

BUSINESS ASSOCIATE AGREEMENT

In the course of satisfying its contractual obligations to Institution pursuant to the Institution's engagement of ACCF through the FOCUS Institutional Terms and Conditions, ACCF is performing a function or activity on behalf of Institution that constitutes ACCF a "Business Associate" of Institution 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 Institution with satisfactory assurance that, as Institution'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 Institution 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 FOCUS Institutional Terms and Conditions 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 Institution agree to amend this Appendix to the extent necessary to allow Institution or the ACCF 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), all as modified or supplemented by the HITECH Act 42 U.S.C. §3000 et. seq., and implementing regulations and guidance (collectively, the "Standards") promulgated, or to be 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 Institution for adoption. Any amendment distributed by ACCF shall be deemed to be accepted by Institution unless ACCF is notified by Institution 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.

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 ACCF

Section 1. Use and Disclosure of Protected Health Information.

(a) ACCF may use and disclose Institution's PHI only as permitted under the FOCUS Institutional Terms and Conditions and this Appendix. ACCF shall use reasonable measures to ensure that its directors, officers, employees, subcontractors, business partners, and agents do not use or disclose Institution's PHI received from Institution in any manner that would constitute a violation of the Privacy Standards if done by Institution, except that ACCF may use and disclose Institution's PHI to ACCF's subcontractors and others: (i) for ACCF's proper management and administration if ACCF enters into a written agreement with a party to whom it releases Institution's PHI, and uses reasonable measures to require such party to hold such Institution'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 Institution'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 Institution and other hospitals or health systems with which ACCF contracts; (iv) to de-identify Institution's PHI it receives from Institution, 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 Appendixre satisfied.

(b) Effective not later than February 17, 2010, or such later date as may be specified pursuant to the HITECH Act, ACCF shall limit its uses and disclosures of Institution's PHI to uses and disclosures that comply with the Business Associate requirements of 45 CFR 164.504 (e) (2). The foregoing shall not be construed to limit the responsibility of the ACCF under the FOCUS Institutional Terms and Conditions and this Appendixs in effect prior to February 17, 2010.

(c) Effective February 17, 2010, ACCF shall determine the Minimum Necessary Protected Health Information to be disclosed for uses, disclosures or requests of or for Institution's PHI, other than those that exempt from the Minimum Necessary requirement specified in 45 CFR 164.502(b)(2), in order to accomplish the intended purpose of the use, disclosure, or request, consistent with the terms of the FOCUS Institutional Terms and Conditions. To the extent practicable and consistent with the terms of the FOCUS Institutional Terms and Conditions, as determined by ACCF, the Minimum Necessary shall be the information contained in a Limited Data Set, as defined in 45 CFR 164.514(e)(2). At such time as the Secretary issues guidance on what constitutes the "Minimum Necessary" for purposes of the HIPAA Privacy Rule, ACCF shall provide Institution with an amendment to this section which complies with the guidance, which shall replace this Section 1 (c) as of the effective date of the guidance.

(d) Effective not later than six (6) months after the date on which the Secretary publishes applicable final regulations, ACCF shall not, directly or indirectly, receive remuneration in exchange for Institution's PHI unless ACCF or the Institution has obtained to an authorization from the subject individual(s) which complies with all applicable requirements or unless an exception specified in Section 13405(d)(2) of the HITECH Act, 42 U.S.C. 17935(d)(2) or regulations published by the Secretary applies. ACCF shall not rely on any of the foregoing exceptions as to Institution's PHI without advance notice to all Institutions which describes the types of circumstances and the applicable exceptions to be relied upon by the ACCF. Such notice may be made through notice published on the FOCUS web site (www.cardiosource.org/focus).

