

ENROLLMENT INSTRUCTIONS

Thank you for your interest in participating in the NCDR[®] ACTION Registry[®]-GWTG[™]. All the materials you need to enroll are attached. ACTION Registry-GWTG is sponsored by Bristol-Myers Squibb/Sanofi Pharmaceuticals Partnership and Schering-Plough Corporation. As a result, there is no cost to hospitals for participation in ACTION Registry-GWTG.

Enrolling is as easy as 1-2-3:

- 1.** The first step in completing the enrollment process is for you to review the following documents:
 - **Participant Contact Information Form:** This form provides the ACTION Registry-GWTG account management team with appropriate contact information for your hospital.
 - **NCDR Master Agreement:** This 22-page agreement details the obligations of NCDR and the obligations of the hospital entity as they relate to general registry operations.
 - **ACTION Registry-GWTG Addendum:** This 4-page document details the obligations of both parties that are unique to ACTION Registry-GWTG.
- 2.** Next, fill out the contact information form; and sign and date the master agreement and the ACTION Registry-GWTG addendum.
- 3.** Send your completed enrollment packet: 1) the Participant Contact Information form, 2) the NCDR Master Agreement, and 3) the ACTION Registry-GWTG Addendum to:

**American College of Cardiology Foundation
Attn: NCDR ACTION Registry-GWTG Enrollment
P.O. Box 79231
Baltimore, MD 21279-0231**

As soon as we receive and process your documents (please allow 15 business days for processing of your enrollment materials), we'll send you an email with your NCDR Participant ID Number and your User ID and Password for the ACTION Registry-GWTG User Website.

If you have any questions about the enrollment process, please call an ACTION Registry-GWTG Support Specialist at **800-257-4737**.

On behalf of NCDR, we look forward to your participation in ACTION Registry-GWTG.

Sincerely,

The NCDR ACTION Registry-GWTG Account Management Team

NCDR is an initiative of the American College of Cardiology Foundation[®], with primary partnering support for ACTION Registry-GWTG from the American Heart Association, and additional partnering support from the Society of Chest Pain Centers.

MASTER AGREEMENT

**NCDR[®] AGREEMENT BY AND BETWEEN
THE AMERICAN COLLEGE OF CARDIOLOGY FOUNDATION
AND**

THIS AGREEMENT is made this _____ day of _____, 200__, between the American College of Cardiology Foundation (“ACCF”), a non-profit, tax-exempt District of Columbia corporation located at 2400 N Street NW, Washington, DC, 20037 and _____ (“Participant”), located at _____ (city/state). ACCF and Participant shall be referred to herein collectively as the “Parties” and individually as a “Party.”

WHEREAS, ACCF has developed the National Cardiovascular Data Registry Program (“NCDR”) to collect and report on standardized, national, clinical cardiovascular data in connection with different cardiovascular procedures, in which Participant desires to participate;

WHEREAS, NCDR permits comparisons of Participant data with national or regional summary data to aid Participants in their data completeness and consistency programs and other efforts to improve patient care;

WHEREAS, NCDR now consists of four unique hospital-based registries: ACTION Registry[®]–GWTG[™], the CARE Registry[®], the CathPCI Registry[®], and the ICD Registry[™], as well as one office-based registry, the IC³ Program[®]; (individually a “Registry” or collectively as the “Registries”);

WHEREAS, Participant desires to participate in NCDR in one or more of the Registries to improve the quality of cardiovascular care;

WHEREAS, the Parties understand that the provision by ACCF of benchmarking and data aggregation services to Participant 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 C.F.R. Parts 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. Participation in NCDR. Participant hereby agrees to participate in NCDR, and ACCF hereby agrees to permit Participant to participate in one or more of the Registries as provided herein. For purposes of this Agreement, a Participant is defined as a single facility or practice located in a discrete geographic area that is enrolled in NCDR through a Participant Agreement, and is eligible to submit relevant cardiovascular data to one of the Registries.
 - a. Additional Registries. If NCDR elects to establish an additional Registry, Participant may elect whether to participate in it.

