Participation and HIPAA Compliance in the ACR National Radiology Data Registry

Your facility has indicated its willingness to participate in the American College of Radiology's National Radiology Data Registry (NRDR). This registry is comprised of a group of databases, each collecting different but specific data and "housed" under the umbrella of the NRDR. Participation in all of the databases is not required. If you wish to participate in any of the databases, it is required that you review, date and sign a Participation Agreement which details the obligations of the NRDR and the obligations of your facility as it relates to the operations of the NRDR.

Since participation in several of the individual databases involves the submission of patient data, the Health Insurance Portability and Accountability Act of 1996 (HIPAA) requires that providers (Covered Entities as that term is defined under HIPAA) have in place an agreement with any Business Associate if the parties in their business dealings exchange Protected Health Information (PHI), as that term is defined in the HIPAA regulations. Under the regulations, submission of PHI (patient data) by your facility (Covered Entity) to the ACR (Business Associate) would require execution of a business associate agreement.

This business associate agreement (BAA) serves the purpose of obtaining satisfactory assurance that the Business Associate will appropriately safeguard any PHI received from the Covered Entity. With this agreement in place, the exchange of information between the Covered Entity and the Business Associate will meet HIPAA requirements without disruption of the business arrangement.

In order to facilitate the submission of your data to the NRDR, the ACR has developed a Participation Agreement and BAA for your use. The BAA fully complies with the requirements of HIPAA and pertinent provisions of the American Recovery and Reinvestment Act of 2009 (ARRA) as found in Subpart D of ARRA, or described as the Health Information Technology of Economic and Clinical Health Act (HITECH). **The attached Participation Agreement and BAA must be signed and returned to the NRDR Administrator before your facility can enter data to the registry.**

This Participation Agreement applies to the following facilities*:

Facility ID**	Facility Name

Corporate Entity or Physician Group: _____

** This information must be provided before the participation agreement can be processed. Please use additional sheets with facility ID and facility name if necessary.*
***Facility ID available upon registration at https:/nrdr.acr.org.*

Please return the properly executed Agreements to:

Mail		**OR EMAIL**
National Radiology Data Registry American College of Radiology 1891 Preston White Drive Reston, VA 20191 USA		nrdr@acr.org

This document is copyright protected by the American College of Radiology. Any attempt to reproduce, copy, modify, alter or otherwise change or use this document without the express written permission of the American College of Radiology is prohibited.

NRDR AGREEMENT BY AND BETWEEN THE AMERICAN COLLEGE OF RADIOLOGY AND

_____

This Agreement is made on _____ (date), between the American College of Radiology (ACR) and _____ ("Participant"). ACR and Participant shall be referred to herein collectively as the "Parties" and individually as a "Party."

Whereas**,** ACR has developed the American College of Radiology National Radiology Data Registry (NRDR), to collect and report on standardized national data related to radiologic, therapeutic or imaging information with the purpose of improving the quality of patient care;

Whereas**,** the NRDR permits comparisons of Participant data with national or regional summary data to aid Participants in their efforts to improve patient care and to contribute to ACR's research efforts to enhance quality improvement in imaging;

Whereas, for purposes of this Agreement, Participant may be defined as a corporate entity or organization with a single discrete geographic location; or a corporate entity or organization with multiple geographic locations; or a number of corporate entities or organizations grouped together for the purpose of creating an alliance. Persons executing an agreement on behalf of a Participant must have the appropriate authority to do so.

Whereas, Participant desires to participate in the NRDR to contribute to the overall quality of patient care through quality assurance and improved peer review;

Whereas, the Parties understand that ACR's provision of benchmarking and data aggregation services to Participant qualifies ACR as a "Business Associate" with respect to Participant pursuant to the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and its implementing regulations (45 C.F.R. Parts 160, 162 and 164, as amended);

NOW, THEREFORE, in consideration of the mutual promises and covenants contained herein, the Parties agree as follows:

1) Participant (as defined above) hereby agrees to participate in the NRDR and ACR hereby agrees to permit Participant to participate in the registry as provided herein. The NRDR includes the following databases:
   a) National Mammography Database (NMD)
   b) CT Colonography Registry (CTC)
   c) General Radiology Information Database (GRID)
   d) Dose Index Registry (DIR)
   e) NRDR PQRS Measures Database
   f) Lung Cancer Screening Registry (LCSR)
   g) Interventional Radiology Registry (IR)

2) Participant Responsibilities

   a. Participant agrees to furnish clinical data for a twelve (12) month period following execution of this Agreement in a manner consistent with the requirements of each registry in which Participant agrees to participate. Participant shall provide data for all eligible patients and exams to ACR for

