amendments to such Participant's PHI that Participant directs in accordance with 45 CFR §164.526, including information, if any, maintained in an Electronic Designated Record Set, to the extent required by the Privacy Standards. ACCF will report any request for amendment of Participant's PHI that it receives directly from an Individual to Participant within twenty (20) business days of receipt. Participant shall be responsible for making all determinations regarding amendments to PHI, and ACCF will make no such determinations.
- 6. **Accounting of Disclosures of Participant's PHI.**
 - a. Within twenty (20) business days of notice by Participant to ACCF that it has received a request from an Individual for an accounting of disclosures of Participant's PHI, other than related to the Treatment, Payment, or Health Care Operations, and not relating to disclosures made earlier than the later of six (6) years prior to the date on which the accounting was requested or April 14, 2003, the effective date of the Privacy Standards, ACCF shall make available to Participant

- such information as is in ACCF's possession and that is required for Participant to make the accounting required by 45 CFR §164.528. In the event the request for an accounting is delivered directly to ACCF, ACCF shall, within twenty (20) days, forward such request to Participant. ACCF hereby agrees to implement an appropriate record-keeping process to enable it to comply with the requirements of this Section.
- b. In addition, at such time as the Secretary issues a final regulation on the requirements of an accounting for purposes of Treatment, Payment or Health Care Operations for purposes of the Privacy Standards, ACCF shall provide Participant with an amendment to this Section II. 6.b. which complies with the regulation, which shall replace this Section II. 6.b. as of the date upon which compliance is required with the Regulation.
7. **Availability of Books and Records.** ACCF hereby agrees to make its internal practices, books, and records relating to the use and disclosure of Participant's PHI received from, or created or received by ACCF on behalf of Participant, available to the Secretary for purposes of determining Participant's compliance with the Privacy Standards, as requested in writing by Participant.
8. **Data Use Agreement.**
- a. **Activities.** The Parties agree that ACCF may use and disclose a Limited Data Set for purposes of Research, Public Health, or Health Care Operations or as otherwise permitted by the Privacy Standards or Required by Law. Such Limited Data Sets need not be for the use of the Participant but ACCF shall endeavor to make any resulting research studies, articles or similar results generally be made available to Participant through posting on the ACCF website or through publication. ACCF shall use reasonable measures to ensure that its directors, officers, employees, contractors, and agents do not use or disclose a Limited Data Set in any manner that would constitute a violation of the Privacy Standards if used or disclosed by Participant. ACCF agrees not to use a Limited Data Set in such a way as to identify any Individual, and further agrees not to contact any Individual. The activities referred to in Section II. 8.a. of this Appendix shall collectively be referred to as the "Activities."
- b. **Limited Data Set.** Participant agrees that ACCF may derive directly or through a subcontractor, who is bound by terms and conditions consistent with ACCF's obligations under this Appendix, a Limited Data Set from Participant's PHI otherwise provided to ACCF pursuant to the Agreement, and use that Limited Data Set, including in combination with other data in the performance of the Activities, provided, however, that no Limited Data Set created by ACCF shall include any direct identifiers set forth at 45 CFR §164.514(e)(2).
- c. **Safeguards Against Misuse of Information.** ACCF shall use reasonable safeguards to prevent the use or disclosure of a Limited Data Set other than as permitted under this Agreement.
- d. **Reporting.** ACCF shall, within thirty (30) business days of becoming aware of any use or disclosure of a Limited Data Set in violation of the Agreement by ACCF, its officers, directors, employees, contractors, or agents, or by a third party to which ACCF disclosed a Limited Data Set, report any such disclosure to Participant.
- e. **Agreements with Third Parties.** ACCF shall obtain and maintain an agreement with each third party that has or will have access to a Limited Data Set, which satisfies the requirements for a Data Use Agreement, as set forth in 45 CFR §164.514(e) (4), with respect to the Limited Data Set.
9. **Other Rights and Obligations of ACCF.**
- a. **HIPAA Obligations of Participant.** To the extent that ACCF will carry out any obligation of Participant under the Privacy Standards, ACCF will perform such obligations in compliance with the provisions of the Privacy Standards that apply to Participant as to such obligations.
- b. **Other Agreements for Services.** To the extent that ACCF provides services to Participant under agreements other than the Agreement, and such services involve ACCF's creation,

maintenance, transmission or access to PHI of Participant as a Business Associate under HIPAA (“Other Service Agreements”), unless the Other Service Agreement specifically provides otherwise or incorporates another form of Business Associate Agreement, the provisions of this Agreement shall apply to ACCF under the Other Service Agreement and all references to the Agreement shall be deemed to refer to the Other Service Agreement.