2. Participant Responsibilities.
 - a. Submission of Clinical Data. Participant agrees to furnish clinical data in a manner consistent with this Agreement, relevant to the Registries in which it is participating, directly to NCDR in quarterly installments for at least a twelve (12) month period as provided under this Agreement.
 - i. Participant agrees that its data may be rejected by ACCF if Participant data is determined by ACCF to fail the NCDR data evaluation and acceptance process.
 - ii. Participant agrees to submit quarterly data within the “call for data period” after the close of each calendar quarter. The “call for data period” is defined as the first 90 days following the end of each calendar quarter.
 - iii. Participant agrees that submitted data will conform to Paragraphs 2.b., 2.d., 2.e., 2.f., and 2.h. of this Agreement.
 - b. Use of ACCF Data Set and ACCF-Approved Software. Participant will submit a data record on each patient who receives medical care and who is eligible for inclusion in the Registries in which Participant is participating under this Agreement. Participant agrees to use the Registry-specific data elements, definitions, and transmission format approved by ACCF and published in the NCDR Core Data Element Documentation (“ACCF Data Set”) provided to Participant, and as amended by ACCF from time to time. Data must be submitted using ACCF-approved software from either ACCF or a vendor otherwise contracting with ACCF to provide such software, in formats that meet required transmission specifications as set forth in Section 2.c., or otherwise communicated to the Participant by ACCF from time to time. Participant agrees that Participant is solely responsible for

selecting a software vendor from those vendors approved by ACCF, and that ACCF approval does not constitute an endorsement or guarantee of the performance of the selected vendor or the selected vendor's product.

- c. Manner of Communication. Participant shall provide data to ACCF for purposes of the NCDR by secure website at www.ncdr.com. In addition, Participant shall designate a valid e-mail address that ACCF shall utilize to communicate with the Participant; such e-mail address shall only be accessible by the Participant's Registry Site Manager. Participant hereby acknowledges that ACCF will use such e-mail address to communicate pertinent information regarding Registry-specific issues. Participant shall submit data to ACCF for Registries electronically, utilizing methods determined by the ACCF. All submissions of data shall be submitted to ACCF utilizing ACCF-approved encryption software. Furthermore, the Participant shall maintain an updated institutional profile including ensuring that ACCF has a valid e-mail address for the Registry Site Manager at all times in the form identified by ACCF.
- d. Corroboration of Patient Data. Participant will furnish to NCDR independent corroboration, in a form satisfactory to ACCF in its sole, reasonable discretion, that all eligible patients' records have been submitted, based upon case volume counts or similar data from Participant's admitting/registration, cath lab log, billing, and/or medical records information or other hospital-based information system.
- e. Data Collection Staff. Participant's data collection will be performed by staff trained through the ACCF training program including Registry-specific offerings from ACCF promptly after any such training program is made available by ACCF to Participant. Participant agrees that its data collection staff will adhere to the standards published in the current NCDR Core Data Element Documentation provided to Participant, and as is updated from time to time. The current ACCF training program, included in the annual fee, consists of self-directed study from the ACCF Participant Reference and Training Manual. ACCF also offers additional and optional training, available for an additional charge, at ACCF workshops and at its annual meeting, which Participant shall encourage its staff to attend.
- f. Registry Site Manager. Participant will designate a Registry Site Manager who will serve as the primary point of contact for each Registry and will supervise the data collection, confirm the accuracy of the data, receive the confidential reports, and act as direct liaison with ACCF. ACCF recommends that the Registry Site Manager be an experienced clinical professional such as the Clinical Service Line Director, a senior-level Registered Nurse, or a similarly trained and qualified representative of

the quality improvement department; and if ACCF determines that any Registry Site Manager is not sufficiently trained or credentialed in this manner, Participant will identify an alternate individual to serve in that capacity. Participant also agrees to notify ACCF within ten (10) working days of any change in the Registry Site Manager. The Participant's Medical Director or his/her designee, identified to ACCF in writing as such, must approve all data submissions.

