

National Oncologic PET Registry (NOPR) Case Report Forms

Form	Version Date
Patient Information Sheet (Spanish translation available at: http://www.cancerpetregistry.org/pdf/patient_info_spanish.pdf)	03/30/09
Referring Physician Information Sheet	03/30/09
PET Facility Pre-Registration Form	03/30/09
PET Facility Registration Form	03/30/09
Case Registration Form	03/30/09
Pre-PET Form	10/30/09
PET Completion Form	03/30/09
PET Report Submission Form	03/30/09
Post-PET Forms (complete one based on initial indication):	
Post-PET <i>Restaging Cancer</i> Form	03/30/09
Post-PET <i>Suspected Cancer Recurrence</i> Form	03/30/09
Post-PET <i>Treatment Monitoring</i> Form	08/18/10
Post-PET <i>Suspected Cancer</i> Form	11/30/09
Post-PET <i>Paraneoplastic Syndrome</i> Form	11/30/09
Post-PET <i>Initial Staging</i> Form	11/30/09

PRA Disclosure Statement

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The National Oncologic PET Registry (NOPR)

Patient Information Sheet

You are being invited to take part in a research study conducted by the National Oncologic PET Registry (NOPR). Before you decide whether or not to participate, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Talk to your family or friends about the study to help you decide whether or not you wish to take part. If you have any questions or if you would like more information after reading the information sheet, please go to the NOPR website, www.cancerpetregistry.org, or contact the NOPR staff by telephone toll free at 800-227-5463, ext. 4859. Your doctor who ordered the PET scan and the staff at the PET facility where your scan will be performed will not be able to answer your questions concerning this research study. The NOPR staff will be able to assist you and answer any questions you may have.

You are being asked to participate in this research study because you are a Medicare patient and your doctor has ordered a PET or a PET/CT scan for you that is currently not covered (paid for) by Medicare. The PET scan has been ordered to evaluate your cancer. Having the PET scan is not the research in this study. PET scans are part of routine clinical care. For the research, the NOPR will study how the information obtained from the PET scan is used by your doctor.

WHY IS THIS STUDY BEING DONE?

The Centers for Medicare and Medicaid Services (CMS), a Federal agency that manages the Medicare program, currently pays for PET scans that are ordered to evaluate cancer only for certain specific cancer types and reasons. CMS has a new policy called “coverage with evidence development” (CED) to pay for PET scans ordered for most other types of cancer and reasons. This means Medicare will pay for these additional PET or PET/CT scans in the same way that it pays for approved cancers and reasons.

CMS wants to determine if they should pay for PET scans for evaluating more types of cancer. In order to collect the information needed to make this decision, CMS will provide payment for the PET scans of patients who are properly registered with the National Oncologic PET Registry (NOPR). In addition, if you and your doctor agree to participate in the research, your information will be entered into the registry and will then be analyzed to determine how PET scans effect the way doctors plan treatment for their patients.

In order for Medicare to pay for your PET scan, Medicare is requiring that your doctor provide certain information about the reason for your scan and how the scan results may influence your treatment. This information will be sent by the PET facility to Medicare as a requirement for payment for your PET scan. In addition, the NOPR is requesting your consent to use this information for research. Specifically, the NOPR plans to study how PET scans affect the treatment plans of the doctors who order PET scans. Eventually, the results of this research may help to obtain coverage by Medicare and other insurers for a wider range of cancers.

WHAT WILL HAPPEN IF I TAKE PART IN THIS STUDY?

CMS will collect information about you from your doctor as a requirement of paying for your PET scan. Your personal information such as your name, date of birth, social security number, and your doctor’s information will be entered into NOPR database through a secure web site. All this information will be stored at the American College of Radiology Imaging Network (ACRIN). ACRIN is a national leader in clinical research involving cancer patients. This database is secure and meets the requirements for the protection of patient confidentiality as required by the U.S. Privacy Rule (HIPAA).

As part of Medicare requirement for payment, your doctor will be asked to complete a brief questionnaire regarding his/her request for PET or PET/CT scan and what the doctor would do if PET or PET/CT were not available. After the

PET scan is performed, your doctor will be asked to complete a second questionnaire about how the results of the scan affected your care. These forms must be completed and submitted to the NOPR within a specified period in order for the scan to be eligible for payment. NOPR will send your information to CMS so that your PET scan will be paid for by Medicare, like any other covered benefit.

If you agree to participate in the research part of the NOPR, you are giving permission to use your health information for research. However, your information will only be used by the NOPR for research if you and your doctor give permission to use it for research purposes.

WHAT OTHER OPTIONS ARE THERE?

You may choose not participate in this study. You can choose to have a PET or PET/CT scan without participating in the registry study. If you choose not to participate in the NOPR research study, the PET scan payment will not be affected.

ARE THERE POTENTIAL BENEFITS TO TAKING PART IN THE STUDY?

There is no immediate direct benefit to you for your participation in this research study. Whether or not you (or your doctor) agree to have your information used for the NOPR research study, Medicare will pay for the PET scan so long as your doctor provides the information Medicare requires for payment. If the research study leads to routine coverage by Medicare of your type of cancer (or the reason for your PET scan), you may benefit in the future if you need another PET scan. Other patients with cancer in the future may also be helped if the research leads to routine coverage of PET by Medicare or other health insurance providers.

