

Referring Physician Information Sheet

The purpose of the National Oncologic PET Registry (NOPR) is to prospectively examine how the use of PET scans impacts the management of patients with suspected or known cancer. This information will be used to develop guidelines for the effective use of PET in a variety of clinical situations and for future requests to the Centers for Medicare and Medicaid Services (CMS) to seek coverage for PET for cancer types and indications that are not covered outside of this registry.

Currently, CMS is providing coverage for PET performed for non-covered cancer types and indications under a program known as “coverage with evidence development” (CED). As a condition of payment, CMS requires that you provide specific patient information before the PET scan and within 30 days after the PET scan. The information is entered into a secure database maintained by the NOPR and forwarded to CMS for payment purposes.

Your participation in the research component is voluntary. You may choose not to participate. If you agree to participate, you may discontinue participation at anytime. If you withdraw from the study, no new data will be collected about you for research purposes. Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are otherwise entitled. If you agree to participate, the NOPR investigators will also use the information you provide for research purposes. Your patient will also be asked to allow his or her information to be used for the same research purposes. Your patient’s data and PET information in the registry will be used for research only if both you and your patient provide consent. However, you or your patient may choose not to allow this information to be used for the research component of the NOPR. If you choose not to participate, your ability to request future PET scans will not be affected.

Whether or not you choose to participate, you will need to complete pre- and post-PET forms which are necessary for payment by CMS. If you choose to participate in the research study, the same information will become part of the research data. The Pre-PET Completion Form, which must be completed before or on the day of the PET scan, will ask you questions related to the reason for requesting the scan, the patient’s cancer type and extent, and the intended management plan if PET were not available. The Post-PET Form, which must be completed and returned to the PET facility within 30 days after the PET scan, will ask you questions about the impact of the PET findings on your assessment of the patient’s disease status and your current management plan for the patient.

You and your patient will not directly benefit from participating in the research component at this time. Your participation will help to identify the most effective applications of PET in oncology patients. The information will be used by CMS and other health insurance providers to decide whether to pay for PET scans for a wider range of cancer types or cancer-related indications in the future. We hope that the decision may help patients with cancer in the future.

There are no direct risks or discomfort associated with your participation. However, the completion of the pre- and post-PET forms is a requirement for CMS reimbursement. Completion of the forms should take approximately 3 minutes for each form. Participation in the research component will not require additional

time for you and your staff. Your patient will not know your answers and of your participation in the research.

The NOPR has implemented the necessary infrastructure to ensure security of all data submitted on the pre- and post-PET forms. However, we cannot guarantee total privacy. The information will be stored permanently at the American College of Radiology Imaging Network (ACRIN). NOPR investigators will only have access to this information for research purposes, if you consent. All data collected through the NOPR will be made available to CMS for payment purposes regardless of whether consent is given for the research component. The staff at the PET facility where the scan will be performed will not be able to answer any questions concerning this research study. If you have any questions or require any assistance, you can contact the NOPR project manager toll free at 800-227-5463, ext.4859, or pet_registry@phila.acr.org. If you have any questions or concerns about your rights as a research subject or about harms related to this research, you can contact Maria Oh, the American College of Radiology (ACR) IRB coordinator, at (800) 227-5463, ext. 4160.

If you choose to participate and allow the information collected on the pre- and post-PET forms be used for the research component of the NOPR, please check the appropriate check box to indicate your participation in the NOPR research study on the Post-PET Form.

Approved by the American College of Radiology Institutional Review Board on April 3, 2009.