- g. Data Evaluation and Acceptance Process. Participant agrees that its submitted patient data may be audited for accuracy and completeness by or on behalf of ACCF. In addition, all submissions are required to meet the NCDR inclusion threshold as defined in the current NCDR release provided to Participant, and as updated by ACCF from time to time, in order for Participant's data to be included in the national averages. Participant understands and agrees that auditing may include an onsite review of patient medical records and additional supporting documentation. The onsite audit process will consist of an audit of randomly selected charts and an evaluation of the process for data collection. In the event that a Participant is selected for an audit, the initial audit will be at the expense of ACCF, and Participant agrees to cooperate in such audit through making available documentation and access to Participant's staff. Participant agrees that if an audit process or the application of threshold criteria find the data do not conform to ACCF standards, as a condition of continued participation in NCDR, the Participant shall submit within forty-five (45) days of notice of the audit an action plan, in a form acceptable to ACCF, to correct such data issues, as well as, in the sole discretion of ACCF, submit to an onsite audit conducted by a third-party auditor chosen by ACCF at the Participant's sole expense. Furthermore, the non-conforming data submitted by the Participant will be withheld from the ACCF database for national reporting purposes until such data is brought up to standard and re-submitted to ACCF by the Participant. Moreover, during any such correction period, while Participant may receive information comparing its data to general data from a Registry, ACCF makes no representation or warranty concerning the reliability of any such comparison or the conclusions Participant may draw from it.
- h. Voluntary Audit Process. If Participant voluntarily chooses to have its data audited, Participant will fund the full cost of the audit, the results of which shall be available to both Parties. Only ACCF-approved auditors may perform the audit process. If such voluntary audit reveals data do not conform to ACCF standards or this Agreement, the process described in Section 2.g. shall be enforced.
- i. Identifiers. Participant agrees that unique patient identifiers and unique physician identifiers will be collected for each record submitted to the NCDR.

- j. Data Confidentiality. Participant shall maintain appropriate procedures to safeguard data confidentiality in compliance with applicable law. Participant will be solely responsible for any and all of its acts or omissions regarding the privacy and security of the data it furnishes hereunder. Participant shall maintain appropriate liability insurance for its acts and omissions under this paragraph.
3. ACCF Responsibility.
- a. Acceptance of Data. ACCF agrees to accept Participant's clinical data, subject to review by ACCF, except where the submitted data does not conform to this Agreement, including, without limitation, the data evaluation and acceptance process and standards established by NCDR, and as updated from time to time by ACCF. In such cases, ACCF reserves the right to either reject the data submission in its entirety, or to limit the use of such data, if it does not meet the required ACCF standards, both with respect to new data and as set forth in Section 2.g. Data may only be accepted if submitted using ACCF-approved software obtained from ACCF or a vendor approved by ACCF, under ACCF-approved formats and processes.
 - b. Reports. ACCF agrees to generate institutional reports for each Registry based on Participant's submitted data, and to distribute reports to Participants. Reports include aggregated demographic, general procedural information, and patient outcomes in a form made available by ACCF to Participants, and as updated by ACCF from time to time. Data Quality Reports will be distributed with each data submission within this Agreement and paid-through-relevant time period. Institution-specific and national reports will be distributed both quarterly and annually within this Agreement and paid-through-relevant time period.
 - c. Use of ACCF Data Set. ACCF agrees to produce, disseminate, and periodically revise the data elements, definitions, and formats, and to certify software that allows Participants to directly transmit their patient data to NCDR.
 - d. Training. ACCF will provide a self-training document to guide Participant's data collection activities.
 - e. Data Accuracy. ACCF will analyze the Participant's submitted data records by means of electronic data checks, consistency checks, and range checks to review data accuracy and completeness and determine aggregate completion rates, and will return Data Quality Reports to Participant within 30 days after submission. All reasonable efforts will be made by ACCF to communicate with Participant's Registry Site Manager to assist the Participant in providing the submitted data.