WHAT ARE THE RISKS OF THE STUDY?

There are no physical risks associated with this study. There is, however, the potential risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed.

WHAT ARE THE COSTS?

There are no additional costs to you associated with participating in the NOPR research study. Medicare will pay for the PET or PET/CT scan if your information is submitted within a specified timeframe by your doctor. You or your Medicare supplemental (Medigap) insurance will be responsible for any co-payment costs or deductible payments, just as occurs with any other medical service covered by Medicare.

WHAT ABOUT CONFIDENTIALITY?

Your information will be kept permanently in a secure electronic database at the ACRIN and may be used for future research. CMS, the NOPR working group and project staff, and the Center for Statistical Sciences at Brown University will have access to your information. They are responsible for making a recommendation to CMS on what types of PET scans should be paid for by Medicare. Your records may be reviewed in order to meet federal regulations. Your name will never be made public.

WHAT ARE MY RIGHTS?

Your participation in the NOPR research study is voluntary. You may choose not to be in the study. If you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for research purposes.

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits. You will continue to receive your usual medical care whether or not you decide to participate in this study. If you decide to withdraw from the study, you will need to let your doctor know in writing.

After you had a chance to read this information sheet and made a decision whether you want to participate, please let the staff at the PET facility know what you have decided. You are not required to sign a consent form to participate in this research, but you must let the PET facility staff know whether or not you wish to participate either before you leave the PET facility or at a later date but no more than two (2) working days after you have your PET scan. If you have any

questions regarding the NOPR research study or the information sheet, please go to the NOPR website, <http://www.cancerpetregistry.org/> and click on “Info for Patients”, or contact NOPR 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. You will be given a copy of this information sheet to take home with you.

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

A Spanish language translation of the NOPR Patient Information Sheet is available on the NOPR Web site at: http://www.cancerpetregistry.org/pdf/patient_info_spanish.pdf

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.

Facility Pre-Registration Form

National Oncologic PET Registry

Thank you for your interest in participating in the National Oncologic PET Registry project.

- Each institution participating in the Registry must complete the Web-based Facility Pre-Registration Form and receive a unique 4-digit Facility Number and Facility Administrator Password. The Facility Administrator will then log in and complete the Facility Registration Form. After registration, but before entering its first case on the Registry, **the facility must pay a one-time application fee of \$50 and send an executed HIPAA Business Associates Agreement (BAA) to NOPR Headquarters.** Payments can be made by credit card or check. Checks should be made payable to the ACR-NOPR and mailed to the American College of Radiology, 1818 Market Street, Suite 1600, Philadelphia, PA 19103. **The facility ID# must be written on the check.** The BAA can be mailed or FAXed to NOPR Headquarters (1818 Market Street – Suite 1600, Philadelphia, PA 19103, FAX 215-928-0153). **The BAA is available from the NOPR Web site and must be submitted before patient entry can begin.** Please allow 48 hours for processing of these materials before scheduling the first patient entry for your facility.
- The entity applying as a PET Facility should be the entity that bills Medicare for either the technical charges or the global charges for PET studies. In the case of a mobile PET provider that bills Medicare directly, a separate application form must be completed and a separate Facility ID number will be assigned for each location of service.
- **NOTE: You will receive a confirmation E-mail with instructions on how to log into the NOPR database to complete the registration process.**

1. Name of Imaging Center _____

2. Facility's E-mail Address (will be used for all communications) _____

3. Person Completing this Form: First Name _____ Last Name: _____

This person will become the PET Facility Administrator, and the official contact person for the NOPR.

NOTE: After this form is completed a 4 digit Facility ID number and a password will be assigned and sent to the Facility via E-mail. The Facility must return to the Login page, follow the instructions in the confirmation e-mail, and complete the Facility Registration Form.

PET Facility Registration Form

National Oncologic PET Registry

- Please complete this form to finalize the NOPR registration process.
- Once this completed form is submitted, a confirmation e-mail will be sent with an invoice for the escrow account start-up funds and the \$50 application fee.
- When the start-up funds are received at NOPR Headquarters an escrow account will be established for the PET Facility. \$50 will be debited from this account each time the facility registers a case on the NOPR. E-mail reminders will be sent to the PET Facility Administrator when the account balance dips below a minimum level as defined by the Facility on this Registration Form.
- The PET Facility can pay the \$50 registration fee and initial escrow deposit either by:
 - Mailing a check made payable to ACR-NOPR together with a copy of the e-mailed invoice to the American College of Radiology, 1818 Market Street, Suite 1600, Philadelphia, PA 19103. **The facility ID# must be written on the check;** or
 - Paying by credit card using the information in the e-mailed invoice and confirmation to log into the facility's account on the NOPR Web site.
- Once the ACR receives the facility registration fee and the executed Business Associates Agreement (BAA), the PET Facility will be sent an e-mail approval notice and the facility will be eligible to participate in the National Oncologic PET Registry via the secure Web site.

