

HIPAA Compliance And Participation in the National Oncologic Pet Registry Project

Your facility has indicated its willingness to participate in the National Oncologic PET Registry Project (NOPR) sponsored by the Centers of Medicare and Medicaid Services (CMS). This project requires the submission of claims data to a national registry administered by the American College of Radiology (ACR) on behalf of the Academy of Molecular Imaging (AMI).

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 claims 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 claims data to the NOPR the ACR has developed a business associate agreement for your use. This agreement fully complies with the requirements of HIPAA. **The attached BAA, without modification, must be signed and returned to the NOPR Project Manager before the PET facility can enter patients on the NOPR.**

Please return the properly executed business associate agreement to:

NOPR Project Manager
American College of Radiology
1818 Market Street, Suite 1600
Philadelphia, PA 19103

or faxed to:

ATTN: NOPR Project Manger – (215) 928-0153





American College of Radiology
1818 Market Street, Suite 1600
Philadelphia, PA 19103-3604

**HIPAA
BUSINESS ASSOCIATE AGREEMENT
NATIONAL ONCOLOGIC PET REGISTRY PROJECT**

Whereas, the American College of Radiology (ACR) acting as an agent on behalf of the Academy of Molecular Imaging (AMI) is collecting and storing data for a project for the Centers of Medicare and Medicaid Services (CMS). This project, known as the National Oncologic PET Registry Project (NOPR), receives and analyzes PET data for the purpose of determining whether such imaging services are appropriate for reimbursement under CMS sponsored programs, and;

Whereas, the below identified health care provider, herein after referred to as a Covered Entity as that term is defined in the Health Insurance Portability and Accountability Act of 1996 (HIPAA), wishes to participate in the NOPR by submitting PET data for review and analysis to the ACR. In connection with receiving these services, the Covered Entity must disclose to ACR certain Protected Health Information (PHI), as defined in 45 C.F.R. Section 164.501 of HIPAA, and;

Whereas, ACR as a recipient of PHI from the Covered Entity is a Business Associate as that term is defined in the HIPAA regulations, and;

Whereas, the parties agree that the following HIPAA regulations, 45 C.F.R. Parts 160, 162 and 164, Subparts A and E, known collectively as the Standards for Privacy of Individually Identifiable Health Information ("Privacy Rule") and The Security Standards, Final Rule ("Security Rule") at 45 C.F.R. Parts 160 and 164, Subparts A and C, govern the activities of the parties related to this project, and;

Whereas, the purpose of this Agreement is to comply with the requirements of the Privacy and Security Rules, including the Business Associate contract requirements at 45 C.F.R. Section 164.504(e).

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

1. **Definitions.** Unless otherwise provided in the Agreement, capitalized terms have the same meanings as set forth in the 45 C.F.R. Parts 160, 162 and 164. For purposes of this Agreement the definition of "Protected Health Information" (PHI) includes electronic PHI as that term is used in the Security Rule.
2. **Scope of Use and Disclosure by ACR of PHI.**
 - A. ACR shall be permitted to use and disclose PHI that is disclosed to it by the Covered Entity as necessary to perform its obligations under this Agreement.

- B. Unless otherwise limited herein, in addition to any other uses and/or disclosures permitted or authorized by this Agreement or required by law, ACR may:
- (a) Use the PHI in its possession for its proper management and administration and to fulfill any legal responsibilities or obligations of ACR under this Agreement and provided that such uses are permitted under federal and state confidentiality laws.
 - (b) Disclose the PHI in its possession to a third party for the purpose of ACR's proper management and administration or to fulfill any legal responsibilities of ACR, provided, however, that the disclosures are required by law or ACR has received from the third party written assurances that (i) the information will be held confidentially and used or further disclosed only as required by law or for the purposes for which it was disclosed to the third party, (ii) any such use or disclosure by the third party does not violate and federal or state confidentiality laws, and (iii) the third party will notify ACR promptly of any instances of which it becomes aware in which the confidentiality of the information has been breached.
 - (c) Aggregate the PHI with that of other Covered Entities for the purpose of providing CMS with data analyses relating to the Health Care Operation of the Covered Entity for the purpose of determining reimbursement, but only to the extent that such aggregated PHI has been properly de-identified for this purpose in accordance with the Privacy Rule. ACR may not disclose the PHI of one Covered Entity to another Covered Entity without the prior written authorization of the Covered Entities involved.

3. **Obligations of ACR.** In connection with its use and disclosure of PHI, ACR agrees that it will:

- A. Use or further disclose PHI only as permitted or required by this Agreement or as required by law.
- B. Use reasonable and appropriate safeguards, including administrative, physical and technical, to prevent the improper transmission, use, disclosure, alteration, destruction or a security violation of PHI other than as provided by this Agreement and to report to the Covered Entity any such transmission, use, disclosure, alteration, destruction or a security incident of PHI that is not permitted by this Agreement or by law within 15 days of the discovery by ACR of the unauthorized transmission, use, disclosure, alteration, destruction or a security incident.
- C. To the extent practicable, mitigate any harmful effect from any improper transmission, use, disclosure, alteration, destruction or security violation of PHI discovered by ACR.
- D. Require subcontractors and agents to whom ACR provides PHI to agree to the same restrictions and conditions that apply to ACR pursuant to this Agreement.
- E. Make available to the Covered Entity and the Secretary of Health and Human Services (HHS) ACR's internal practices, policies, procedures, books and records relating to the use and disclosure of PHI for purposes of determining the Covered Entity's compliance with the HIPAA Regulations, subject to any applicable legal privileges.