- f. Data Assessment Audit. ACCF may, at its option, audit submitted patient data to review its accuracy and completeness. ACCF will notify Participant within forty-five (45) days of the completion of the audit process (completion and return of data from the auditor) of the results of the audit and any action that the Participant may need to take as a result of the audit, and may take any actions in response as provided in Section 2.g. of this Agreement.
 - g. Identifiers. ACCF will accept unique patient identifiers and unique physician identifiers for each record submitted to NCDR by Participant.
- 4. Privacy Laws; Security.
 - a. Compliance with Privacy 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. 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 Appendix A to this Agreement (“HIPAA Appendix”). ACCF will have all rights, as well as all responsibilities, set forth in Appendix A as if fully set forth herein.
 - b. Security. ACCF will take reasonable steps to maintain its security policies and procedures to protect Participant data as provided in Appendix A. If ACCF determines that a breach of security has occurred, ACCF will promptly notify Participant. ACCF will be responsible for its acts and omissions regarding the privacy and security of the data it maintains under this Agreement.
- 5. Participant Training and Reference Manual. A Participant Training and Reference Manual will be provided to Participant upon enrollment in NCDR. ACCF reserves the right to revise the Participant Training and Reference Manual (“Manual”) as it deems appropriate, in its sole discretion, and will provide updates to the Participants of any such revisions. Participant’s continued submission of data to NCDR after the date on which the Manual revisions are provided to Participant constitutes acceptance of such revisions. If Participant does not agree to accept such revisions by continuing to submit data to NCDR, that shall constitute notice of termination of this Agreement by Participant under Section 9.b., provided that during the ninety (90) day termination period, Participant shall not have the right to submit data to NCDR, but the other provisions of this Agreement shall apply.
- 6. 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, 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.

7. 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 HIPAA Appendix. Participant hereby agrees the return of that information is infeasible as it has been integrated into the Registries. 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 NCDR program, aggregate data and the compilation of the same with any other data received in connection with the NCDR program, and any derivative works using the Registries, including, without limitation, any reports, calculations and models based thereon, and De-identified Data as described in Section 7.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 NCDR. Once Participant data is accepted by ACCF into NCDR for analysis and reporting, this data becomes part of the NCDR aggregate data and it cannot be retracted from NCDR by Participant. Information to which ACCF has access or ownership under this Section 7 shall not be considered Confidential Information to be returned to Participant under Section 10.

- c. Publication. If Participant desires to publish or otherwise distribute or use, in whole or in part, any aggregate data or reports provided by ACCF, or produced in connection with or derived from NCDR, with the exception of strictly internal use within the Participant as defined in Section 1, Participant must first obtain the prior express written consent of ACCF. To the extent Participant is permitted to publish aggregate data, such aggregate data and any related information published in connection with it must be reviewed and approved by ACCF prior to publication.
8. Participant Fees. Participant will pay ACCF an annual fee for each Registry to participate in that Registry. Payment of the annual fee includes quarterly submission of data, ACCF-supplied self-training documentation, and distribution of Data Quality Reports and Institution-specific Reports. From time to time, ACCF may develop other reports and products for an additional charge. Unless overnight delivery is requested by Participant, there are no handling or shipping charges. The entire annual fee is non-refundable even if this Agreement is terminated prior to the end of the term.
9. Term, Enforcement and Termination. This Agreement shall be effective until December 31, 2009, 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 Registry, without initiating or impairing any Party’s right to enforce any right with respect to any other Registry 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 non-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 Without Cause. Either Party may terminate this Agreement without cause by providing the other with at least ninety (90) days written notice.
- c. Termination for Failure to Meet Data Completeness and Consistency Requirements. ACCF reserves the right to immediately terminate this Agreement and Participant's participation in NCDR if it determines that any two (2) calendar quarters of Participant's data within a rolling twelve (12) calendar-month period are noncompliant with NCDR standards or otherwise unacceptable for inclusion in the NCDR national averages. ACCF may, in its sole discretion, provide the Participant with the opportunity to cure the inadequate data as stated in Section 2.g. without affecting the rights of ACCF to terminate this Agreement under this Section or otherwise.
- d. Termination of Software Use. Upon termination of this Agreement, Participant agrees that it shall not use NCDR software or the NCDR dataset for collecting and reporting data, or any other purpose, without the express written consent of ACCF, except as necessary to wind down Participant's participation in a Registry or the NCDR as a whole. Furthermore, Participant agrees that ACCF may notify Participant's approved software vendor of the termination of this Agreement as to any Registry or in its entirety, and agrees that it will allow its approved software vendor under Section 2.b. to terminate any such software license to Participant without penalty to such vendor, and to prevent further use of the software, including its use for data entry by Participant into the NCDR dataset.