Only cases that meet the criteria listed in the Coverage Decision will be eligible for registration and CMS reimbursement.

Facility ID #: _____

1. PET FACILITY INFORMATION

Name of Imaging Center (will be supplied by the system from pre-registration information) _____

Mailing Address (street 1) _____ (street 2) _____

(city) _____ (state) _____ (zip) _____

Telephone _____ x _____ FAX: _____

Business entity responsible for payment _____

Medicare Provider Number or National Provider Identifier Number: _____

PHYSICAL ADDRESS OF THE PET FACILITY

Address (street 1) _____ (street 2) _____

(city) _____ (state) _____ (zip) _____

Telephone _____ x _____

2. PET FACILITY ADMINISTRATOR

Official facility contact person for the National Oncologic PET Registry (will be supplied by the system from pre-registration information) _____

E-mail address (will be supplied by the system from pre-registration information) _____

3. PARTICIPATING PHYSICIANS - who will interpret PET scans. (Web form will accept as many as needed)

First Name _____ Last Name _____ UPIN _____

First Name _____ Last Name _____ UPIN _____

4. STAFF - who are allowed to register patients and enter data into the database. A username and password will be emailed to the staff person.

Case Registration Form

National Oncologic PET Registry

- This form will be completed by the PET facility via Web-based data entry.
- The PET scan and the Pre-PET form must be completed within 2 weeks of registering the patient. The pre-PET form must be completed (and data entered on the Registry web site) no earlier than 2 weeks before the PET scan and no later than midnight on the day of the PET scan
- Upon form completion a case number will be assigned.
- The referring clinician may elect to complete and submit the Pre-PET Form at the time of referral. If the clinician did not submit a Pre-PET Form with the referral, a case specific Pre-PET Form will be sent electronically with the e-mail confirmation of case registration to the PET facility for delivery to the referring physician.

PET Facility Log-in Info (facility ID# & password): _____

1. PATIENT INFORMATION

Date: ____/____/____

First Name: _____ Last Name: _____

Date of Birth ____/____/____

SSN#: _____

Gender: Male Female

Ethnicity: Hispanic Not Hispanic Unknown
[Note: "Hispanic" is defined as a person of Cuban, Mexican, Puerto Rican, South or Central American, or other Spanish culture or origin, regardless of race.]

Race: *(must check one)*

- Asian
- Black or African American
- White or Caucasian
- Other
- Unknown

Patient's 5-Digit Zip Code (if outside the U.S. enter 00000): ____ _

2. REFERRING PHYSICIAN INFORMATION

UPIN#: _____ OR NPI#: _____

Last Name: _____ First Name: _____

Office Telephone: (____) _____ Office Fax: (____) _____

3. HAS THE PRE-PET FORM BEEN COMPLETED?

(if Yes is checked the PET facility will not be E-mailed a Pre-PET form to complete)

Yes No

4. PATIENT IS SCHEDULED TO HAVE A PET SCAN ON: ____/____/____

(must be within 14 days of registration)

5. NAME OF PERSON SUBMITTING THIS FORM

First Name: _____ Last Name: _____ Date: _____

Pre-PET Form
National Oncologic PET Registry

- You have requested a PET scan for an indication for which the Centers for Medicare and Medicaid Services (CMS) requires pre- and post-PET information from the referring physician as a condition for reimbursement. In order for the imaging center to be reimbursed this form must be completed and returned to the PET facility before the PET scan is performed.
 - **You will be required to complete a follow-up form in a timely fashion after the PET scan is done.** Thank you for your assistance completing the brief pre- and post-PET forms.
-

PET Facility ID #: _____ Registry Case #: _____

PATIENT INFORMATION

Date: ____/____/____

First Name: _____ Last Name: _____

Date of Birth ____/____/____

SSN#: _____

REFERRING PHYSICIAN

UPIN#: _____ or NPI#: _____

First Name: _____ Last Name: _____ UPIN#: _____

Office Telephone: (____) _____ Office Fax: (____) _____

Comment to Clinician: The required follow-up questionnaire will be sent to you by the PET facility. **By requesting that this patient be entered on the NOPR you agree to also complete the post-PET follow-up form and return it to the PET scan facility within 30 days of the PET scan.**

The following definitions/instructions are provided to assist you in the completion of Question 1 (“SPECIFIC REASON FOR PET STUDY”) on the next page of this form. This information is derived from the [Medicare National Coverage Determination for PET](#).

< <http://www.cms.hhs.gov/mcd/viewdecisionmemo.asp?id=218> >

Covered Indications for PET Scans and Limitations/Requirements for Usage

Initial Treatment Strategy

PET performed as part of an evaluation for determination of an *initial treatment strategy* (formerly **diagnosis and initial staging**) is covered by CMS as an approved indication for PET with specific exceptions (see below):

PET is explicitly not covered by CMS for initial treatment strategy evaluation for four specific cancer types/indications: 1) diagnosis and axillary nodal staging of breast cancer; 2) assessment of regional lymph nodes in melanoma; and 3) diagnosis of prostate cancer and initial staging of newly diagnosed prostate cancer; and 4) diagnosis of cervical cancer.

