# Bulletin

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**SUBJECT: Accessing Positron Emission Tomography (PET) Studies/Program Funded by the Ministry of Health and Long-Term Care, Ontario, Canada**

This Bulletin is an update to Bulletin #4464 distributed February 1, 2008.

Positron emission tomography is a nuclear medicine diagnostic imaging procedure using positron emitting radiopharmaceuticals, often F18 fluorodeoxyglucose (FDG). Evidence supports a role for PET in the assessment of certain cancers and myocardial viability. The FDG produced by most Ontario PET centres is currently not approved by Health Canada for routine clinical use, but may be used for research purposes.

At present, PET scanning is not an insured health service in Ontario. The Ministry of Health and Long-Term Care (MOHLTC) has adopted an evidence-based approach to the introduction of PET imaging in the province. To ascertain the effectiveness of FDG-PET in the clinical management of patients, the MOHLTC is funding FDG-PET evaluative studies for specific indications.

This Bulletin provides a brief description of the ministry-funded PET studies/programs. Please read each section to determine which study or program may best meet the needs of your patient and **refer to the appropriate attachment for details and referral process.** Should you have any questions relating to the referral of patients to any of the ministry-funded PET evaluation studies or the Ontario PET Access Program, please call, **1-877-4PET-411** *(1-877-473-8411)*.

**PET Clinical Trials (Attachment 1)**

- Five PET clinical trials were funded by the MOHLTC. **Three** of these trials are still recruiting patients while two have completed patient accrual and are now closed.

*Eligibility for the three active trials:*

- Patients with locally advanced head and neck cancer
- Stage III non-small cell lung cancer
- Liver metastases from colorectal cancer being considered for surgical resection

| Processing Sites | | | |
|---|---|---|---|
| **Hamilton**<br>119 King Street West, 10th Floor<br>P.O. Box 2280, Stn A<br>L8P 4Y7 | **Kingston**<br>1055 Princess Street, Suite 401<br>P.O. Box 9000<br>K7L 5A9 | **London**<br>217 York Street, 5th Floor<br>Station A<br>N6A 5P9 | **Mississauga**<br>201 City Centre Drive<br>Suite 300<br>L5B 2T4 |
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**Cancer PET Registry Study (Attachment 2)**

*Indications:*

- **New Indication Added** - Potentially resectable non-small cell lung cancer
- **New Indication Added** – Evaluation of residual masses following chemotherapy in patients with potentially curative Hodgkin's lymphoma or non-Hodgkin's lymphoma; assessment of response to chemotherapy in stage IA-IIA, non-bulky classical Hodgkin's lymphoma
- A solitary pulmonary nodule which may be cancer and suitable for surgical resection
- Suspected recurrent thyroid, colorectal, or germ cell cancer with elevated biomarker but negative MRI or CT findings

**Cardiac PET Registry study (CADRE) (Attachment 3)**

*Indication:*

- Pre-revascularization myocardial viability assessment for patients with severe left ventricular dysfunction

**Ontario PET Access Program (Attachment 4)**

- A review process established by the MOHLTC to assess applications for PET scans for patients **not** eligible for the clinical trials or registry studies.

Physicians may make a referral to one of the active clinical trials, or a registry study that matches the patient's condition. Eligible patients can receive a PET scan at participating health sciences centres in Toronto, Hamilton, London, or Ottawa. There will be no charge to the patient.

***Please Note:*** *Before requesting a PET scan under the Ontario PET Access Program, it is advisable for physicians to first review the information on the clinical trials (Attachment 1) and registries (Attachment 2 & 3). If eligible, the patient should be offered enrolment in one of the clinical studies or registry studies. The Ontario PET Access Program should only be considered for patients who do* ***not*** *meet the criteria for any of the clinical trials or registry studies.*

**NEW – Northern Health Travel Grant Program**

Effective October 1, 2007, patients residing in Northern Ontario who travel to Southern Ontario for a PET scan as a result of enrolment in the Ontario-funded PET evaluation/program are eligible for the Northern Health Travel Grant.