Section 2. Safeguards Against Misuse of Information. ACCF agrees that it shall use reasonable safeguards to prevent the use or disclosure of Institution's PHI except as otherwise provided for in this Appendixnd the FOCUS Institutional Terms and Conditions 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 Institution's PHI created, maintained, received, or transmitted by ACCF. ACCF shall further use reasonable measures to ensure that any agent to whom it provides Institution's PHI, including a subcontractor, agrees to implement reasonable and appropriate safeguards to protect such Institution's PHI. Effective not later than February 17, 2010, or such later date as may be specified pursuant to the HITECH Act, 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) (collectively, the “Security Requirements”) in the same manner as the Security Requirements apply to a Covered Entity under HIPAA. ACCF shall also comply with additional or modified requirements set forth in any Annual Guidance as to the Security Requirements published by the Secretary and with the additional requirements of the HITECH Act that relate to security of Institution’s PHI.

Section 3. Reporting of Disclosures of Protected Health Information or Security Incidents.

(a) ACCF shall maintain systems to monitor and detect a Breach of Unsecured Protected Health Information 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. ACCF shall provide to notice of a Breach involving Institution’s PHI 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 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 Institutions Privacy Officer, as stated by Institution on the cardiosource.org website. The Parties agree that notice in accordance with the foregoing satisfies the notice requirements of this Section 5. Following the notice, ACCF shall conduct such further investigation and analysis as is reasonably required, and shall promptly advise Institution of additional information pertinent to the Breach which ACCF obtains. ACCF shall cooperate with Institution to support the provision of required notices in a timely manner, including the determination of whether the use, access, or disclosure is one that “poses a significant risk of financial, reputational, or other harm to the individual”, thereby requiring notice. Institution is responsible for the provision of notice in a timely manner, provided that Institution shall consult with ACCF in good faith regarding the details of the notice.

(b) ACCF shall also, promptly on becoming aware of it, report any Security Incident involving Institution’s PHI to Institution, unless the Security Incident was the subject of a notice under Section 3 (a).

Section 4. Agreements with Third Parties. ACCF shall obtain and maintain an agreement with each of the ACCF subcontractors or agents that has or shall have access to Institution’s PHI, which is received from, or created or received by ACCF on behalf of Institution, 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 Institution’s 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 Institution for access to Institution’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 Institution such Institution’s PHI provided that such Institution’s PHI constitutes a Designated Record Set, such determination to be made by ACCF. In the event any individual requests access to Institution’s PHI directly from ACCF, ACCF shall within twenty (20) days forward such request to Institution. Any denials of access to the Institution’s PHI requested shall be the responsibility of Institution.

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

Section 7. Accounting of Disclosures.

(a) Within twenty (20) days of notice by Institution to ACCF that it has received a request from a patient for an accounting of disclosures of Institution's PHI, other than related to the treatment of the patient, the processing of payments related to such treatment, or the operation of Institution 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 Institution such information as is in ACCF possession and that is required for Institution 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 Institution. ACCF hereby agrees to implement an appropriate record-keeping process to enable it to comply with the requirements of this Section.

(b) In addition, Institution shall advise ACCF in writing if Institution uses or maintains an Electronic Health Record(s) ("EHR") through which disclosures of Institution's PHI are made and of the effective date upon which the requirement to provide an Accounting for EHR disclosures for purposes of Treatment, Payment and Health Care Operations ("TPO Accounting") is effective as to Institution. Such notice shall be provided to the ACCF in writing at least thirty days (30) in advance of the date the requirements to provide a TPO Accounting are applicable to Institution ("TPO Notice Period"). ACCF shall capture and store information required for a TPO Accounting for EHR disclosures of Institution's PHI through or by ACCF for a minimum of a rolling three (3) year period beginning with the later of the date specified in the Institution's notice or the end of the TPO Notice Period, in accordance with the applicable regulations published by the Secretary. From and after the effective date specified in the Institution's notice, ACCF shall, as instructed by the Institution, either provide the TPO Accounting directly to the individual making the request or provide the information required for the TPO Accounting to the Institution. In either case, the information required for the TPO Accounting shall be available to the individual or to the Institution, as appropriate, within twenty (20) days of ACCF's receipt of a request. To the extent not expressly prohibited by the HIPAA, the ACCF reserves the right to make a reasonable charge to Institution for each TPO Accounting provided to Institution or to an individual at Institution's request.

