

Heart House

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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. Thank you for your interest in the NCDR – the American College of Cardiology's suite of data registries helping hospitals and private practices measure and improve the quality of cardiovascular care they provide.

When you take part in the ACC's cardiovascular data registries, you join a global community of cardiovascular professionals committed to improving patient outcomes by using data to inform research, change practice and, ultimately, save lives.

Get started today

Enclosed materials include:

- □ Master Agreement (required for new NCDR sites only)
- \Box Order Form & Invoice
- □ Payment Form
- □ Contact Information Sheet

Once we receive your complete paperwork and 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,

Barbara J. Christensen, MSHA, RN, CPHQ, AACC Senior Director, NCDR Registry Services American College of Cardiology





2017 ENROLLMENT DOCUMENTS

All forms below are <u>required</u> before activation of an account/registry.

- Hospital Master Agreement
- Order Form & Invoice
- Payment Form
- Contact Information Sheet

MAIL ALL COMPLETED FORMS TO:

American College of Cardiology Foundation Attn: Hospital and NCDR Enrollment P.O. Box **37095** Baltimore, MD 21297-**3095**

Please be advised that the NCDR switched banking services effective June 1, 2016 and is now using BB&T. Updated banking information is reflected throughout this enrollment packet. Please update your system immediately if you have not done so already.

ORDER FORM & INVOICE

If you are an existing NCDR Participant, please enter your NCDR Participant ID here \rightarrow

Please indicate which registries your hospital wishes to enroll in for calendar year 2017

NCDR REGISTRY	2017 ENROLLMENT	
- Participation through December 31, 2017 -	-Check all that apply-	AMOUNT
ACTION Registry	🗆 Enroll today	\$4,500.00
AFib Ablation Registry	🗆 Enroll today	\$995.00
CathPCI Registry	🗆 Enroll today	\$6,200.00
ICD Registry	🗆 Enroll today	\$5,950.00
IMPACT Registry	🗆 Enroll today	\$4,495.00
LAAO Registry	🗆 Enroll today	\$15,000.00
PVI Registry	🗆 Enroll today	\$4,700.00
One-time Implementation Fee	🗆 We're new!	\$1,000.00
TOTAL INVOICE AMOUNT		
Total fees from "Amount" column		





PAYMENT OPTIONS

Method of payment:
Check
Electronic Fund Transfer

Note: For credit card payments, please contact us at <u>ncdr@acc.org</u> or 800-257-4737

If you are paying by **CHECK**, please indicate the amount enclosed below. Checks should be made payable to the **"American College of Cardiology Foundation"** and sent along with the invoice above (required).

Amount Enclosed \$_____

If you are paying by Electronic Fund Transfer (EFT), please see below:

Bank: BB&T (Branch Banking and Trust Co.) 1909 K St. NW, Washington, DC 20006
Account Name: American College of Cardiology Foundation
Routing #: 054001547
Account#: 0005163211329
Swift Code: BRBTUS33





CONTACT INFORMATION SHEET

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

Note: Health systems must complete <u>one form</u> (Steps 1-3) <u>for each hospital</u> enrolling.

Health System (if applicable):

Hospital's legal entity name:

Hospital Physical Address (no PO boxes):

STEP 2: Please provide contact details for a designated **Program Manager for Quality Improvement for Institutions** here:

Note: Only one Program Manager per hospital.

Program Manager's Name:	Program Manager's Title:	
Physical Address (no PO boxes):		
Program Manager's Email Address:	Program Manager's Telephone:	





STEP 3: Please provide contact details for the designated **REGISTRY SITE MANAGER (RSM)** for <u>each registry</u> you are enrolling in.

Please note the following:

- 1. Each of the sections below allows for the designation of **one RSM per registry** enrollment.
- 2. An individual may serve as the RSM for more than one registry, but only one RSM may be assigned to a registry.
- 3. Enter the contact information for each designated RSM. All fields are required.
- 4. If your site is enrolling in more than 2 registries at this time, please duplicate this page.