This document is copyright protected by the American College of Radiology. Any attempt to reproduce, copy, modify, alter or otherwise change or use this document without the express written permission of the American College of Radiology is prohibited.

purposes of the NRDR by securely transmitting the data as prescribed by the specific registry. These data will be entered into the NRDR. Specific requirements for each database are as follows (please check and initial all that apply):

- ☐ CTC: Participant will submit a case record on each patient who receives a CT colonography at Participant's facility.
- ☐ GRID: Participant will submit annual data as well as monthly data for each month of participation.
- ☐ NMD: Participant will submit a case record on each patient who receives a mammogram at Participant's facility.
  DIR: Participant agrees to allow the DICOM Structured Report or equivalent dose information for each exam type checked below to be transmitted from Participant's facility to ACR. Personal Health Information included in the Structured Report will be anonymized. Only the anonymized data will be included in the transmission.
  - ☐ CT
  - ☐ CR/DR
  - ☐ Fluoro
- ☐ NRDR PQRS measures database: Participant will submit one record for each exam that is eligible for a PQRS measure. Available measures and data element definitions for PQRS measures are updated annually by the Centers for Medicare and Medicaid Services (CMS). NRDR will update its list of measures and data elements annually following CMS announcements.
- ☐ LCSR: Participant will submit one record for each lung cancer screening CT exam, as well as any available follow-up information. Patients' personally identifiable information will be masked and not visible to ACR staff. If Participant uses LCSR for Medicare reimbursement, Participant agrees that certain fields on Medicare patients (for example, NPI, patient ID, and date of exam) may be sent to CMS for validation, and that Participant's name will be posted on the ACR website for patients' reference.
- ☐ IR: Participant will submit one record for each IR exam, as well as any available follow-up information. Limited patient personally identifiable information will be collected. Personally identifiable information will be masked and not visible to ACR staff.

b. Upon request by ACR, Participant will furnish to ACR independent corroboration, in a form satisfactory to ACR 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, radiology information system, billing, and/or medical records information or other hospital-based information system.

c. Participant's data submission will be performed per specifications posted on the web-site.

d. Participant will designate a Facility Administrator who will serve as the primary point of contact for participation in any of the registries and will supervise the data collection, confirm the accuracy of the data, receive the confidential reports and act as direct liaison with ACR. If ACR determines that any Facility Administrator is consistently failing to report data as specified in 2(c) above, Participant will identify an alternate individual to serve in that capacity.

e. Participant agrees that its submitted data may be audited for accuracy and completeness by or on behalf of ACR. If ACR requests an audit, Participant agrees to provide corroborating evidence of the accuracy of submitted data in the form of additional supporting documentation. Participant agrees that if an audit process or the application of threshold criteria finds the data do not conform to ACR standards, as a condition of continued participation in the NRDR, Participant

This document is copyright protected by the American College of Radiology. Any attempt to reproduce, copy, modify, alter or otherwise change or use this document without the express written permission of the American College of Radiology is prohibited.

shall submit within forty-five (45) days of notice of the audit an action plan, in a form acceptable to ACR, to correct such data issues. Furthermore, the non-conforming data submitted by the Participant will be withheld from the NRDR database for national reporting purposes, until such data are brought up to standard and re-submitted to ACR by Participant. Moreover, during any such correction period, while Participant may receive information comparing its data to general data from the registry, ACR makes no representation or warranty concerning the reliability of any such comparison or the conclusions Participant may draw from it.

f. 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.

g. Participant will promptly deactivate the NRDR user account of any staff member who is no longer employed by the participant or any staff member whose responsibilities no longer require access to the NRDR. Participant is responsible for the actions of any former staff member or current staff member who accesses the NRDR account without proper authority.

3) ACR Responsibilities

a. ACR agrees to accept Participant's clinical data, subject to review by ACR, except where the submitted data do not conform to this Agreement including without limitation the data quality standards established by the NRDR as updated from time to time by ACR. In such cases, ACR 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 ACR's required standards, both with respect to new data and as set forth in Section 2e.

b. ACR agrees to generate institutional reports for the registry based on Participant's submitted data and make reports available to Participant through the NRDR website. Reports include aggregated demographic, general procedural information and patient outcomes as appropriate in a form made available by ACR to Participant and as updated by ACR from time to time. Data Quality Reports will be made available as needed. National reports will be made available on a semi-annual basis.

c. ACR agrees to produce and periodically revise the data elements, definitions and formats used by the registry. Participant will be notified of any such revisions.

d. ACR will provide a self-training document to guide Participant's data collection activities. ACR 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, . All reasonable efforts will be made by ACR to communicate with Participant's Facility Administrator to assist the Participant in providing the submitted data.

e. ACR may, at its option, audit Participant's submitted data to review its accuracy and completeness. ACR 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 2e of this agreement.