10. 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 10, any information governed by Section 7.a. or 7.b. or the provisions of the HIPAA Appendix shall be governed, respectively, by those Sections of this Agreement, as applicable.

11. Indemnification.

- a. ACCF Indemnity. 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 NCDR and to disclose such information to ACCF; and (4) the use of Registry 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.

12. Limitation of Liability. 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 11.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 NCDR 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.

13. 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) to the following addresses:

If to the Participant: _____

With a copy to: _____

If to ACCF: American College of Cardiology Foundation
2400 N Street NW
Washington, DC 20037
Attn: General Counsel

14. 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.
15. 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.
16. 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.
17. 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.
18. 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.
19. 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.
20. Governing Law. 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 consents to the exclusive personal jurisdiction and venue of the courts located in the District of Columbia.

21. 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.
22. 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.
23. Survival. The following sections of this Agreement survive its termination as to any Registry or in its entirety, for any reason: Sections 4, 6, 7, 9.d., 10, 11, 20 and the HIPAA Appendix.
24. 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.

IN WITNESS WHEREOF, each of the Parties hereto has caused this Agreement to be executed as of the _____ day of _____, 200__:

**AMERICAN COLLEGE OF CARDIOLOGY
FOUNDATION**

Date: _____

By: _____

Title: _____

PARTICIPANT

Date: _____

By: _____

Title: _____

APPENDIX A
HIPAA APPENDIX

In the course of satisfying its contractual obligations to Participant pursuant to the Participant's engagement of ACCF, 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 C.F.R. Parts 160 and 164, as amended) ("HIPAA"). The purpose of this Appendix is to provide the Participant with satisfactory assurance that, as Participant's Business Associate, ACCF will 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

Section 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.

Section 2. **Amendment.** ACCF and Participant agree to amend this Appendix to the extent necessary to allow Participant to comply with the Standards for Privacy of Individually Identifiable Health Information (45 C.F.R. Parts 160 and 164, as amended) (hereinafter "Privacy Standards"), the Standards for Electronic Transactions (45 C.F.R. Parts 160 and 162), and the Security Standards (45 C.F.R. Parts 160, 162 and 164) (collectively, the "Standards") promulgated, or to be promulgated, by the Secretary. 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. Participant is responsible for determining the adequacy of the amendment for its compliance with HIPAA.

Section 3. **Definitions.** Capitalized terms used herein without definition shall have the respective meanings assigned to such terms in the Agreement, or Part V of this Appendix.

II. OBLIGATIONS OF VENDOR

Section 1. **Use and Disclosure of Protected Health Information.** ACCF may use and disclose PHI only as permitted under the Agreement and this Appendix A. ACCF shall

use reasonable measures to ensure that its directors, officers, employees, subcontractors, business partners, and agents do not use or disclose 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 PHI to ACCF's subcontractors and others: (i) for ACCF proper management and administration if ACCF enters into a written agreement with a party to whom it releases PHI, and uses reasonable measures to require such party to hold such 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 PHI is breached; (ii) to carry out ACCF 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 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 9 of this Appendix are satisfied.

