Appendix B-III

HIPAA Compliance and IRB Approval for the NOPR (NaF-PET)

HIPAA Compliance and Participation in the NOPR
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 a PET facility (Covered Entity) to the American College of Radiology (ACR) (Business Associate) requires execution of a business associate agreement.

The American Recovery and Reinvestment Act of 2009 (ARRA) contained provisions called the Health Information Technology and Economic and Clinical Health Act (HITECH) that extend the original requirements related to administrative, physical and technical safeguards that applied to covered entities under HIPAA to the business associates of those covered entities.

The 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. The HITECH amendment serves as an amendment to our current BAA that extends to the NOPR. With these agreements 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 associates agreement (BAA) and a HITECH amendment to the HIPAA BAA for your use. (The BAA and HITECH amendment to the BAA are available on the NOPR web site at http://www.cancerpetregistry.org/ under NOPR Forms.) These agreements fully comply with the requirements of HIPAA and the new requirements under the law.

Institutional Review Board (IRB) Approval for Registry
The only entity engaged in research is the registry itself (i.e., NOPR) because the NOPR intends to use the data it is collecting for research purposes when both the patient and the referring physician have consented to the use of the information for this purpose. The ACR IRB has granted approval for the NOPR to engage in research using these data as described in the original NOPR research plan and this revised research plan (ACR IRB approval letters are posted on the NOPR website).

Individual PET facilities, interpreting physicians, referring physicians and their staffs are not engaged in research and therefore are not required to have IRB approval for their participation in the activities of the NOPR. Submission of the information for the registry (pre-PET and post-PET case report forms, the PET scan report and the interpreting physician scan assessment form) is required by CMS for payment for PET studies for all Medicare-insured patients with cancer indications included in the registry. Additionally, CMS is not conducting research.

Any participating PET facility may nevertheless elect to have its local IRB review its participation in the NOPR. Some IRBs require, as a matter of institutional policy, that they review all research conducted in the institution, even if only to determine that the facility is not engaged in the research. Materials are provided below to assist in this process (See below, Submission Materials for Institutional IRB Review). The Office of Human Research Protections (OHRP) has reviewed the NOPR procedures for protection of human research subjects and finds them to be in compliance with the applicable DHHS regulations. Any individual IRBs with questions can contact the NOPR Working Group co-chairs or OHRP.