This document is copyright protected by the American College of Radiology. Any attempt to reproduce, copy, modify, alter or otherwise change or use this document without the express written permission of the American College of Radiology is prohibited.

f. ACR will accept unique patient identifiers and unique physician identifiers for each record submitted to the NRDR by Participant.

4) Privacy Laws and Security

a. 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. ACR acknowledges that it is a "Business Associate" as defined and referred to under HIPAA. Accordingly, ACR shall take reasonable steps to comply with the requirements under HIPAA and the HITECH Act for Business Associates as set forth in the HIPAA Business Associate Agreement (BAA) attached hereto.

b. ACR will take reasonable steps to maintain its security policies and procedures to protect Participant data as provided in the BAA. If ACR determines that a breach of security has occurred, ACR will notify Participant in accordance with the provisions of the BAA. ACR will be responsible for its acts and omissions regarding the privacy and security of the data it maintains under this Agreement.

5) Use of Names and Logos

a. Without the express prior written consent of ACR, Participant shall not make any announcements concerning the matters set forth in this Agreement, use the word or symbol, ACR or NRDR or any trademarks or service marks of ACR or make any reference to ACR 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. Without the express prior written consent of Participant, ACR shall not use the Participant's logos, trademarks or service marks of Participant.

6) Data and Copyright Ownership

a. The data for individual patients submitted by Participant shall be the exclusive property of Participant, subject to the rights, if any, of Participant's patients in Individually Identifiable Health Information, and subject to the rights granted to ACR in this Agreement including the HIPAA BAA. Participant hereby agrees the return of that information is not feasible as it has been integrated into the registry. Participant grants to ACR 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 and the HIPAA BAA. To the extent ACR develops de-identified or similar data that are not Individually Identifiable Health Information from the data submitted by Participant for individual patients, ACR shall exclusively own such data and any derivative works from it, as Intellectual Property Rights owned by ACR and may use such data and derivative works in publication and quality improvement research. ACR expressly agrees that such data exclude any and all Individually Identifiable Health Information received from Participant, and any information that identifies Participant.

b. All Intellectual Property Rights and title to all proprietary information in and rights to any software, database, any data submitted and accepted by ACR for use in the NRDR, aggregate data and the compilation of the same with any other data received in connection with the NRDR and

This document is copyright protected by the American College of Radiology. Any attempt to reproduce, copy, modify, alter or otherwise change or use this document without the express written permission of the American College of Radiology is prohibited.

any derivative works using the registry including, without limitation, any reports, calculations and models based thereon and de-identified data as described in Section 6a, 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 ACR. 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. ACR reserves the right to use Participant's De-identified Data, protected health information ("PHI") or create a Limited Data Set in electronic or other format to support ongoing improvements and enhancements to the NRDR. Once Participant data are accepted by ACR into the NRDR for analysis and reporting, these data become part of the NRDR aggregate data and they cannot be retracted from the NRDR by Participant. Information to which ACR has access or ownership under this Section 6 shall not be considered Confidential Information to be returned to Participant under Section 9.

c. If Participant desires to publish or otherwise distribute or use, in whole or in part, any aggregate data or reports provided by ACR or produced in connection with or derived from the NRDR, 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 ACR. 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 ACR prior to publication.

7) At the time of execution of activation of the first registry Participant will pay a one-time registration fee of $500. There is an annual participation fee of between five hundred dollars ($500) and ten thousand dollars ($10,000), depending on the number of radiologists and sites in Participant's facility or practice. There will be no additional registration fee for participation in additional registries covered by this agreement. Please see the NRDR Participation Fee Schedule. All fees are non-refundable.

8) This Agreement shall be effective until December 31, _____, then renew automatically for additional one (1) year terms unless Participant provides ACR with ninety (90) days advance written notice of its desire to terminate this Agreement in its entirety or withdraw from participation in any of the other registries. If the first annual fee is for a period of less than six months, the fee will be prorated for a half year.

a. Either Party may terminate this Agreement without cause by providing the other with at least ninety (90) days written notice.

b. ACR reserves the right to immediately terminate this Agreement and Participant's participation in the NRDR if it determines that any one year of the Participant's data are noncompliant with NRDR standards or otherwise unacceptable for inclusion in NRDR national reporting data. ACR may, in its sole discretion, provide Participant with the opportunity to cure the inadequate data as stated in Section 2e without affecting ACR's rights to terminate this Agreement under this Section or otherwise.