Patients wishing to apply for the Northern Health Travel Grant for a PET scan must:

- Have possession of a valid Ontario Health Card on the date of the scheduled PET scan and meet all other eligibility criteria;
- Be enrolled in one of the ministry-funded FDG-PET evaluation studies or registry that require travel from Northern Ontario to one of the ministry-funded PET imaging centres to receive a PET scan;
- Have a signed form letter from the coordinator of the PET study or PET registry at the enrolment hospital, verifying enrolment in a ministry-funded study.
- Complete the Northern Health Travel Grant application form and submit with it the above signed verification letter to one of the Ministry of Health & Long-Term Care offices listed on the application form.

To obtain additional details on the Northern Health Travel Grant program for PET and access a copy of the application form, please visit: http://www.health.gov.on.ca/english/public/pub/ohip/northern.html

**NEW - Toll Free Ontario PET Information Line**

Should referring physicians have any questions relating to the referral of patients to any of the ministry-funded PET evaluation studies or the Ontario PET Access program, please call the toll free Ontario PET Info Line:

**1-877-4PET-411** *(1-877-473-8411)*

## Attachment 1 - PET Clinical Trials

Three of the five Ontario ministry-funded clinical trials are still recruiting patients. These trials are summarized in Table 1.

**Patient Referral Procedure:** Physicians may refer patients to these clinical trials by contacting a principal investigator listed in Table 1 for the appropriate clinical trial.

**Table 1: Summary of MOHLTC-Funded PET Clinical Trials**

| Clinical trial | Purpose | Eligible Cancer Types | Target Sample Size | Contacts for Principal Investigators |
|---|---|---|---|---|
| **PET PREVENT** | Prospective cohort study to determine the ability of FDG-PET to detect metastatic cancer in neck lymph nodes in patients with head and neck cancer and to determine whether the cancer has responded to treatment. All enrolled patients will receive a PET scan before & after treatment | Squamous cell carcinoma of the head and neck arising in either the oral cavity, larynx and pharynx (except non-nasopharyngeal cancer) with $N_2$ or $N_3$ lymph nodes being considered for neck dissection following primary curative radiation therapy. | 400 | **Hamilton- Juravinski Cancer Centre**: Dr. Ian Hodson *(905) 387-9711 ext. 64702* **London Regional Cancer Centre:** Dr. Alex Hammond *(519) 685-8650* **Ottawa Regional Cancer Centre:** Dr. Libni Eapen *(613) 737-7700 ext. 70199* **Toronto- Princess Margaret Hospital** Dr. John Waldron *(416) 946-6522* |
| **PET START** | A prospective randomized controlled trial to determine (1) whether PET will help detect how far the lung cancer has spread beyond the chest after the patient has undergone all the usual standard diagnostic tests for lung cancer and (2) determine whether PET results will change how much of the chest will need radiation. Half of the enrolled patients will receive a PET scan. | Stage III non-small cell lung cancer suitable for combined modality therapy, radical radiation therapy, or trimodality therapy | 400 | **Hamilton – Juravinski Cancer Centre** Dr. Jim Wright *(905) 387-9495 ext. 64417* **London Regional Cancer Centre** Dr. Edward Yu (*519) 685-8500 ext. 53347* **Ottawa Regional Cancer Centre** Dr. Rob MacRae *(613) 737-7700 ext. 70205* **Toronto -Princess Margaret Hospital** Dr. Alex Sun *(416) 946-6522* **Toronto – Odette Cancer Centre** Cindy Foden *(416) 480-5846* |
| **PET CAM** | A prospective randomized controlled trial to determine the impact of pre-operative FDG-PET on patients who have been assessed as having resectable colorectal cancer liver metastases by conventional imaging, by determining the proportion of patients who have a change in management resulting from PET imaging. Half of the enrolled patients (randomised to the PET arm) will receive a PET scan. | Colorectal adenocarcinoma (excluding carcinoid, squamous cell cancer, gastrointestinal stromal tumour, or lymphoma) with resectable metastasis isolated to the liver. | 400 | **Toronto: Princess Margaret Hospital** Dr. Steven Gallinger *(416) 586-8550* **Toronto- Odette Cancer Centre** Linda Last *(416) 480-5000 ext. 3885* **London: St. Joseph's Health Centre** Dr. Richard Hart *(416) 530-6841* **Hamilton: St. Joseph's Healthcare & Hamilton Health Sciences Centre** Dr. Ved Taqndan *(905) 521-6148* |
| **PET PREDICT** | Patient accrual completed | Study closed. | | |
| **ELPET** | Patient accrual completed | **Study closed; patients should be referred to the Cancer PET Registry. Please see Attachment 2.** | | |