- c. **Permitted Charges.** To the extent ACCF takes any action, such as providing information in electronic form under Section II., for which a charge or cost is allowed to be collected under HIPAA, ACCF may collect such charge or cost from Participant as an addition to the fees otherwise due under the Agreement.

III. OBLIGATIONS OF PARTICIPANT

1. Participant shall be responsible for assuring Participant’s compliance with HIPAA.
2. Participant shall provide ACCF with at least thirty (30) business days advance written notice of any restrictions on uses and disclosures of Participant’s PHI that it agrees to pursuant to 45 CFR §164.522 that may affect ACCF’s use or disclosure of Participant’s PHI. Notwithstanding the foregoing, in the event of an agreement of Participant not to disclose an item or service paid for entirely out-of-pocket by an Individual to a Health Plan for Payment or Health Care Operations purposes unless such disclosure is required by law, the Parties agree that such information shall not be provided to the ACCF, notwithstanding any contrary provision of the Agreement.
3. Participant shall notify ACCF of any limitation in its notice of privacy practices or any changes in, or revocation of, the authorization of an Individual to use or disclose Participant’s PHI to the extent such limitations, changes, or revocations may affect ACCF’s use of disclosure or Participant’s PHI.

IV. TERMINATION OF AGREEMENT

1. **Termination For Cause.** Upon either Party’s determination of a breach of a material term of this Appendix by the other Party, the non-breaching Party shall provide the breaching Party written notice of that breach in sufficient detail to enable the breaching Party to understand the specific nature of that breach and afford the breaching Party an opportunity to cure the breach; provided, however, that if the breaching Party fails to cure the breach within thirty (30) business days of receipt of such notice, the non-breaching Party may terminate this Appendix and the Agreement.
2. **Return or Destruction of Participant’s PHI Upon Termination.** Participant and ACCF have determined that return or destruction of Participant’s PHI is not feasible upon termination of the Agreement. Therefore, ACCF shall have the applicable rights and shall comply with the applicable requirements of this Appendix for so long as Participant’s PHI is held by ACCF. In the event that ACCF determines that it shall no longer maintain Participant’s PHI, it shall either return Participant’s PHI to Participant or destroy it (with certification of such destruction) at the sole option of ACCF. The terms and provisions of this Appendix shall survive termination of the Agreement, and Participant’s PHI shall be used or disclosed solely for such purpose or purposes which prevented the return or destruction of Participant’s PHI and shall be maintained as confidential. De-identified Data shall not be subject to this obligation. Participant’s PHI contained in a Limited Data Set shall continue to be governed by the Data Use Agreement provisions of Section II. 8. of this Appendix.

V. DEFINITIONS FOR USE IN THIS APPENDIX

- “Breach” shall have the meaning set forth at 45 CFR §164.402.
- “Data Aggregation” shall mean, with respect to Participant’s PHI created or received by ACCF in its capacity as the Business Associate of Participant, the combining of such Participant’s PHI by

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ACCF with the Participant's PHI received by ACCF in its capacity as a Business Associate of another participant, to permit data analyses that relate to the Health Care Operations of the respective participants.