This document is copyright protected by the American College of Radiology. Any attempt to reproduce, copy, modify, alter or otherwise change or use this document without the express written permission of the American College of Radiology is prohibited.

c. Upon termination of this Agreement Participant agrees that it shall not use NRDR software or the NRDR dataset for collecting and reporting data or any other purpose without ACR's express written consent, except as necessary to wind down Participant's participation in the registry.

9) Confidentiality

a. 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. 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. 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 9, any information governed by Sections 6a or 6b or the provisions of the HIPAA BAA shall be governed, respectively, by those Sections of this Agreement, as applicable.

10) Indemnification

This document is copyright protected by the American College of Radiology. Any attempt to reproduce, copy, modify, alter or otherwise change or use this document without the express written permission of the American College of Radiology is prohibited.

a. ACR will indemnify, defend, and hold Participant and its employees, officers, directors, agents, contractors and business partners (collectively the "Participant Indemnities") harmless from any third party claim, demand, cause of action, lawsuit or proceeding brought against Participant based upon 1) any gross negligence or willful misconduct on the part of ACR; 2) any errors or inaccuracies contained in the data as created or derived by ACR; 3) any claim that is based, in whole or in part, on a breach of any warranty, representation or covenant made by ACR under this Agreement, including but not limited to any third party lawsuit or proceeding brought against Participant or any of the Participant Indemnities based upon a claim that any data created or derived by ACR infringe any third party rights. Such indemnification shall include: (1) all reasonable attorneys' fees and costs associated with defense of such claim; (2) all damages and costs finally awarded; and (3) the full cost of any settlement entered into by ACR. Such indemnification obligation is contingent on Participant (i) notifying ACR of any such claim within thirty (30) days of Participant's notice of such claim, (ii) providing ACR with reasonable information, assistance and cooperation in defending the lawsuit or proceeding (to the extent requested by ACR), and (iii) giving ACR full control and sole authority over the defense and settlement of such claim. ACR 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 will indemnify, defend, and hold ACR and ACR's employees, officers, directors, agents, contractors and business partners (collectively the "ACR Indemnitees") harmless from any third party claim, demand, cause of action lawsuit or proceeding brought against one or more ACR Indemnitees based upon (1) any errors or inaccuracies contained in the data as delivered by Participant to ACR; (2) any medical treatment, diagnosis or prescription rendered by Participants or its agents (including physicians and healthcare professionals); (3) Participant failing to have all rights in the data necessary to use the NRDR and to disclose such information to ACR; (4) the use of Registry report 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 ACR or any of the ACR Indemnitees based upon a claim that any data submitted by Participant infringe any third party rights. Participant's indemnification shall include (i) all reasonable 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. Such indemnification obligation is contingent on ACR (i) notifying Participant of any such claim within thirty (30) days of ACR's notice of such claim, (ii) providing Participant with reasonable information, assistance and cooperation in defending the lawsuit or proceeding (to the extent requested by Participant), and (iii) giving Participant full control and sole authority over the defense and settlement of such claim. Participant will not enter into any settlement or compromise of any such claim without ACR's prior consent, which shall not be unreasonably withheld.

11) The aggregate liability of ACR 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 10a 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 ACR has been advised of the possibility of such damages or any remedy set forth herein fails of its essential purpose or otherwise. The ACR 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

This document is copyright protected by the American College of Radiology. Any attempt to reproduce, copy, modify, alter or otherwise change or use this document without the express written permission of the American College of Radiology is prohibited.

otherwise. Participant acknowledges that the NRDR fees and business model reflects this allocation of risk.

12) 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., FedEx, DHL, or UPS) to the following addresses:

If to Participant: _____Name
_____Address
_____
_____
_____Phone
_____Email

With a copy to: _____Name
_____Address
_____
_____
_____Phone
_____Email

If to ACR: ATTN: NRDR Data Registry
American College of Radiology
1891 Preston White Drive
Reston, VA 20191

Service of such notice or demand so made shall be deemed complete on the day of actual delivery. Any Party hereto may, from time to time, by notice in writing served upon the other Party as aforesaid, designate a different mailing address or a different person to which all further notices or demands shall thereafter be addressed.

13) 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.

14) 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.

15) 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.