Section 2. **Safeguards Against Misuse of Information.** ACCF agrees that it will use reasonable safeguards to prevent the use or disclosure of PHI except 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 EPHI created, maintained, received, or transmitted by ACCF. ACCF shall further use reasonable measures to ensure that any agent to whom it provides EPHI, including a subcontractor, agrees to implement reasonable and appropriate safeguards to protect such EPHI.

Section 3. **Reporting of Disclosures of Protected Health Information or Security Incidents.** ACCF shall, within twenty (20) days of becoming aware of any use or disclosure of PHI or EPHI in violation of this Agreement by ACCF, its officers, directors, employees, subcontractors, or agents, or by a third party to which ACCF disclosed PHI or EPHI pursuant to Section 1 of this Appendix, report any such disclosure to the Participant. ACCF will also, promptly on becoming aware of it, report any Security Incident involving EPHI to Participant.

Section 4. **Agreements with Third Parties.** ACCF shall obtain and maintain an agreement with each of the ACCF subcontractors or agents that has or will have access to PHI, which is received from, or created or received by ACCF on behalf of Participant, pursuant to which agreement such subcontractor or agent agrees to be bound by

restrictions, terms and conditions that are consistent with those applicable to ACCF pursuant to this Appendix and the Agreement with respect to such PHI, provided however that this Section shall not apply to disclosures by ACCF of a Limited Data Set, as such disclosures shall be governed by Section 9 of this Appendix.

Section 5. **Access to Information.** Within twenty (20) days of a request by Participant for access to 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 PHI provided that such PHI constitutes a Designated Record Set, such determination to be made by ACCF. In the event any individual requests access to PHI directly from ACCF, ACCF shall within twenty (20) days forward such request to Participant. Any denials of access to the PHI requested shall be the responsibility of Participant.

Section 6. **Availability of Protected Health Information for Amendment.** Within twenty (20) days of receipt of a request from Participant for the amendment of an individual's PHI, or a record regarding an individual maintained by ACCF in a Designated Record Set, ACCF shall provide such information to Participant for amendment, and incorporate any such amendments in the PHI as required by 45 C.F.R. Part 164.526.

Section 7. **Accounting of Disclosures.** 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 PHI, other than related to the treatment of the patient, the processing of payments related to such treatment, or the operation of Participant or its business associate, 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 C.F.R. Part 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.

Section 8. **Availability of Books and Records.** ACCF hereby agrees to make its internal practices, books, and records relating to the use and disclosure of 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.

Section 9. **Data Use Agreement.**

Section 9.1. **Activities.** ACCF will use and disclose a Limited Data Set for purposes of cardiovascular research, 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. 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 9.1. of this Appendix shall collectively be referred to as the “Activities.”

Section 9.2. **Limited Data Set.** Participant agrees to disclose, and ACCF agrees to use, PHI 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 C.F.R. Part 164.514(e)(2).

Section 9.3. **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.

Section 9.4. **Reporting of Wrongful Disclosures.** 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.

Section 9.5. **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 C.F.R. Part 164.514(e) (4), with respect to the Limited Data Set.

III. OBLIGATIONS OF PARTICIPANT

Participant shall be responsible for assuring Participant compliance with the HIPAA Standards. Participant will provide ACCF with at least thirty (30) days advance written notice of any restrictions on uses and disclosures of PHI that it agrees to, pursuant to 45 C.F.R. Part 164.522, which will affect the uses and disclosures of PHI which ACCF is permitted to make pursuant to the Agreement, including this Appendix A.

III. TERMINATION OF AGREEMENT

Section 1. **Termination Upon Breach of Provisions Applicable to Protected Health Information.** Any other provision of this Agreement notwithstanding, this Agreement 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 will 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.