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 Institution's PHI received from, or created or received by ACCF on behalf of, Institution available to the Secretary for purposes of determining Institution's compliance with the Privacy Standards, as requested in writing by Institution.

Section 9. Data Use Agreement.

Section 9.1. Activities. 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 Institution but ACCF shall endeavor to make any resulting research studies, articles or similar results generally be made available to Institution 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 Institution. 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. Institution 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 Limited Data Set from Institution’s PHI otherwise provided to ACCF pursuant to the FOCUS Institutional Terms and Conditions 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 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 Institution.

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 INSTITUTION

Section 1. Institution shall be responsible for assuring Institution’s compliance with the HIPAA Standards.

Section 2. Institution shall provide ACCF with at least thirty (30) days advance written notice of any restrictions on uses and disclosures of Institution’s PHI that it agrees to, pursuant to 45 C.F.R. Part 164.522, which will affect the uses and disclosures of Institution’s PHI, which ACCF is permitted to make pursuant to the FOCUS Institutional Terms and Conditions, including this Appendix.

IV. TERMINATION OF AGREEMENT

Section 1. Termination Upon Breach of Provisions Applicable to Protected Health Information or Institution’s Obligations. Any other provision of this Appendix or the FOCUS Institutional Terms and Conditions notwithstanding, the FOCUS Institutional Terms and Conditions and this Appendix may be terminated by the Institution 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 Institution's sole discretion, ACCF hereby acknowledges that Institution shall have the right to report the breach to the Secretary, notwithstanding any other provision of this Agreement to the contrary. Effective February 17, 2010, in the event that ACCF becomes aware of a pattern of activity or a practice of the Institution that constitutes a material violation of the obligations of Institution under its this Appendix, ACCF shall provide Institution 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 FOCUS Institutional Terms and Conditions and this Appendix on notice to Institution provided, however, that in the event that termination of the FOCUS Institutional Terms and Conditions and this Appendix is not feasible, in ACCF's sole judgment, Institution 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.

Section 2. Return or Destruction of Protected Health Information Upon Termination.

Institution and ACCF have determined that return or destruction of Institution'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 Institution's PHI is held by ACCF. In the event that ACCF determines that it shall no longer maintain such Institution's PHI, it shall either return such Institution's PHI to Institution 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 Institution's PHI shall be used or disclosed solely for such purpose or purposes which prevented the return or destruction of such Institution's PHI, and shall be maintained as confidential. Aggregate data, De-identified Data shall not be subject to this obligation. Institution's PHI contained in a Limited Data Set shall continue to be governed by the Data Use Agreement provisions of Section 9 of this Appendix.

V. DEFINITIONS FOR USE IN THIS APPENDIX

"Data Aggregation" shall mean, with respect to Institution's PHI created or received by ACCF in its capacity as the Business Associate of Institution, the combining of such Institution's PHI by ACCF with the Institution's PHI received by ACCF in its capacity as a Business Associate of another Institution, to permit data analyses that relate to the health care operations of the respective Institutions.

"De-identified Data" shall have the meaning set forth in 45 C.F.R. Part 164.514 regarding de-identification of Institution's 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 "EParticipant's PHI" shall have the same meaning as the term "electronic protected health information" at 45 C.F.R. 160.103.

“FOCUS Institutional Terms and Conditions” shall mean the FOCUS Institutional Terms and Conditions between the Parties including any general policies, supplements or notices posted on the cardiosource website (www.cardiosource.org/focus).

“Health Care Operations” shall have the meaning set forth in 45 C.F.R. Part 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 U.S.C. §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 Institution’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 C.F.R. Part 164.514 (e) (1).

“Institution’s PHI” shall mean the Protected Health Information of the Institution to which the FOCUS Institutional Terms and Conditions and this Appendix applies.

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

“PHI”, “Protected Health Information” or “Institution’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 “Institution’s PHI”. “Protected Health Information” or “Institution’s 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 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 C.F.R. parts 160, 162, and 164.

All other defined terms in this HIPAA Appendix have the meaning assigned in the HITECH Act, unless otherwise defined in the HIPAA Privacy Rule or the HIPAA Security Rule.