However, PET for initial treatment strategy evaluation is covered only with participation in the NOPR for certain patients with suspected or proven leukemia.

Note: PET is covered only in clinical situations in which (1) the PET results may assist in avoiding an invasive diagnostic procedure, or in which (2) the PET results may assist in determining the optimal anatomical location to perform an invasive diagnostic procedure. In general, for most solid tumors, a tissue diagnosis is made prior to doing a PET scan and therefore the scan is performed for staging rather than diagnosis.

PET is not covered as a screening test (i.e., testing patients without specific signs and symptoms of disease).

Subsequent Treatment Strategy

PET is also a CMS-covered service when used in subsequent treatment strategy evaluation (formerly restaging, detection of suspected recurrence, and treatment monitoring) patients with the following cancers: breast, cervix, colorectal, esophageal, head and neck, lymphoma, melanoma, myeloma, non-small cell lung, ovary, and thyroid. For all other cancers, PET coverage for subsequent treatment strategy evaluation requires participation in this registry.

PET is covered for restaging and detection of suspected recurrences:

- (1) *after* completion of treatment for the purpose of detecting residual disease; or
- (2) for detecting suspected recurrence or metastasis; or
- (3) to determine the extent of a known recurrence;
- (4) if it could potentially replace one or more conventional imaging studies when it is expected that conventional study information is insufficient for the clinical management of the patient.
- (5) *Restaging* applies to testing *after* a course of treatment is completed, and is covered subject to the conditions above.

Comment: As noted above, PET is not covered as a screening test (i.e., testing patients without specific signs and symptoms of disease) and thus is not covered for surveillance of patients treated for cancer in whom there is no clinical reason to suspect recurrent disease.

Treatment monitoring refers to use of PET to monitor tumor response to treatment during the planned course of therapy (i.e., when a change in therapy is anticipated).

Comment: As an example, PET performed under NOPR may be covered for monitoring after 2 or 3 of a planned 6 cycles of chemotherapy in a patient considered not to be responding as expected.

1. SPECIFIC REASON FOR PET STUDY

Check the single best match for the reason for the PET (you must check only one of the following)

- Restaging** after completion of therapy
- Suspected Recurrence** of a previously treated cancer
- Monitoring Treatment Response** during chemotherapy (including biologic modifiers)
- Monitoring Treatment Response** during radiation therapy
- Monitoring Treatment Response** during combined modality therapy (e.g., chemotherapy ± radiation ± surgery)
- Diagnosis (Leukemia Only):** To determine if a suspicious lesion is cancer (answer 2a and 2b)
- Diagnosis/Paraneoplastic (Leukemia Only):** To detect occult leukemia in a patient with a presumed paraneoplastic syndrome (answer 2a and 2b)
- Initial Staging (Leukemia Only)** of pathologically confirmed, newly diagnosed leukemia (answer 2a and 2b)

2. CANCER TYPE

- Please mark the corresponding box of the cancer type in section 2a and answer question 2b. If your patient's cancer is not listed, check the Other box and enter as text the cancer type. For a patient with metastatic cancer of unknown primary origin, please also mark the corresponding box of the site of metastatic disease in section 2c.
-

a. Cancer Type (ICD-9 Code) - check the one cancer that most closely relates to the specific reason for the PET study indicated in response to Question 1. (Check only one)

Note: The three-digit ICD-9 codes included on this form are for purposes of identifying the cancer type in the NOPR database, but the one selected is not necessarily the one that should be used for claim submission.

- | | |
|--|---|
| <input type="checkbox"/> Stomach (151) | <input type="checkbox"/> Kaposi's sarcoma (176) |
| <input type="checkbox"/> Small Intestine (152) | <input type="checkbox"/> Uterus, unspecified (179) |
| <input type="checkbox"/> Anus (154) | <input type="checkbox"/> Uterus, body (182) |
| <input type="checkbox"/> Liver and intrahepatic bile ducts (155) | <input type="checkbox"/> Prostate (185) |
| <input type="checkbox"/> Gallbladder & extrahepatic bile ducts (156) | <input type="checkbox"/> Testis (186) |
| <input type="checkbox"/> Pancreas (157) | <input type="checkbox"/> Penis and other male genitalia (187) |
| <input type="checkbox"/> Retroperitoneum and peritoneum (158) | <input type="checkbox"/> Bladder (188) |
| <input type="checkbox"/> Lung, small cell (162) | <input type="checkbox"/> Kidney and other urinary tract (189) |
| <input type="checkbox"/> Pleura (163) | <input type="checkbox"/> Eye (190) |
| <input type="checkbox"/> Thymus, heart, mediastinum (164) | <input type="checkbox"/> Primary Brain (191) |
| <input type="checkbox"/> Bone/cartilage (170) | <input type="checkbox"/> Leukemia (204-208) |
| <input type="checkbox"/> Connective/other soft tissue (171) | <input type="checkbox"/> Neuroendocrine tumor (209) |
| <input type="checkbox"/> Gastrointestinal stromal tumor (171) | <input type="checkbox"/> Metastatic cancer of unknown primary origin (answer question 2c below) |
| <input type="checkbox"/> Non-melanoma skin (173) | |