16) 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) This Agreement and any subsequent addendums executed by the Parties (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

This document is copyright protected by the American College of Radiology. Any attempt to reproduce, copy, modify, alter or otherwise change or use this document without the express written permission of the American College of Radiology is prohibited.

otherwise indicated, may not be modified or otherwise changed in any manner except by a written instrument executed by both Parties.

18) The following sections of this Agreement survive its termination, for any reason: Sections 4, 5, 6, 9, and 10 and the HIPAA BAA.

19) The parties agree there are no third party beneficiaries, intended or otherwise, to this Agreement, including without limitation, patients of Participant.

IN WITNESS WHEREOF, each of the Parties hereto has caused this Agreement to be executed as of _____ _____ (date):

AMERICAN COLLEGE OF RADIOLOGY

Date: 12/21/2016 By: _____

Name: Mythreyi Bhargavan-Chatfield, PhD

Title: Executive Vice President for Quality and Safety

PARTICIPANT

Date: _____ By: _____(Signature)

Name: _____

Title: _____

Email: _____

This document is copyright protected by the American College of Radiology. Any attempt to reproduce, copy, modify, alter or otherwise change or use this document without the express written permission of the American College of Radiology is prohibited.

1891 Preston White Drive
Reston, VA 20191

BUSINESS ASSOCIATE AGREEMENT

This Business Associate Agreement (BAA) is entered into by and between_____ (Covered Entity) and the **American College of Radiology** (Business Associate) as of the date of last signature below.

WHEREAS, Covered Entity has a business relationship with Business Associate as evidenced by a separate agreement (Underlying Agreement) under which Business Associate performs or assists Covered Entity with a function or activity involving the use or disclosure of Protected Health Information (PHI), as that term is defined under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). For purposes of this Agreement the definition of PHI includes electronic PHI.

WHEREAS, Covered Entity and Business Associate desire to comply with the requirements and regulations promulgated pursuant to HIPAA, which privacy regulations are codified at 45 CFR, Parts 160 and 164, and which security regulations are codified at 45 CFR, Parts 160, 162 and 164, and as amended by the American Recovery and Reinvestment Act of 2009 (ARRA), which pertinent provisions are found in Subtitle D of the Health Information Technology of Economic and Clinical Health Act (HITECH Act), 42 USC Sections 17921, 17931-17932 and 17934, further modified by 45 CFR Parts 160 and 164, dated January 25, 2013, and hereafter described as the HITECH Final Rule. In all other matters, so long as not inconsistent with HIPAA, the HITECH Act or attendant regulations, the provisions of the Underlying Agreement are binding.

WHEREAS, Covered Entity and Business Associate desire to enter into an agreement as required by 45 CFR 164.502(e) to provide satisfactory assurances to Covered Entity that Business Associate will appropriately safeguard PHI disclosed to it pursuant to any and all contracts with Covered Entity.

This document is copyright protected by the American College of Radiology. Any attempt to reproduce, copy, modify, alter or otherwise change or use this document without the express written permission of the American College of Radiology is prohibited.

THEREFORE, in consideration of the mutual covenants contained herein, and for good and lawful consideration as set forth in the Underlying Agreement, Covered Entity and Business Associate enter into this Agreement for the purpose of ensuring compliance with the requirements of HIPAA, its implementing regulations, the HITECH Act and the Final Rule, and intending to be legally bound, the Parties hereby agree as follows:

1. **Definitions.** All terms and phrases in this Agreement shall have the same meanings as set forth in HIPAA, 45 CFR Parts 160, 162 and 164, Subparts A through E, and as amended by the HITECH Act and the Final Rule.

2. **Permitted Uses and Disclosures by Business Associate**

A. Except as otherwise limited in this BAA, Business Associate may use or disclose PHI to perform functions, activities or services for, or on behalf of Covered Entity as specified in the Underlying Agreement, provided that such use or disclosure would not violate HIPAA, the Privacy or Security Rules or the HITECH Act if done by Covered Entity.

B. Except as otherwise limited in this BAA, Business Associate may use PHI for the proper management and administration of Business Associate or to carry out the legal responsibilities of Business Associate, including reporting violations of the law to appropriate Federal and State authorities, consistent with CFR 164.502(j)(1).

C. Except as otherwise limited by this BAA, Business Associate may disclose PHI for the proper management and administration of Business Associate, provided that such disclosures are for the purpose of performing Business Associate's obligations under the Underlying Agreement or are required by law or Business Associate obtains reasonable assurances from any third party to whom PHI is disclosed that it will remain confidential and used or further disclosed only as required by law or for the purpose for which it was disclosed to the third party and the third party notifies Business Associate within five (5) business days of any instances of which it becomes aware in which the confidentiality of the information has been breached.