- F. Within 15 days of receiving a written request from the Covered Entity, make available the information necessary for the Covered Entity to make an accounting of disclosures of PHI about an individual.
 - G. Within 15 days of receiving a written request from the Covered Entity, make available PHI necessary for the Covered Entity to respond to individuals' requests for access to PHI about them that is not in the possession of the Covered Entity in the event that the PHI in ACR's possession constitutes a Designated Record Set, as that term is defined in the Privacy Rule.
 - H. Within 15 days of receiving a written request from the Covered Entity incorporate any amendments or corrections to the PHI in ACR's control in accordance with the Privacy Rule in the event that the PHI in ACR's possession constitutes a Designated Record Set.
 - I. ACR will not make any disclosure of PHI that the Covered Entity would be prohibited from making.
 - J. ACR will provide appropriate training for its workforce on the requirements of the HIPAA Regulations as those regulations affect the proper handling, use, confidentiality and disclosure of the Covered Entity's PHI. Such training will include specific guidance relating to sanctions against workforce members who fail to comply with security policies and procedures and the obligations of ACR under this Agreement.
4. **Obligations of the Covered Entity.** The Covered Entity agrees that it:
- A. Will and/or has obtained from individuals consents, authorizations and other permissions, and taken such other necessary steps as required by law for ACR and the Covered Entity to fulfill their obligations under this Agreement.
 - B. Will promptly notify ACR in writing of any restrictions on the use or disclosure of PHI about Individuals that the Covered Entity has agreed to that may affect ACR's ability to perform its obligations under this Agreement.
5. **Termination.**
- A. **Termination for Breach.** The Covered Entity may terminate this Agreement if the Covered Entity determines that ACR has breached a material term of this Agreement. Alternatively, the Covered Entity may choose to (i) provide ACR with 30 days written notice of the existence of an alleged material breach, and (ii) afford ACR an opportunity to cure the alleged material breach upon mutually agreeable terms. In the event ACR fails to cure the breach to the satisfaction of the Covered Entity, the Covered Entity may immediately terminate this Agreement.
 - B. **Automatic Termination.** This Agreement will automatically terminate upon the termination or expiration of the NOPR and when all of the PHI provided by the Covered Entity to ACR or created or received by ACR on behalf of the Covered Entity is destroyed or returned to the Covered Entity.
 - C. **Effect of Termination.**
 - (a) Upon termination of this Agreement, ACR will return or destroy all PHI received from the Covered Entity, if it is feasible to do so. ACR will also recover any PHI

in the possession of its subcontractors or agents and return or destroy such PHI, if feasible to do so. If such return or destruction is not feasible, ACR will notify the Covered Entity in writing and specifically note the reasons for such determination. ACR will extend the protections of this Agreement, the Privacy Rule and the Security Rule to the PHI and limit further uses and disclosures to those purposes that make the return or destruction of the information infeasible.

6. **Amendments.** The parties agree to take such action as is necessary to amend this Agreement from time to time to comply with the requirements of the Privacy Rule and the Security Rule. Any amendment must be in writing and signed by both parties.
7. **Survival.** The obligations of ACR under Section 5 C (a) of this Agreement shall survive any termination of this Agreement.
8. **No Third Party Beneficiaries.** Nothing expressed or implied in this Agreement is intended to confer, nor shall anything herein confer, upon any person other than the parties and their respective successors or assigns, any rights, remedies, obligations or liabilities whatsoever.
9. **Notices.** All notices pursuant to this Agreement must be in writing and shall be effective when received if hand-delivered or upon dispatch if sent by reputable overnight delivery service or U.S. Mail, or via facsimile.

To ACR:

American College of Radiology
ATTN: NOPR
1818 Market Street, Suite 1600
Philadelphia, PA 19103-3604

To Covered Entity:

Name of Facility: _____
Attention: _____
Address: _____

City, State, ZIP Code: _____

10. **Alterations.** Any alteration of this Agreement and the entire Agreement is null and void unless such alteration is approved by ACR as evidenced by specific notation from an appropriate ACR official.
11. **Waiver.** No provision of this Agreement may be waived except by an agreement in writing signed by the waiving party. A waiver of any term or provision shall not be construed as a waiver of any other term or provision.

12. **Conflict.** In the event of any conflict between the terms and conditions stated within this Agreement and those contained within any other agreement or understanding between the parties, written, oral or implied, the terms of this Agreement shall govern.

COVERED ENTITY

ACR

By: _____

By: _____

Name: _____

Name: Steven R King, MS, FACHE

Title: _____

Title: Assistant Executive Director

Date: _____

Date: _____