Other, or not listed. Please describe cancer type: _____

and give the first 3 digits of the ICD-9 code. .XX

[Acceptable responses are 159, 165, 181, 183, 184, 192 - 195, and 235-238. Note: Ovarian cancer is a covered indication; use 183 only for other adnexal cancers.]

b. Has this cancer diagnosis been pathologically proven? Yes No

c. Unknown primary: dominant site of pathologically proven or strongly suspected metastatic disease

(196-199)

- | | |
|--|---|
| <input type="checkbox"/> Lymph node(s) | <input type="checkbox"/> Brain |
| <input type="checkbox"/> Lung | <input type="checkbox"/> Bone/bone marrow |
| <input type="checkbox"/> Liver | |
| <input type="checkbox"/> Other, or not listed. Please describe metastatic site: _____ | |

and give the first 3 digits of the ICD-9 code. .XX [Acceptable responses are 196-199.]

3. YOUR WORKING SUMMARY STAGE FOR THE PATIENT BEFORE THE PET SCAN IS:

(you must check only one)

- No evidence of disease / In remission
- Localized only
- Regional by direct extension or lymph node involvement or both
- Metastatic (distant) with a single suspected site
- Metastatic (distant) with multiple suspected sites
- Unknown or uncertain

4. PATIENT PERFORMANCE STATUS

Check the box best describing your patient's global functional status (ECOG Performance Score) (you must check only one)

- (0) Asymptomatic: *fully active, able to carry on all activities without restriction.*
- (1) Symptomatic, fully ambulatory: *restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature.*
- (2) Symptomatic in bed <50% of the day: *ambulatory and capable of all self-care but unable to carry out any work activities. Up and about more than 50% of waking hours.*
- (3) Symptomatic in bed >50% of the day, but not bedridden: *capable of only limited self-care, confined to bed or chair 50% or more of waking hours.*
- (4) Bedridden: *Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair.*

5. ADDITIONAL RESPONSES REQUIRED ONLY IF THE SPECIFIC REASON FOR THE PET STUDY IS MONITORING TREATMENT RESPONSE

- a. Is the currently ongoing treatment intended to be:
 - Curative
 - Palliative
- b. If the patient is receiving or has recently completed (within the last month) radiation therapy, *check one* of the following.
 - Not applicable; no radiation therapy
 - Now in week 1 – 2 of radiation therapy
 - Now in week 3 – 4 of radiation therapy
 - Now in week 5 – 7 of radiation therapy
 - Completed radiation therapy within the last month
- c. If the patient is receiving chemotherapy (including biologic modifiers), how many months of the treatment has been delivered? (*check one*)
 - < 1 month
 - 1- 3 months
 - 3- 6 months
 - > 6 months.

- d. If your patient completes the currently ongoing therapy, how many total months of treatment (radiation therapy and/or chemotherapy) do you expect to provide? (*check one*)
- 1- 3 months
 - 3- 6 months
 - 6-12 months
 - Expect to continue treatment for > 12 months
- e. What is your current impression (before PET) of your patient's response to currently ongoing therapy? (*check one*)
- Clearly responding, but uncertain about degree of response
 - Possible partial response, but uncertain about degree of response
 - Suspect no response
 - Suspect progressive disease
- f. If you were to continue your patient's management without doing any other testing first (e.g., PET, CT, MRI, biopsy), what would be your treatment plan today? (*check one*)
- Continue and complete currently ongoing therapy
 - Modify dose or schedule of currently ongoing therapy
 - Switch to another therapy or add another mode of therapy
 - Stop therapy and switch to supportive care

6. MANAGEMENT PLAN

If PET were not available, your current **management strategy** would be? (*you must check only one*)

- Observation** (with close follow-up)
- Additional Imaging** (CT, MRI) or other non-invasive diagnostic tests
- Tissue Biopsy** (surgical, percutaneous, or endoscopic).

Note: If concurrent biopsy and total surgical resection are planned, then mark "surgical" treatment below.

- Treatment (see additional required responses below)**

Treatment Goal: (*check one*)

- Curative
- Palliative

Type(s): (*check all that apply*)

- Surgical
- Chemotherapy (including biologic modifiers)
- Radiation
- Other
- Supportive care

Will treatment be directly provided by you? (*check one*)

- Yes
- No

6. NAME OF PERSON WHO COMPLETED THE PAPER FORM

First Name: _____ Last Name: _____ Date _____

PHYSICIAN ATTESTATION OF DATA ACCURACY

By signing below I verify that, to the best of my knowledge, the information on this form is accurate.

Physician Signature: _____ Date _____

Printed Name of Physician: _____

Thank you for your assistance.