D. Business Associate may use PHI to provide Data Aggregation services to Covered Entity as permitted by 45 CFR 164.504(e)(2)(i)(B) to the extent specifically required under the Agreement.

E. Business Associate shall not use or disclose PHI for fundraising or marketing purposes nor shall Business Associate receive indirectly or directly any remuneration in exchange for any PHI or any other purpose not permitted by this Agreement, the Underlying Agreement, the Privacy Rule or HITECH Act or the Final Rule.

3. **Obligations and Activities of Business Associate**

A. Business Associate shall not use or further disclose PHI other than as permitted or required by this BAA or as required by law.

This document is copyright protected by the American College of Radiology. Any attempt to reproduce, copy, modify, alter or otherwise change or use this document without the express written permission of the American College of Radiology is prohibited.

B. Business Associate shall use appropriate safeguards as required by HIPAA and the HITECH Act to prevent use or disclosure of PHI not provided for by this BAA or the Underlying Agreement, including but not limited to administrative, physical and technical safeguards as defined in the Security Rule, 45 CFR Part 164, Subpart C, including using appropriate safeguards for electronic PHI..

C. Business Associate shall ensure that any subcontractor to whom it provides PHI received from, or created or received by Business Associate on behalf of Covered Entity, agrees in writing to the same restrictions and conditions that apply through this BAA to Business Associate with respect to such information. In the event that Business Associate creates, maintains, receives or transmits electronic PHI on behalf of Covered Entity, Business Associate shall implement appropriate safeguards as mentioned in Section 3(B) above with respect to such electronic PHI.

D. Business Associate shall report to Covered Entity within five (5) business days any use or disclosure of PHI or an Individual's information not provided for by this BAA, including without limitation any Breach of PHI, Unsecured PHI or an Individual's information, and any Security Incident that compromises PHI or an Individual's information of which Business Associate becomes aware.

E. Business Associate shall take any action necessary to mitigate, to the extent practical, any harmful effect that is known to Business Associate of a Security Incident, use or

F. If Business Associate maintains PHI in a Designated Record set, Business Associate shall:

(1) Provide access, at the request of the Covered Entity, in a time and manner mutually agreed upon by both parties, to PHI in a Designated Record set, to Covered Entity, or as directed by Covered Entity, to an individual in order to meet the requirements under 45 CFR 164.524; and

(2) Make any amendments to PHI in a designated Record Set that Covered Entity directs or agrees to pursuant to 45 CFR 164.526 at the request of Covered Entity or an individual and in a time and manner mutually agreed upon by both parties.

G. Business Associate agrees to make its internal practices, books and records, including policies and procedures relating to the use and disclosure of PHI received from, or created or received by Business Associate on behalf of Covered Entity available to the Secretary, for purposes of the Secretary determining Covered Entity's or Business Associate's compliance with HIPAA.

H. Business Associate shall make available to Covered Entity the information required to provide an accounting of disclosures to enable Covered Entity to fulfill its obligations under the Privacy Rule, the HITECH Act and the Final Rule. Such information for an accounting will be collected and maintained by Business Associate for at least six (6) years prior to the request. The accounting should include (1) the date of disclosure, (2) the name of the entity or person, and address if known, who received the PHI, (3) a brief description of PHI disclosed, and (4) a brief statement of the purpose of the disclosure. In the event that a request for accounting is delivered directly to Business Associate, Business Associate

This document is copyright protected by the American College of Radiology. Any attempt to reproduce, copy, modify, alter or otherwise change or use this document without the express written permission of the American College of Radiology is prohibited.

will promptly forward the request to Covered Entity.

I . Business Associate acknowledges that if it violates any of the requirements provided under this BAA, Business Associate will be subject to the same civil and criminal penalties that a Covered Entity would be subject to if such Covered Entity violated the same requirements.

J. Business Associate shall implement and maintain safeguards as necessary to ensure that all PHI is used or disclosed only as authorized under HIPAA, the HITECH standards, the Final Rule and this BAA. Business Associate agrees to assess potential risks and vulnerabilities to PHI in its possession and develop, implement and maintain the administrative, physical and technical safeguards required by the HIPAA and HITECH standards that protect the confidentiality, availability and integrity of the PHI that Business Associate creates, receives, maintains or transmits on behalf of the Covered Entity. Business Associate also agrees to implement policies and procedures required under the Final Rule that address Business Associate's compliance with applicable HIPAA standards and its efforts to detect, prevent and mitigate the risks of identity theft from the improper use and/or disclosure of an Individual's information.