***Please Note:*** *Two trials have completed patient accrual and are now closed. The results of these trials are being analyzed, and will be reported to the Ontario PET Steering Committee shortly. In addition to the current clinical trials, the Ontario PET Steering Committee provides advice to MOHLTC regarding new indications and the need for additional trials based on ongoing international research.*

# Attachment 2 – Ontario Cancer PET Registry Study

## Ontario Cancer PET Registry: New Additions

The Cancer PET Registry study provides a PET scan and tracks the outcomes of patients who meet the eligibility criteria for specific indications. This registry study is coordinated by Hamilton Health Sciences and registry data is being maintained by the Institute for Clinical Evaluative Sciences.

**NOTE: NEW INDICATIONS ADDED**

The Ontario Ministry of Health and Long-Term Care provides PET imaging through the Ontario PET Registry for the following indications:

- Solitary pulmonary nodule (SPN) for which a diagnosis has not been established by fine needle aspiration (FNA), is inaccessible to FNA or there is a contra-indication to the use of FNA to obtain cytology;

- Thyroid cancer where recurrent or persistent disease is suspected on the basis of an elevated and/or rising thyroglobulin but standard imaging studies are negative;

- Germ cell tumours where recurrent disease is suspected on the basis of elevated tumour markers (beta HCG and/ or alpha fetoprotein) and standard imaging tests are negative, or a mass persists after primary treatment and surgical resection is being considered;

- Colorectal cancer where recurrent disease is suspected on the basis of elevated or rising carcinoembryronic antigen (CEA) during follow-up after surgical resection, but standard imaging studies are negative;

- Patients with potentially resectable non-small cell lung cancer (NSCLC); and

- Patients with lymphoma for:

    - The evaluation of residual masses following chemotherapy, in patients with potentially curative Hodgkin's lymphoma or non-Hodgkin's lymphoma, where adequate biopsy cannot readily be performed and further potentially curative therapy (such as radiation or stem cell transplantation) can be offered at the judgment of the treating physician if an incomplete response is documented; or

    - The assessment of response in patients with stage IA-IIA, non-bulky classical Hodgkin's lymphoma after 2 - 3 cycles of chemotherapy in patients where chemotherapy as a single modality is being considered as definitive therapy.

**As noted** in Bulletin #4464, as of December 15, 2007, FDG-PET imaging will also be provided within the Registry for the evaluation of patients with potentially resectable non-small cell lung cancer (NSCLC), based upon conventional physical exam, blood work and imaging, and histological or cytologic proof of NSCLC. The addition of NSCLC to the Registry is an interim decision based on preliminary findings in the ELPET (Early Lung Cancer) Study. Further changes regarding this indication may occur when the analysis of ELPET is complete and results reported.

**Repeat PET Scans**

- For Solitary Pulmonary Nodule (SPN)
  If the prior PET scan was negative but follow-up radiologic evidence shows progressive increase in the size of the SPN, a repeat PET scan may be performed at least 3 months after the previous PET scan.

- For Biomarker Positive and Anatomical Imaging Negative Tumours
  If the prior PET scan of a patient with colorectal cancer or germ cell tumour was negative and repeat radiologic imaging remains negative, but the biomarkers continue to rise over a 3 month period, a repeat PET scan may be performed.

- For Recurrent Thyroid Cancer
  A repeat PET scan may be undertaken in the face of a rising thyroglobulin above 1 ng/ml with the patient on thyroid suppression therapy and/or when the thyroglobulin level is 10 ng/ml or greater with thyroid stimulation (induced hypothyroidism or use of Thyrogen). The repeat PET scan may be performed at least 6 months after the previous scan unless there is a marked clinical change.