If you are an existing NCDR Participant, please enter your NCDR Participant ID here \rightarrow

□ ACTION Registry [®] □ AFib Ablation Registry [™] □ CathPCI Registry [®] □ ICD Registry [™] □ IMPACT Registry [®] □ LAAO Registry [™] □ PVI Registry [™]

RSM's Name:	RSM's Title:
RSM's Physical Address:	
RSM's Email Address:	RSM's Telephone:

□ ACTION Registry [®] □ AFib Ablation Registry [™] □ CathPCI Registry [®]

□ ICD Registry [™] □ IMPACT Registry [®] □ LAAO Registry [™] □ PVI Registry [™]

RSM's Name:	RSM's Title:	
RSM's Physical Address:		
RSM's Email Address:	RSM's Telephone:	

AGREEMENT BY AND BETWEEN THE AMERICAN COLLEGE OF CARDIOLOGY FOUNDATION AND

THIS AGREEMENT is made this day of , 20 ("Effective Date"), between the American College of Cardiology Foundation ("ACCF"), a non-profit, tax-exempt District of Columbia corporation located at 2400 Ν Street NW, Washington, DC 20037 and ("Participant"), located at _ . ACCF and Participant shall be referred to herein collectively as the "Parties" and individually as a "Party".

WHEREAS, ACCF has developed a suite of hospital products in which Participant desires to participate;

WHEREAS, Participant desires to participate in one or more of hospital offerings that ACCF offers;

WHEREAS, the Parties understand that many of the hospital 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:

IT IS AGREED:

- 1. <u>Participation in ACCF Hospital Offerings</u>. Participant hereby agrees to the offering specific program requirements which can be found at <u>http://www.ncdr.com/programrequirements</u> and will be updated from time to time. In the event of a change in offering specific program requirements, Participant will be notified and is expected to review changes to the program requirements prior to further use of the product. For purposes of this Agreement, a Participant is defined as a single facility or practice located in a discrete geographic area that elects to participate in one of more products through a Hospital Master Agreement.
 - a. <u>Existing Programs</u>. To the extent applicable, the Parties agree that any previously executed Data Release Consent Form(s) under the previous NCDR Master Agreement by and between the ACCF and Participant shall remain in force during the term of this Agreement and that this Hospital Master Agreement shall replace the terms and conditions of the previously executed NCDR Master Agreement.
- 2. Privacy and Security.
 - a. <u>Compliance with Laws</u>. 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. ACCF acknowledges that it is a "Business Associate" as defined and referred to under HIPAA. Accordingly, ACCF shall take reasonable steps to comply with the requirements under HIPAA for Business Associates as set forth in <u>Appendix A</u> to this Agreement ("Business Associate Agreement"). ACCF will have all rights, as well as all responsibilities, set forth in Appendix A as if fully set forth herein.
- 3. <u>Use of Names and Logos</u>.
 - a. <u>Use of ACCF Name</u>. 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, 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. <u>Use of Participant's Logo/Trademarks</u>. 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 hospitals for each product offering.
- 4. Data and Copyright Ownership.
 - a. <u>Individual Patient Data</u>. 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 the return of that information is infeasible as it has been integrated into an aggregate database. 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 submitted by Participant in such manner that is consistent with this Agreement. To the extent ACCF develops de-identified or similar data that is not Individually Identifiable Health Information from the data submitted by Participant for individual patients, ACCF shall exclusively own such data, and any derivative works from it, as Intellectual Property Rights owned by ACCF.
 - b. Intellectual Property; Aggregate Data. All Intellectual Property Rights and title to all proprietary information in and rights to any software, database, NCDR, registries, any data submitted and accepted by ACCF for use in the hospital product offerings, aggregate data and the compilation of the same with any other data received in connection with the hospital product offering, and any derivative works using the deliverables of the hospital; product offerings including, without limitation, any reports, calculations and models based thereon, and De-identified Data as described in Section 4.a., 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 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 Appendix A, including, without limitation, to support ongoing improvements and enhancements to hospital 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 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. <u>Term, Enforcement and Termination</u>. This Agreement shall be effective until December 31, 2017 then renew automatically for additional one (1) year terms unless 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. The Parties agree that this Agreement may be enforced or terminated with respect to any particular hospital product offering, without initiating or impairing any Party's right to enforce any right with respect to any other hospital product offering or this Agreement as a whole.
 - a. <u>Termination for Breach</u>. 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. <u>Termination Without Cause</u>. Either Party may terminate this Agreement without cause by providing the other with at least ninety (90) days written notice.
- 6. Confidentiality.
 - Confidentiality. For the purposes of this Agreement, "Confidential Information" means any a. 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. <u>Return of Confidential Information</u>. 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. <u>ACCF Indemnity</u>. 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. 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 hospital 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. <u>Limitation of Liability</u>. 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 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. <u>Notices</u>. 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) to the following addresses:

If to the Participant:	
With a copy to:	
24	American College of Cardiology Foundation
	2400 N Street NW
	Washington, DC 20037
	Attn: General Counsel

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. <u>Headings</u>. 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. <u>Assignment</u>. 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. <u>Relationship of Parties</u>. 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. <u>Counterparts</u>. 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. <u>Waiver</u>. 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. <u>Governing Law</u>. 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. Any suit or proceeding relating to this Agreement shall be brought only in the District of Columbia. Each Party consent to the exclusive personal jurisdiction and venue of the courts located in the District of Columbia.
- 16. <u>Severability</u>. 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. <u>Survival</u>. The following sections of this Agreement survive its termination as to any hospital product offering or in its entirety, for any reason: Sections 4, 6, 7, 8, 15 and the Business Associate Agreement.
- 19. <u>No Third-Party Beneficiaries</u>. The Parties agree there are no third-party beneficiaries, intended or otherwise, to this Agreement, including, without limitation, patients of any Participant.

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

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

<u>APPENDIX A</u> BUSINESS ASSOCIATE AGREEMENT

In the course of satisfying its contractual obligations to Participant pursuant to the Participant's engagement of ACCF through the Hospital 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 Hospital Master 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 and its implementing regulations as amended. Accordingly, ACCF and Participant agree as follows:

I. GENERAL PROVISIONS

- 1. <u>Effect.</u> The terms and provisions of this Appendix shall supersede any other conflicting or inconsistent terms and provisions in the Hospital Master 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 Protected Health Information ("PHI") under HIPAA that is transmitted, accessed or maintained by the ACCF under the Hospital Master Agreement.
- 2. <u>Amendment.</u> ACCF and Participant agree to amend this Appendix to the extent necessary to allow Participant and the ACCF to comply with the Standards for Privacy of Individually Identifiable Health Information (45 CFR §160 and 164, as amended) (hereinafter "Privacy Standards"), the Standards for Electronic Transactions (45 CFR §160 and 162), and the Security Standards (45 CFR §160, 162 and 164), all as modified or supplemented by the HITECH Act 42 USC §3000 et. seq., the Omnibus HITECH Regulations and subsequent implementing regulations and guidance (collectively, the "Standards") promulgated by the Secretary or other authorized agencies. The ACCF agrees to develop amendments to this Appendix to incorporate any material provisions required by the Standards, 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. <u>Definitions.</u> Capitalized terms used herein without definition shall have the respective meanings assigned to such terms in the Agreement, or Part V of this Appendix or by HIPAA, if not otherwise defined.

II. OBLIGATIONS OF ACCF

1. Use and Disclosure of Protected Health Information.

a. ACCF agrees to not use or further disclose 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 Rule and the Security Rule applicable to the ACCF as a Business Associate. ACCF shall use reasonable measures to ensure that it does not use or disclose Participant's PHI received from Participant in any manner that would constitute a violation of the Privacy

Standards if done by Participant, except that ACCF may use and disclose Participant's PHI : (i) for ACCF's proper management and administration if 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 in a manner consistent with ACCF's obligations under this Appendix; (ii) to carry out ACCF's legal responsibilities hereunder, or as otherwise required by law or regulation; (iii) to provide Data Aggregation services relating to the health care operations of Participant and other hospitals or health systems with which ACCF contracts; (iv) 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 (v) to create and disclose a Limited Data Set, provided that the conditions set forth in Section II. 9. of this Appendix are satisfied.