PRA Disclosure Statement

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PET Completion Form

National Oncologic PET Registry

- This form is completed by the PET Facility via Web-based data entry within 14 days of case registration.
 - The PET scan must be completed within 14 days of case registration. If the case was registered more than 14 days prior to the PET scan the patient must be re-registered. The original case registration will be cancelled and the \$50 will be refunded.
-

PET FACILITY ID #: _____

REGISTRY CASE #: _____

1. DATE SCAN COMPLETED: ____/____/____

(must be within 14 days of registration)

2. Scan Type *(you must check one)*

PET PET-CT

3. Region(s) Scanned *(you must check only one)*

Body Only

(Study will be billed using one of the following CPT Codes: 78811-78816. Select this entry even if the brain was intentionally or incidentally included in a body PET imaging study.)

DEDICATED Brain Only

(Study was performed with a brain acquisition protocol and will be billed using CPT Code 78608.)

Both DEDICATED Body AND Brain

(Brain study was performed with a brain acquisition protocol and will be billed using CPT Code 78608 AND body study was performed and will be billed using one of the following CPT Codes: 78811-78816.)

4. SCANNER INFORMATION

Facility's Scanner Identifier *(facility's name for scanner)* - Pull Down Menu of Facility's Scanner Info

5. NAME OF PERSON SUBMITTING THIS FORM

First Name: _____ Last Name: _____ Date (auto filled)

PET Report Submission Form

National Oncologic PET Registry

- This form is used to transmit the PET Report. It is completed by the PET facility via Web-based data entry within 30 days of completing the PET scan.

PET FACILITY ID #: _____

REGISTRY CASE #: _____

1. DATE SCAN COMPLETED: ____/____/____

2. DATE PET REPORT COMPLETED: ____/____/____

3. INTERPRETING PHYSICIAN INFORMATION - Pull Down Menu of Facility's Interpreting Physicians

4. PET REPORT (you must either attach a report file OR enter the report as free text)

Free Text Entry is Preferred

Note that, if both a body PET study and a dedicated brain PET study were performed and reported separately (rather than in a combined single report), both reports should be submitted. If you are submitting a PDF or JPEG file, both reports must be combined into a single file.

Attached: PDF JPEG

Or

Free Text Entry – if checked enter text here:

(Cut & paste from Microsoft Word document or other text document. **You must enter the complete text of the PET report.**)

5. AFTER BEING GIVEN THE NOPR PATIENT INFORMATION STATEMENT, DID THE PATIENT CONSENT TO HAVE HIS OR HER DATA USED FOR NOPR RESEARCH?

YES NO

6. NAME OF PERSON SUBMITTING THIS FORM

First Name: _____ Last Name: _____ Date (auto filled) _____

Post-PET Restaging Cancer Form
National Oncologic PET Registry

Facility ID #: _____

Registry Case Number: _____

Patient Name: _____

Your patient had a PET scan on: mm/dd/yyyy.

The PET scan was done for **restaging of (cancer type)**. (auto fill cancer type from Pre-PET Form).

-
- After reviewing the PET report, please complete the following questions and return the form to the PET Facility.
 - **This form must be completed and entered into the NOPR database within 30 days of the PET scan.**
-

1. Compared to your Pre-PET assessment, your impression of the overall extent of disease is? (*choose one*)
 - More extensive
 - No change
 - Less extensive
2. Did the PET scan show evidence of cancer activity that was not previously documented?
 - Yes No
 - a. If yes, is some type of tissue biopsy planned of the area? Yes No
3. Your Post-PET working clinical staging is: (select *only one*)
 - No evidence of disease / In remission
 - Low probability of local recurrence (including regional lymph nodes) or metastases
 - Local recurrence (including regional lymph nodes)
 - Metastatic disease with single site
 - Metastatic disease with multiple sites
4. Did the PET scan enable you to avoid more tests or procedures? Yes No
5. In light of the PET findings, which of the following management strategies are you now planning or have you already undertaken? (*you must check only one*)
 - Observation** (with close follow-up)
 - Additional Imaging** (CT, MRI) or other non-invasive diagnostic tests
 - Tissue Biopsy** (surgical, percutaneous, or endoscopic).
Note: If concurrent biopsy and total surgical resection are planned, then mark “surgical” treatment below.
 - Treatment (see additional required responses below)**
 - Treatment Goal:** (*check one*)
 - Curative
 - Palliative
 - Type(s):** (*check all that apply*)
 - Surgical
 - Chemotherapy (including biologic modifiers)
 - Radiation
 - Other
 - Supportive care

6. I have read the Referring Physician Information Statement and:

- I do give my consent for the inclusion of data collected for this patient in NOPR research.
- I do NOT give my consent for the inclusion of data collected for this patient in NOPR research.

7. NAME OF PERSON WHO COMPLETED THE PAPER FORM

First Name: _____ Last Name: _____ Date _____

PHYSICIAN ATTESTATION OF DATA ACCURACY

By signing below I verify that, to the best of my knowledge, the information on this form is accurate.

Physician Signature: _____ Date _____

Printed Name of Physician: _____

PRA Disclosure Statement

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Post-PET Suspected Cancer Recurrence Form
National Oncologic PET Registry

Facility ID #: _____

Registry Case Number: _____

Patient Name: _____

Your patient had a PET scan on: mm/dd/yyyy.

The PET scan was done for **a suspected recurrence of (cancer type)**. (auto fill cancer type from Pre-PET Form).