Section 2. **Return or Destruction of Protected Health Information Upon Termination.** Participant has determined that return or destruction of PHI contained in ACCF Registries or other databases ("ACCF Data Set") is not feasible upon termination of the Agreement. Therefore, ACCF shall comply with the requirements of this Section 2 for so long as it is held by ACCF in an ACCF Data Set. In the event that ACCF determines that it will no longer maintain such PHI, it shall either return such PHI to Participant or destroy it (with certification of such destruction) at the sole option of ACCF. Aggregate data, De-identified Data, and PHI contained in a Limited Data Set shall not be subject to this obligation. The terms and provisions of this Appendix shall survive termination of the Agreement, and such PHI shall be used or disclosed solely for such purpose or purposes which prevented the return or destruction of such PHI, and shall be maintained as confidential.

V. DEFINITIONS FOR USE IN THIS APPENDIX

"Data Aggregation" shall mean, with respect to PHI created or received by ACCF in its capacity as the Business Associate of Participant, the combining of such PHI by ACCF with the 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 C.F.R. Part 164.514 regarding de-identification of PHI.

"Designated Record Set" shall have the meaning set forth in 45 C.F.R. Part 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 C.F.R. 160.103.

“Health Care Operations” shall have the meaning set forth in 45 C.F.R. Part 164.501.

“Individually Identifiable Health Information” shall mean information that is a subset of health information, including demographic 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 C.F.R. Part 164.514 (e) (1).

“Privacy Standards” shall mean the Standard for Privacy of Individually Identifiable Health Information, 45 C.F.R. Parts 160 and 164.

“Protected Health Information” or “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 “PHI”. “Protected Health Information” or “PHI” shall not include: (i) education records covered by the Family Educational Right and Privacy Act, as amended, 20 U.S.C. §1232g; and (ii) records described in 20 U.S.C. §1232g(a)(4)(B)(iv).

“Research” shall have the meaning set forth in 45 C.F.R. Part 164.501.

“Secretary” shall mean the Secretary of the Department of Health and Human Services.

“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 C.F.R. parts 160, 162, and 164.

ACTION Registry®-GWTG™ Addendum

**ADDENDUM OF AGREEMENT BETWEEN
NCDR® PARTICIPANT AND THE
AMERICAN COLLEGE OF CARDIOLOGY FOUNDATION**

THIS ADDENDUM (“Addendum”) is made this ___ of _____ 200__ and is effective as of the ___ day of _____, 200__ (“Effective Date”) between the American College of Cardiology Foundation (“ACCF”), a non-profit, tax-exempt organization with office located in Washington, DC, and _____ (“Participant”) (collectively “Parties”). This Addendum adds certain terms, including participation in a new ACCF Registry, to the Master Agreement relating to Participant’s participation in the American College of Cardiology Foundation – National Cardiovascular Data Registry (“NCDR®”) dated the ___ of _____, 200__ (“Master Agreement”);

RECITALS:

WHEREAS, in accordance with Section 1.a of the Master Agreement, the Parties wish to add an additional Registry to the Master Agreement and to document Participant’s participation in the additional Registry on the terms and conditions of the Master Agreement, except to the extent additional or modified terms and conditions are specifically added by this Addendum.

WHEREAS, the additional Registry to which the Parties desire to extend the Master Agreement to is the ACTION Registry®-GWTG™, a Registry that the ACCF and the American Heart Association (“AHA”) have developed collaboratively;

WHEREAS, the ACCF has contracted with Duke Clinical Research Institute to provide certain technology management services to Participant on the behalf of the ACCF;

NOW, THEREFORE, in consideration of the mutual promises and agreements hereinafter 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. The Parties agree that all of the Recitals are true and correct and are hereby incorporated by reference into this Agreement. All defined terms in the Master Agreement have the same meaning in this Addendum unless otherwise specifically stated.
2. The Parties recognize that all obligations detailed in the existing Agreement apply to participation in ACTION Registry-GWTG except as expressed in this Addendum