- b. 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, to substantially the same restrictions and obligations that apply through this Appendix 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 ten (10) business days after the notice, for the Subcontractor to end the violation. ACCF will terminate the agreement with the Subcontractor if the Subcontractor does not end the violation within the time specified by the ACCF in the notice.
- c. ACCF shall request and Participant shall provide, no more than the "Minimum Necessary" 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 HIPAA Privacy Rule, ACCF shall provide Participant with an amendment to this Section II. 1.c. which complies with the Guidance, which shall replace this Section II. 1.c. 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 be sufficient to meet the requirements of the Agreement and that the amount of 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.
- d. ACCF shall not engage in the Sale of PHI or it use for Marketing using Participant's PHI unless ACCF or 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. ACCF shall not rely on any exceptions to the foregoing requirements as to Participant's PHI without advance notice to all Participants which describes the circumstances and the exceptions to be relied upon by the ACCF. Such notice may be made through a general notice published on the product offering web site.
- 2. <u>Safeguards Against Misuse of Information</u>. ACCF agrees that it shall use reasonable safeguards to prevent the use or disclosure of Participant's PHI other than as otherwise provided for in this Appendix and the Agreement or as otherwise permitted by the Standards. 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 HIPAA Standards for Privacy of Individually Identifiable Health Information 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 result from a use or disclosure of 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. <u>Reporting of Disclosures of Protected Health Information or Security Incidents.</u>

- a. ACCF shall report a Breach of Unsecured Protected Health Information of Participant accessed, maintained, retained, modified, stored, destroyed or otherwise held or used in Unsecured form by ACCF, whether the Unsecured Protected Health Information is in paper or electronic form to Participant within five (5) business days of the first day the Breach is known, or reasonably should have been known, to the ACCF, including for this purpose any employee, officer, or other agent of the ACCF (other than the individual committing the 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 notice in a timely manner, provided that Participant shall consult with ACCF in good faith regarding the details of the notice. If ACCF believes that the facts related to a Breach justify the application of any statutory exceptions specified at Section 13400 of the HITECH Act or the regulatory exclusions specified at 45 CFR \$164.402, ACCF shall describe those facts in or within a reasonable time after it provided notice of the Breach and ACCF and Participant shall thereafter discuss the possible application of an exception or an exclusion, provided that any final decision on the availability of an exclusion or exception will be that of the Covered Entity.
- b. 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.a. The parties agree, however, that this Section II. 3.b. satisfies any notices necessary 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 Iog-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 electronic PHI or interference with information system operations related to the ePHI, 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. **Data Use Agreements.** Section II. 1.b. shall not apply to disclosures by ACCF of a Limited Data Set, as such disclosures shall be governed by Section II. 9. of this Appendix.

- 5. <u>Access to Information.</u> Within twenty (20) days of a request by Participant for access to Participant's PHI about an individual contained in a Designated Record Set so that it may respond to said individual's request for such information, ACCF shall make available to Participant such Participant's PHI provided that such Participant's PHI constitutes a Designated Record Set, such determination to be made by ACCF. 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.
- 6. <u>Availability of Protected Health Information for Amendment.</u> Within twenty (20) days of receipt of a request from Participant for the amendment of an individual's Participant's PHI which is maintained by the ACCF in a Designated Record Set, ACCF shall provide such information to Participant for amendment, and incorporate any such amendments in the Participant's PHI as required by 45 CFR §164.526, including information, if any, maintained in an Electronic Designated Record Set, to the extent required by the Privacy Rule. 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. ACCF will report any request for access that it receives directly from an Individual to Participant within twenty (20) business days of receipt.

7. Accounting of Disclosures.

- a. Within twenty (20) days of notice by Participant to ACCF that it has received a request from a patient 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 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 HIPAA Privacy Rule, ACCF shall provide Participant with an amendment to this Section II.
 7.b. which complies with the Regulation, which shall replace this Section II. 7.b. as of the date upon which compliance is required with the Regulation.
- 8. <u>Availability of Books and Records.</u> 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.

9. Data Use Agreement.

a. <u>Activities.</u> The Parties agree that ACCF may use and disclose a Limited Data Set for purposes of cardiovascular research initiated by ACCF, 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. 9.a. of this Appendix shall collectively be referred to as the "Activities."