- After reviewing the PET report, please complete the following questions and return the form to the PET Facility.
 - **This form must be completed and entered into the NOPR database within 30 days of the PET scan.**
-

1. Compared to your Pre-PET assessment, your impression of the overall extent of disease is: (*choose one*)
- More extensive
 - No change
 - Less extensive

2. Did the PET scan show evidence of cancer activity that was not previously documented?

Yes No

If yes, is some type of tissue biopsy planned of the area? Yes No

3. Your Post-PET working clinical summary staging is: (*select only one*)

- No evidence of disease / In remission
- Low probability of local recurrence (including regional lymph nodes) or metastases
- Local recurrence (including regional lymph nodes)
- Metastatic disease with single site
- Metastatic disease with multiple sites

4. Did the PET scan enable you to avoid more tests or procedures? Yes No

5. In light of the PET findings, which of the following management strategies are you now planning or have you already undertaken? (*you must check only one*)

- Observation** (with close follow-up)
- Additional Imaging** (CT, MRI) or other non-invasive diagnostic tests
- Tissue Biopsy** (surgical, percutaneous, or endoscopic).

Note: If concurrent biopsy and total surgical resection are planned, then mark “surgical” treatment below.

- Treatment (see additional required responses below)**

Treatment Goal: (*check one*)

- Curative
- Palliative

Type(s): (*check all that apply*)

- Surgical
- Chemotherapy (including biologic modifiers)
- Radiation
- Other
- Supportive care

Will treatment be directly provided by you? (*check one*)

- Yes
- No

6. I have read the Referring Physician Information Statement and:

- I do give my consent for the inclusion of data collected for this patient in NOPR research.
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7. NAME OF PERSON WHO COMPLETED THE PAPER FORM

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Post-PET Treatment Monitoring Form
National Oncologic PET Registry

Facility ID #: _____
Registry Case Number: _____
Patient Name: _____

Your patient had a PET scan on: mm/dd/yyyy.

The PET scan was done for **treatment response monitoring of (cancer type) to chemo/radiation/or other therapy** (auto fill from Pre-PET data form the cancer type and treatment type).

-
- After reviewing the PET report, please complete the following questions and return the form to the PET Facility.
 - **This form must be completed and entered into the NOPR database within 30 days of the PET scan.**
-

1. In light of the PET findings, which of the following management strategies are you now planning or have you already undertaken? (*you must check only one*)

- Observation** (with close follow-up)
- Additional Imaging** (CT, MRI) or other non-invasive diagnostic tests
- Tissue Biopsy** (surgical, percutaneous, or endoscopic).

Note: If concurrent biopsy and total surgical resection are planned, then mark “surgical” treatment below.

- Treatment (see additional required responses below)**

Treatment Goal: (*check one*)

- Curative
- Palliative

Type(s): (*check all that apply*)

- Surgical
- Chemotherapy (including biologic modifiers)
- Radiation
- Other
- Supportive care

Will treatment be directly provided by you? (*check one*)

- Yes
- No

2. What is your current impression (in light of the PET findings) of your patient’s response to currently ongoing therapy? (*check one*)

- Clearly responding
- Partial response
- No response or stable disease
- Progressive disease

3. Please indicate if and how you will modify your therapeutic plan in light of the PET findings. (*You must check only one*)

- Continue and complete currently ongoing therapy
- Modify dose or schedule of currently ongoing therapy
- Switch to another therapy or add another mode of therapy
- Stop therapy and switch to supportive care

4. If PET were not available, would you have done some type of alternative assessment at this time?
 Yes No
5. Did the PET scan enable you to avoid more tests or procedures?
 Yes No
6. In light of the PET results, how has the prognosis for your patient changed? (*check one*)
 Better No change Worse
7. I have read the Referring Physician Information Statement and:
 I do give my consent for the inclusion of data collected for this patient in NOPR research.
 I do NOT give my consent for the inclusion of data collected for this patient in NOPR research.

8. NAME OF PERSON WHO COMPLETED THE PAPER FORM

First Name: _____ Last Name: _____ Date _____

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Post-PET Suspected Leukemia Form
National Oncologic PET Registry

Facility ID #: _____
Registry Case Number: _____
Patient Name: _____

Your patient had a PET scan on: mm/dd/yyyy.

You previously indicated that the PET scan was done for assessing **whether a suspicious lesion is leukemia.**

-
- After reviewing the PET report, please complete the following questions and return the form to the PET Facility.
 - This form must be entered into the database within 30 days of the PET scan.
-

2. Has a tissue biopsy been performed of a suspicious site? Yes No
3. Did the PET scan enable you to avoid any tests or procedures? Yes No
4. In light of the PET findings, which of the following management strategies are you now planning or have you already undertaken? (*you must check only one*)
- Observation** (with close follow-up)
 - Additional Imaging** (CT, MRI) or other non-invasive diagnostic tests
 - Tissue Biopsy** (surgical, percutaneous, or endoscopic).
Note: If concurrent biopsy and total surgical resection are planned, then mark “surgical” treatment listed below.
 - Treatment (see additional required responses below)**
Treatment Goal: (*check one*)
 - Curative
 - Palliative**Type(s):** (*all that apply*)
 - Surgical
 - Chemotherapy (including biologic modifiers)
 - Radiation
 - Other
 - Supportive care**Will treatment be directly provided by you?** (*check one*)
 - Yes
 - No

4. I have read the Referring Physician Information Statement and:
- I do give my consent for the inclusion of data collected for this patient in NOPR research.
 - I do NOT give my consent for the inclusion of data collected for this patient in NOPR research.

