The National Oncologic PET Registry (NOPR):
Development, Design and Methods
of Data Collection, and Analysis

NOPR Operations Manual for
NOPR 2009

and

NOPR (NaF-PET)

Sponsored by: World Molecular Imaging Society
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Managed by: American College of Radiology
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Introduction

The National Oncologic PET Registry was initiated in response to the Centers for Medicare and Medicaid Services (CMS) proposal to expand coverage for positron emission tomography (PET) with F-18 fluoro-deoxyglucose (FDG) to include cancers and indications not eligible for Medicare reimbursement under a “coverage with evidence development” (CED) policy. This approach required the collection of data prospectively that could be used to help evaluate the effectiveness of FDG-PET when used in the evaluation of patients with these otherwise “non-covered cancers”. From May 2006 to April 2009, NOPR collected data on approximately 130,000 registry participants.

In April 2009, based in part on the evidence generated by NOPR, CMS expanded coverage for FDG-PET used for initial evaluation of patients with cancer to nearly all cancer types and also used in subsequent treatment strategy evaluations for an expanded number of cancer types. However, for certain other cancers, the use of FDG-PET in initial treatment strategy evaluations and, particularly, in subsequent treatment strategy evaluations remain covered by CMS only via a CED mechanism. Accordingly, the original NOPR was modified to meet these continuing data collection requirements and is referred to as NOPR 2009. This operations manual provides details about ongoing enrollment, work schema, and case report forms for participants in NOPR 2009.

In 2010, the NOPR investigative team initiated a second registry component under the overall umbrella of the NOPR infrastructure. This second component within NOPR will collect data similar but not identical to that being collected for NOPR 2009 on the use of positron emission tomography with sodium fluoride F-18 (NaF-PET) to identify osseous metastasis of cancer. As in NOPR 2009, CMS will only cover the use of NaF-PET under the CED mechanism. The NOPR (NaF-PET) registry has a similar design as NOPR 2009, yet has its own specific clinical details and analytic plan, thus requiring a separate operations manual.

This document includes two separate sections representing the operations manuals for (A) NOPR 2009 and (B) NOPR (NaF-PET). Below are links to each section and to the case report forms for each section.

Section A:  
NOPR 2009 Operations Manual (complete including Case Report Forms)  
and  
NOPR 2009 Case Report Forms

Section B:  
NOPR (NaF-PET) Operations Manual (complete including Case Report Forms)  
and  
NOPR (NaF-PET) Case Report Forms