**Patient Referral Procedure:** To refer patients to the Ontario Cancer PET Registry, physicians will need to complete the *Ontario Cancer PET Registry Physician Fax Back Form (following page).* This will ensure that you are enrolled with the trial office at Hamilton Health Sciences for the Ontario Cancer PET Registry Study. Once your registration is received, you will be provided with a package explaining the registry process, along with the necessary consent forms. To contact the Ontario PET Registry Coordinating Centre at Hamilton Health Sciences, please call: **905- 521-2100 ext. 74445**.

**Attachment 2** **Ontario Cancer PET Registry**

## PHYSICIAN FAX BACK FORM

**Please fax this form to Ontario Cancer PET Registry - Angela Bonin at (905) 521-2356.**

Physician's Name: _____

Office Address: _____

_____Postal Code: _____

Phone: _____ Ext. _____

Fax: _____ Email: _____

Please indicate below which patients you see in your practice who may require a PET scan. (Indicate all that apply)

- ☐ Solitary Pulmonary Nodule
- ☐ Recurrent Thyroid Cancer
- ☐ Recurrent Germ Cell Tumours
- ☐ Recurrent Colorectal Cancer
- ☐ Potentially Resectable Lung Cancer
- ☐ Lymphoma

Please indicate to which PET Centre you would normally refer your patients for a PET scan.

| | | |
|---|---|---|
| **Hamilton** | – McMaster University Medical Centre | ☐ |
| | – St. Josephs Healthcare **Hamilton** | ☐ |
| **Ottawa** | – Ottawa Hospital, General Campus | ☐ |
| **Toronto** | – Princess Margaret Hospital | ☐ |
| | – Sunnybrook Hospital | ☐ |
| **London** | – St. Joseph's Healthcare **London** | ☐ |

By completing this form, your practice will be enrolled into the Ontario Cancer PET Registry and you will be informed of the protocol and information regarding access and consent procedures for your patients who may be eligible.

Thank you for your participation.

Dr. W.K (Bill) Evans
Chair, Provincial PET Steering Committee
Sr. Medical Officer, Ontario PET Registry

# Attachment 3 – Ontario Cardiac PET Registry Study

MOHLTC is funding a province wide Cardiac FDG-ET Registry (CADRE). The objective of this study is to evaluate, in the clinical setting, the role of FDG-PET viability imaging in providing additional diagnostic information in patients with coronary artery disease and severe left ventricular dysfunction that are being considered for revascularization or a heart transplant. This registry will be conducted at 4 PET centres in Ontario: the University of Ottawa Heart Institute (Coordinating Centre), Hamilton Health Sciences Centre, London Health Sciences Centre and the University Health Network, Toronto.

The CADRE registry will facilitate FDG PET imaging in Ontario. Through this registry a PET scan will be provided to patients who meet all of the following criteria.

- Severe ischemic left ventricular dysfunction (Left ventricular ejection fraction < 35%), and
- Symptomatic (New York Heart Association or Canadian Cardiovascular Society Class II-IV) despite maximal medical therapy, and
- Suitable candidates for revascularization if there was viable myocardium OR who would be considered for heart transplantation if there is no viable myocardium, and
- For patients referred from centres without direct access to PET, have undergone myocardial viability assessment using other modalities (i.e. SPECT using Thallium or MIBI or dobutamine echocardiography) and the results of those tests are equivocal or negative in terms of the existence of viable myocardium.

Through data collection and telephone follow-up, the registry will characterize the patient population, referral patterns upstream, clinical outcomes, and downstream resource utilization of those eligible patients that participate in the study.

**Patient Referral Procedure**

To refer a patient to the CADRE Registry a referring physician will:

- **Complete** the patient registration form available online at **http://www.ottawaheart.ca/UOHI/doc/CADRE.pdf**
- **Append** to the registration form, all relevant reports of previous diagnostic imaging tests
- **Send** the completed registration form and all appended reports to the University of Ottawa Heart Institute Coordinating Centre by Fax (613)-761-4344 or via e-mail to cadre@ottawaheart.ca

Following receipt of the registration form by the Coordinating Centre:

- The CADRE coordinator will review the form and accompanying documentation to confirm that the patient meets eligibility criteria. Registration forms that meet the above criteria will be forwarded (within 24 hours of receipt) to the closest PET facility for booking. (In the rare circumstance that there is a question regarding eligibility, the case will be reviewed by the Principal Investigator, Dr. Rob Beanlands and one other participating CADRE investigator. Rare exceptions to the eligibility as outlined above may be considered on a case-by-case basis.)