4. **Obligations of Covered Entity**

A. It is the responsibility of Covered Entity to notify patients of any breach of PHI, including any breach of PHI involving more than 500 individuals. At no time is Business Associate to contact or speak directly to any of Covered Entity's patients/individuals who are the subject of a breach or to the media regarding any such breach. Business Associate shall cooperate with Covered Entity as necessary to provide notification and any details pertaining to any breach.

B. Covered Entity shall provide Business Associate with the Notice of Privacy Practices that Covered Entity produces in accordance with 45 CFR 164.520, as well as any changes to such Notice to the extent they may affect Business Associate's use or disclosure of PHI; Business Associate shall comply with such Notice of Privacy Practices.

C. Covered Entity shall provide Business Associate with any changes in, or revocation of, permission by individual to use or disclose PHI, if such changes affect Business Associate's permitted or required uses and disclosures. Business Associate shall act promptly upon notification of any such change to ensure that its future uses and disclosures of PHI comply with such a change. Covered Entity shall notify Business Associate of any restriction to the use or disclosure of PHI that Covered Entity has agreed to in accordance with 45 CFR 164.522 to the extent such restriction relates to PHI used or disclosed by Business Associate. Business Associate shall act promptly upon notification of any such restriction to ensure that its future uses or disclosures of PHI comply with such restriction.

D. Covered Entity shall not request Business Associate to use or disclose PHI in any manner that would not be permissible under HIPAA or the HITECH standards if done by Covered Entity.

5. **Term and Termination**

This document is copyright protected by the American College of Radiology. Any attempt to reproduce, copy, modify, alter or otherwise change or use this document without the express written permission of the American College of Radiology is prohibited.

A. The obligations of Business Associate shall commence on the Effective Date and shall terminate when the Agreement terminates and all of the PHI provided by Covered Entity to Business Associate, or created or received by Business Associate on behalf of Covered Entity is destroyed or returned to Covered Entity, or if it is not feasible to return or destroy PHI, the terms of this Agreement are extended to cover such information and survive termination of this Agreement.

B. Upon Covered Entity's knowledge of a material breach by Business Associate to the terms of this Agreement, Covered Entity shall provide an opportunity for Business Associate to cure the breach or end the violation upon mutually agreeable terms. If Business Associate does not cure the breach or end the violation according to such terms, or if Covered Entity and Business Associate are unable to agree upon such terms, Covered Entity may terminate this Agreement and any Underlying Agreement between Covered Entity and Business Associate which is the subject of such breach.

C. In the event Business Associate has breached a material term of this Agreement and a cure is not possible, Covered Entity may immediately terminate this Agreement and any Underlying Agreement between Covered Entity and Business Associate which is the subject of such breach.

6. **Effect of Termination**

A. Except as provided in Section 6(B) of this BAA, upon termination of the Underlying Agreement or this BAA, for any reason, Business Associate shall return or destroy all PHI received from Covered Entity, or created or received by Business Associate on behalf of Covered Entity. This provision shall apply to PHI that is in the possession of any subcontractors or agents of Business Associate. Business Associate shall retain no copies of PHI.

B. In the event that Business Associate determines that returning or destroying the PHI is not feasible and unless the Underlying Agreement already specifies that return or destruction of PHI is not feasible, Business Associate shall provide Covered Entity notification of the conditions that make return or destruction of PHI not possible. Upon mutual agreement of the parties that return or destruction is not feasible, Business Associate shall extend the protections of this BAA to such PHI and limit further uses and disclosures of such PHI to those purposes that make the return or destruction not feasible for so long as Business Associate maintains such PHI.

Notwithstanding the termination provisions of this BAA, the provisions of Section 6 shall survive termination of this BAA.

7. **Miscellaneous**

A. Business Associate acknowledges that Business Associate has no ownership rights with respect to Covered Entity's PHI.

This document is copyright protected by the American College of Radiology. Any attempt to reproduce, copy, modify, alter or otherwise change or use this document without the express written permission of the American College of Radiology is prohibited.

B. The parties understand and agree that the terms of this BAA are reasonable and necessary to protect the interests of the Covered Entity and the Business Associate. The parties further agree that Covered Entity would suffer irreparable harm if the Business Associate breached this BAA. Thus, in addition to any other rights or remedies the Covered Entity may have, the Covered Entity shall be entitled to obtain injunctive relief to enforce the terms of this BAA.

C. Any ambiguity in the terms of this BAA shall be resolved in favor of a meaning that permits the parties to comply with the HIPAA, HITECH and the Final Rule.