- b. <u>Limited Data Set.</u> 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. <u>Safeguards Against Misuse of Information</u>. ACCF shall use reasonable safeguards to prevent the use or disclosure of a Limited Data Set other than as permitted under this Agreement.
- d. <u>**Reporting of Wrongful Disclosures.**</u> ACCF shall, within twenty (20) 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. <u>Agreements with Third Parties.</u> 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.

10. Other Rights and Obligations of ACCF.

- a. <u>HIPAA Obligations of Participant.</u> To the extent that ACCF will carry out any obligation of Covered Entity under the Security and Privacy provisions set out in Subpart E of 45 CFR §164, ACCF will perform such obligations in compliance with the provisions of such Subpart that apply to the Covered Entity as to such obligations.
- b. <u>Other Agreements for Services.</u> 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 Hospital Master Agreement shall be deemed to refer to the Other Service Agreement.
- c. <u>Permitted Charges.</u> 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 the HIPAA Standards.
- 2. Participant shall provide ACCF with at least thirty (30) 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, which will affect the uses and disclosures of Participant's PHI, which ACCF is permitted to make pursuant to the Agreement, including this Appendix A. 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.

IV. TERMINATION OF AGREEMENT

- 1. Termination Upon Breach of Provisions Applicable to Protected Health Information or Participant's Obligations. Any other provision of this Appendix or the Agreement notwithstanding, the Agreement and this Appendix may be terminated by the Participant upon thirty (30) days written notice to ACCF in the event that ACCF breaches any provision contained in this Appendix, which notice shall describe the breach in reasonable detail. If such breach is not cured within such thirty (30) day period; provided, however, that in the event that termination of this Agreement is not feasible, in Participant's sole discretion, ACCF hereby acknowledges that Participant shall have the right to report the Breach to the Secretary, notwithstanding any other provision of this Agreement to the contrary. In the event that ACCF becomes aware of a pattern of activity or a practice of the Participant that constitutes a material violation of the obligations of Participant under its this Appendix, ACCF shall provide Participant with written notice describing the material violation in reasonable detail and a period of not less than thirty (30) days after receipt of such notice to cure the material violation. If such breach is not cured within such thirty (30) day period, ACCF may terminate the Agreement and this Appendix on notice to Participant provided, however, that in the event that termination of the Agreement and this Appendix is not feasible, in ACCF's sole judgment, Participant hereby acknowledges that ACCF shall have the right to report the Breach to the Secretary, notwithstanding any other provision of this Agreement to the contrary.
- 2. **Return or Destruction of Protected Health Information 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 such Participant's PHI, it shall either return such 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 such Participant's PHI shall be used or disclosed solely for such purpose or purposes which prevented the return or destruction of such Participant's PHI, and shall be maintained as confidential. Aggregate data and 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. 9. of this Appendix.

V. DEFINITIONS FOR USE IN THIS APPENDIX

- "Breach" shall mean the unauthorized acquisition, access, use, or disclosure of Unsecured Protected Health Information which compromises the security or privacy of such information, subject to the statutory exceptions specified at Section 13400 of the HITECH Act and to the regulatory exclusions specified at 45 CFR §164.402 and any future amendments thereto.
- "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 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.
- "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) (1).
- "Hospital Master Agreement" shall mean the Hospital 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 Hospital Master Agreement and this Appendix applies.
- "Privacy Standards" shall mean the Standard for Privacy of Individually Identifiable Health Information, 45 CFR §160 and 164.
- "PHI", "Protected Health Information" or "Participant's PHI" 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 or Activity Data as that term is used in the Agreement. Under no circumstances shall aggregate data or

De-identified Data constitute "Protected Health Information" or "Participant's PHI". "Protected Health Information" or "Participant's PHI" 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).

- "ePHI" shall mean PHI in electronic form as defined in the Security Standards.
- "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 Health Insurance Reform Security Standards at 45 CFR §160, 162, and 164.
- "Subcontractor" shall mean a person or entity to which ACCF delegates a function, activity or service involving access to PHI or ePHI of Participant, other than as a member of ACCF's Work Force.
- "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 defined terms in this Business Associate Agreement have the meaning assigned in the HITECH Act, unless otherwise defined in the HIPAA Privacy Rule or the HIPAA Security Rule.