ACTION Registry®–GWTG™ Addendum

3. The Parties acknowledge that the ACTION Registry–GWTG Call for Data period as it is defined in provision 2.a.ii of the Master Agreement shall be the first thirty (30) days following the end of a calendar quarter.
4. The Parties acknowledge that for the purposes of the ACTION Registry–GWTG provision 7.a and 7.b of the Master Agreement shall not apply. The following provisions only apply to participation in the ACTION Registry–GWTG:

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 HIPAA Appendix. Participant hereby agrees the return of that information is infeasible, as it has been integrated into the ACTION Registry–GWTG. 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 and AHA shall jointly own such data, and any derivative works from it, as Intellectual Property Rights owned by ACCF and AHA.
- b. Intellectual Property; Aggregate Data. All Intellectual Property Rights and title to all proprietary information and rights to any software, database, and any data submitted and accepted by ACCF for use in ACTION Registry–GWTG, aggregate data and the compilation of the same with any other data received in connection with ACTION Registry–GWTG and any derivative works using the ACTION Registry–GWTG data including, without limitation, any reports, calculations and models based thereon, and De-identified Data as described in Section 7.a above 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 and/or the AHA depending on claimant of such intellectual property. 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. Once Participant data is accepted by ACCF into

ACTION Registry®–GWTG™ Addendum

ACTION Registry–GWTG for analysis and reporting, this data becomes part of the ACTION Registry–GWTG aggregate data and it cannot be retracted from ACTION Registry–GWTG by Participant. Information to which ACCF has access or information to which ACCF and/or AHA have ownership under this Section shall not be considered Confidential Information to be returned to Participant under Section 10 of the Master Agreement.

5. A web-based data entry tool (“Tool”) has been developed for submission of Participant’s clinical data in ACTION Registry–GWTG and this Tool meets the requirements of ACCF-approved software as outlined in paragraph 2.b of the existing Agreement.
6. Participant acknowledges that data submitted by Participant will be held, maintained and analyzed by Duke Clinical Research Institute as a contractor of ACCF.
7. The Participant recognizes that use of the Tool will require Internet Explorer 6.0 or higher.
8. The ACCF shall produce a training mechanism detailing the functionality of the Tool. The training mechanism is specifically the intellectual property of the ACCF and AHA under Section 4.b of this Addendum. It is the responsibility of the Participant to review the provided training materials and use the Tool as detailed in the materials. The ACCF reserves the right to amend or update the training materials periodically. The ACCF will notify the Participant of amendment of the training material and will make the material available to the Participant.
9. The ACCF will provide support via telephone and e-mail during normal business hours Monday-Friday from 9:00 a.m.-5:00 p.m. eastern time. Support will not be offered on the weekend or federal holidays. The ACCF will provide technical support for the utilization of Tool only. It is the responsibility of the Participant to handle any issue related to hardware requirements required to utilize the Tool.
10. Upon notice and with the cooperation of the Participant. The ACCF shall use reasonable efforts to promptly resolve any failure of the Tool to perform which materially impairs the Participant’s use of the Tool or any malfunction or defect of the Tool, including through updates or corrections.
11. The ACCF shall deliver corrections to the Tool in the form of updated versions or revisions to the Tool.
12. The Parties recognize that all Protected Health Information submitted to ACCF is protected under Appendix A of the Agreement.
13. To the extent any inconsistency exists between this Addendum and the terms of the Agreement, the terms of this addendum shall control with the exception of the terms and condition of Appendix A of the Agreement (HIPAA Appendix) and if any

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inconsistency exist between Appendix A and this Addendum, the terms of Appendix A shall control.

14. All other terms of the Master Agreement shall remain in force and unchanged.

WITNESS WHEREOF, each of the parties hereto has caused this Addendum to be executed by its duly authorized agents

**American College of
Cardiology Foundation**

Participant

By: _____

By: _____

Date: _____

Date: _____