5. NAME OF PERSON WHO COMPLETED THE PAPER FORM:

First Name: _____ Last Name: _____ Date: _____

PHYSICIAN ATTESTATION OF DATA ACCURACY

By signing below I verify that, to the best of my knowledge, the information on this form is accurate.

Physician Signature: _____ Date _____

Printed Name of Physician: _____

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Post-PET Paraneoplastic Syndrome Form
National Oncologic PET Registry

Facility ID #: _____
Registry Case Number: _____
Patient Name: _____

Your patient had a PET scan on: mm/dd/yyyy.

You previously indicated that the PET scan was done to detect occult leukemia in a patient with a **suspected paraneoplastic syndrome**. (auto fill reason from Pre-PET Form)

-
- After reviewing the PET report, please complete the following questions and return the form to the PET Facility.
 - This form must be entered into the database within 30 days of the PET scan.
-

1. Was leukemia (or another primary cancer site) identified by PET? Yes
 No

2. Was a tissue biopsy or surgical excision performed of a suspected tumor? Yes No

3. Did the PET scan enable you to avoid any tests or procedures? Yes No

4. In light of the PET findings, which of the following management strategies are you now planning or have you already undertaken? (*you must check only one*)

Observation (with close follow-up)

Additional Imaging (CT, MRI) or other non-invasive diagnostic tests

Tissue Biopsy (surgical, percutaneous, or endoscopic).

Note: If concurrent biopsy and total surgical resection are planned, then mark “surgical” treatment listed below.

Treatment (see additional required responses below)

Treatment Goal: (*check one*)

Curative

Palliative

Type(s): (*check all that apply*)

Surgical

Chemotherapy (including biologic modifiers)

Radiation

Other

Supportive care

Will treatment be directly provided by you? (*check one*)

Yes

No

5. I have read the Referring Physician Information Statement and:

I Do give my consent for the inclusion of data collected for this patient in NOPR research.

I DO NOT give my consent for the inclusion of data collected for this patient in NOPR research.

6. NAME OF PERSON WHO COMPLETED THE PAPER FORM:

First Name: _____ Last Name: _____ Date: _____

PHYSICIAN ATTESTATION OF DATA ACCURACY

By signing below I verify that, to the best of my knowledge, the information on this form is accurate.

Physician Signature: _____ Date _____

Printed Name of Physician: _____

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Post-PET Initial Staging Form
National Oncologic PET Registry

Facility ID #: _____

Registry Case Number: _____

Patient Name: _____

Your patient had a PET scan on: mm/dd/yyyy.

The PET scan was done for **initial staging of leukemia**.

- After reviewing the PET report, please complete the following questions and return the form to the PET Facility.
 - This form must be entered into the database within 30 days of the PET scan.
-

1. Compared to your Pre-PET assessment, your impression of the extent of the patient's leukemia is? (*check one*)
 More extensive
 No change
 Less extensive
2. Did the PET scan, show evidence of leukemic involvement that was not previously documented?
 Yes No
 - a. If yes, is some type of tissue biopsy planned of the area? Yes No
3. Are any more tests or imaging or biopsies planned before starting treatment? Yes No
4. Did the PET scan enable you to avoid any tests or procedures? Yes No
5. Your Post-PET working clinical summary staging is? (*you must check only one*)
 No evidence of disease / In remission
 Localized disease only
 Systemic disease
 Unknown or uncertain
6. In light of the PET findings, which of the following management strategies are you now planning or have you already undertaken? (*you must choose only one*)
 Observation (with close follow-up)
 Additional Imaging (CT, MRI) or other non-invasive diagnostic tests
 Tissue Biopsy (surgical, percutaneous, or endoscopic).
Note: If concurrent biopsy and total surgical resection are planned, then mark "surgical" treatment listed below.
 Treatment (see additional required responses below)
Treatment Goal: (*check one*)
 Curative
 Palliative
Type(s): (*check all that apply*)
 Surgical
 Chemotherapy (including biologic modifiers)
 Radiation
 Other
 Supportive care
Will treatment be directly provided by you? (*check one*)
 Yes
 No

7. I have read the Referring Physician Information Statement and:

- I do give my consent for the inclusion of data collected for this patient in NOPR research.
- I do NOT give my consent for the inclusion of data collected for this patient in NOPR research.

8. NAME OF PERSON WHO COMPLETED THE PAPER FORM:

First Name: _____ Last Name: _____ Date: _____

PHYSICIAN ATTESTATION OF DATA ACCURACY

By signing below I verify that, to the best of my knowledge, the information on this form is accurate.

Physician Signature: _____ Date _____

Printed Name of Physician: _____

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