- “De-identified Data” shall have the meaning set forth in 45 CFR §164.514 regarding de-identification of Participant's PHI.
- “Designated Record Set” shall have the meaning set forth in 45 CFR §164.501.
- “Electronic Media” shall mean the mode of electronic transmissions. It includes the Internet, extranet (using Internet technology to link a business with information only accessible to collaborating parties), leased lines, dial-up lines, private networks, and those transmissions that are physically moved from one location to another using magnetic tape, disk, or compact disk media.
- “Electronic Protected Health Information” or “ePHI” shall have the same meaning as the term “electronic protected health information” at 45 CFR §160.103.
- “Guidance” shall mean official guidance of the Secretary as specified in the HITECH Act and any other official guidance or interpretation of HIPAA by a federal governmental agency with jurisdiction.
- “Health Care Operations” shall have the meaning set forth in 45 CFR §164.501.
- “HITECH Act” shall mean the provisions of Division A, Title XIII of the American Recovery and Reinvestment Act of 2009 (“ARRA”), known as The Health Information Technology for Economic and Clinical Health, Act 42 USC §3000 et. seq., and implementing regulations and guidance including all implementing regulations and other official guidance, set forth.
- “Individual” shall have the meaning set forth in 45 CFR §160.103 and shall include a person who qualifies as a personal representative in accordance with 45 CFR §164.502(g).
- “Individually Identifiable Health Information” shall mean information that is a subset of health information Participant's PHI information collected from an Individual, and:
 - i. is created or received by a health care provider, health plan, employer, or health care clearinghouse; and
 - ii. relates to the past, present, or future physical or mental health or condition of an Individual; the provision of health care to an Individual; or the past, present or future payment for the provision of health care to an Individual; and (a) identifies the Individual, or (b) with respect to which there is a reasonable basis to believe the information can be used to identify the Individual.
- “Limited Data Set” shall have the meaning ascribed to it in 45 CFR §164.514(e)(2).
- “Agreement” shall mean the Participant Master Agreement between the Parties including any general policies, supplements or notices posted on the website.
- “Participant's PHI” shall mean the Protected Health Information of the Participant to which the Agreement and this Appendix applies.

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- “Privacy Standards” shall mean the Standards for Privacy of Individually Identifiable Health Information, 45 CFR §§160 and 164, Subparts A and E.
- “PHI” or “Protected Health Information” shall mean Individually Identifiable Health Information that is: (i) transmitted by Electronic Media; (ii) maintained in any medium constituting Electronic Media; or (iii) transmitted or maintained in any other form or medium. Under no circumstances shall De-Identified Data constitute “Protected Health Information”. “Protected Health Information” shall not include: (i) education records covered by the Family Educational Right and Privacy Act, as amended, 20 USC §1232g; and (ii) records described in 20 USC §1232g(a)(4)(B)(iv).
- “Research” shall have the meaning set forth in 45 CFR §164.501.
- “Secretary” shall mean the Secretary of the Department of Health and Human Services or such other federal agency as is authorized to publish regulations or guidance pursuant to the HITECH Act.
- “Security Incident” shall mean the attempted or successful unauthorized access, use, disclosure, modification, or destruction of information, or interference with systems operations in an information system.
- “Security Standards” shall mean the Security Standards for the Protection of Electronic Protected Health Information at 45 CFR §§160 and 164, Subparts A and C.
- “Subcontractor” shall mean a person or entity to which ACCF delegates a function, activity or service involving access to Participant’s PHI other than as a member of ACCF’s workforce.
- “Unsecured” as applied to Protected Health Information shall mean Protected Health Information in any form, electronic, paper or oral, that is not secured through the use of a technology or methodology specified by the Secretary in Regulations or Guidance.

All other terms used, but not otherwise defined, in this Appendix have the same meaning as those terms in HIPAA.



CONTACT INFORMATION SHEET

STEP 1: Please provide the **facility information** requested below.

Note: Health systems must complete one form (Steps 1-2) for each facility enrolling.

Date: _____

Health System (if applicable):
Facility's legal entity name:
Facility Physical Address (no PO boxes) Including City and Zip Code:

If you are an existing NCDR Participant, please enter your **NCDR ACC ID** (Participant ID) here

STEP 2: Please provide contact details for the designated **REGISTRY SITE MANAGER (RSM)** for each registry you are enrolling in.

Please note the following:

1. Each registry requires one designated Registry Site Manager (RSM) per site.
2. The same individual may serve as the RSM for more than one registry, but **only one RSM may be assigned to a registry**.
3. Enter the complete contact information for the designated RSM (including checking boxes for any registry for which they will be RSM). All fields are required.
4. If your site is enrolling in more than one registry with different RSMs, please duplicate this page.

☐ AFib Ablation Registry™ ☐ CathPCI Registry® ☐ Chest Pain - MI Registry®
☐ CV ASC Registry Suite® ☐ EP Device Implant Registry® ☐ IMPACT Registry® ☐ LAAO Registry™
☐ Renal Denervation Module™ Data Collection Only ☐ Renal Denervation Module™ with Dashboard

RSM's Name:	RSM's Title:
RSM's Email Address:	NCDR existing username (if applicable):
RSM's Office Telephone:	RSM's Cell Phone Number:
RSM's Physical Office Address:	