D. This BAA is not intended to and does not create a private cause of action by any individual other than the parties to this BAA, as a result of any claim arising out of a breach of this BAA, the HIPAA or HITECH standards or any state of federal law or regulation relating to privacy or confidentiality.

E. In the event that any law or regulation is enacted or promulgated regarding the protection of health information that is in any way inconsistent with the terms of this BAA or that interferes with either party's obligations with respect to the protection of health information so as to warrant a modification of this BAA or in the event any HIPAA standard is amended or modified, either party shall have the right to amend this BAA so as to bring it into compliance with any such change by providing written notice to the other party, which notice shall allow the other party fifteen (15) business days to contest such amendment before implementation. If such proposed amendment(s) are contested, the Parties shall negotiate in good faith to amend the terms of this Agreement to comply with applicable law. If, following such good faith negotiations, the Parties cannot agree upon an amendment to implement the requirements of said law or final rule, then either Party may terminate this Agreement and the Underlying Agreement(s) upon written notice to the other Party. Except as set forth above in this Section 7(E), this BAA shall only be amended or modified upon written consent of the parties.

F. If any provision of this BAA shall be declared invalid or illegal for any reason whatsoever, then notwithstanding such invalidity or illegality, the remaining terms and provisions of this BAA shall remain in full force and effect in the same manner as if the invalid or illegal provision had not been contained herein, and such remaining provisions shall be valid, enforceable and legal to the maximum extent permitted by law.

G. Any notice or other communication given pursuant to this BAA must be in writing and personally delivered or sent by registered or certified mail, postage prepaid, to the address as specified below:

Covered Entity: _____

_____

_____

This document is copyright protected by the American College of Radiology. Any attempt to reproduce, copy, modify, alter or otherwise change or use this document without the express written permission of the American College of Radiology is prohibited.

Business Associate: Department of Quality and Safety
Attn: Q&S Operations
American College of Radiology
1891 Preston White Drive
Reston, VA 20191-4326

Center for Research and Innovation
Attn: Valerie Castle
American College of Radiology
1818 Market Street, Suite 1720
Philadelphia, PA 19103

Notices pertaining to any unauthorized use or access to PHI or breach of PHI shall be submitted to the Covered Entity in accordance with the information provided below:

Contact person: _____

Address: _____

_____

_____

Signature: _____ Signature: _____

Print Name: _____ Print Name: Mythreyi Chatfield

Title: _____ Title: Executive Vice President for Quality & Safety

Date: _____ Date: December 21, 2016

This document is copyright protected by the American College of Radiology. Any attempt to reproduce, copy, modify, alter or otherwise change or use this document without the express written permission of the American College of Radiology is prohibited.

NRDR PARTICIPATION FEE SCHEDULE
Effective January 1, 2015

One time registration fee (billed when first registry is activated): $500

Annual fee for participation in the NRDR (including NMD, CTC, GRID, DIR, LCSR and IR, and excluding NOPR) for participants with 5 facilities or fewer:

Number of Radiologists	1-5 facilities
1-5	$500.00
6-15	$750.00
16 - 25	$1,000.00
26 - 35	$1,250.00
36 - 45	$1,500.00
46 - 55	$1,750.00
> 55	$2,000.00

Annual fee for participation in the NRDR (including NMD, CTC, GRID, DIR, LCSR and IR, and excluding NOPR) for participants with more than 5 facilities:

Number of Radiologists	Number of distinct sites or locations					
	6-15	**16 - 25**	**26 - 35**	**36 - 45**	**46 - 55**	**> 55**
1-5	$1,000.00	$2,500.00	$4,000.00	$5,500.00	$7,000.00	$8,500.00
6-15	$1,250.00	$2,750.00	$4,250.00	$5,750.00	$7,250.00	$8,750.00
16 - 25	$1,500.00	$3,000.00	$4,500.00	$6,000.00	$7,500.00	$9,000.00
26 - 35	$1,750.00	$3,250.00	$4,750.00	$6,250.00	$7,750.00	$9,250.00
36 - 45	$2,000.00	$3,500.00	$5,000.00	$6,500.00	$8,000.00	$9,500.00
46 - 55	$2,250.00	$3,750.00	$5,250.00	$6,750.00	$8,250.00	$9,750.00
> 55	$2,500.00	$4,000.00	$5,500.00	$7,000.00	$8,500.00	$10,000.00

This document is copyright protected by the American College of Radiology. Any attempt to reproduce, copy, modify, alter or otherwise change or use this document without the express written permission of the American College of Radiology is prohibited.