- The Coordinating Centre will fax a letter to the referring physician to confirm whether the patient is eligible for CADRE, and if so, the location of the PET facility performing the scan.

- If eligible, the PET facility will contact the patient directly with the date, time, and location of the FDG-PET scan.

- Standard reports will be forwarded by the PET facility to referring physicians in a timely fashion following the PET scan procedure.

**To refer your patient to CADRE, fax a completed registration form to 613-761-4344.**

**Registration** forms are available online
**http://www.ottawaheart.ca/UOHI/doc/CADRE.pdf**

**Contact** the CADRE coordinator at 613-798-5555 ext 18817 or via email
**cadre@ottawaheart.ca**

**Information and contacts** visit our web link at
**http://www.ottawaheart.ca/UOHI/doc/CADRE_intro.pdf**

# Attachment 4 – Ontario PET Access Program

If a patient is **not** a candidate for any of the clinical trials or registry studies, the patient might still be able to receive a funded PET scan in Ontario through the Ontario PET Access Program.

The Ontario PET Access Program is a review process established by the MOHLTC to assess requests for PET scans in cases where conventional diagnostic tests have not answered the clinical question (referring physicians will generally need to provide evidence of this within the application). Through the review process, applications for a funded PET scan are assessed on a case-by-case basis by an expert panel consisting of a radiologist, a nuclear medicine physician, and an oncologist. If on review it is determined that a PET scan would be appropriate, the PET Access Program Office located at Hamilton Health Sciences is notified and arrangements will be made for the patient's referral to an appropriate Ontario PET Centre.

***Please Note:*** *Before requesting a PET scan under the Ontario PET Access Program, it is advisable for physicians to first review the information on the clinical trials (Section 1) and registries (Section 2). If eligible, the patient should be offered enrolment to one of the clinical studies or registry studies. The Ontario PET Access Program should only be considered for patients who do* ***not*** *meet the criteria for any of the clinical trials or the registry studies.*

## Application Procedure for the Ontario PET Access Program

The procedure for requesting a PET scan under the Ontario PET Access Program is as follows:

- **Verify that the patient is not a candidate for any of the clinical trials or registry studies;**

- Complete the *Ontario PET Scan Access Program Request* and *Patient Consent Form* (see following pages). These application forms must be completed for a patient to be considered for a PET scan under the Ontario PET Access Program. The *Ontario PET Scan Access Program Request* must be signed by the referring physician and the patient must sign the *Patient Consent Form* so that his/her personal health information can be forwarded to the Ministry of Health and Long-Term Care and to Cancer Care Ontario for the purposes of the review process described above, and

- Include the following documents with the application (*the review cannot occur without these documents*):
  - A brief summary of the patient's medical history, and
  - Recent consult letters either to or from other physicians that describe the relevant medical circumstances of the patient or provide a brief written account of the patient's relevant medical history including the problem that PET is being asked to address;
  - Recent diagnostic reports that are relevant to the application, and
  - Provide an opinion of what PET might demonstrate that cannot be proven by other means, and
  - Provide an opinion of what difference the information provided by PET may make to the management of the case, and

- Fax the completed forms and all additional reports/documents in support of a PET scan to the Provider Services Branch at **(613) 536 -3184**.

**Please note that failure to submit results of previous diagnostic tests may delay the review of the application.**

If you have any questions about the Ontario PET Access Program, please call: 1-888-359-8807.

# Ontario PET SCAN Access Program Request

**TO BE COMPLETED BY THE REQUESTING PHYSICIAN**

***This Ontario PET Access Program request should be considered only for patients who do not meet the criteria for any of the clinical trials or the registry studies.***

**Referring Physician's Name:** _____

**Referring Physician's Telephone**: _____ **and Fax:** _____

**Provider Number:** _____

**Patient Name:** _____

**OHIP Number** ☐☐☐☐-☐☐☐-☐☐☐-☐☐

**Telephone:** _____

**Date of birth:** _____/_____/_____ **Sex:** ☐ M ☐ F
YYYY MM DD

**Postal Code** __ __ __ __ __ __

**Indications for the PET scan:**

_____

_____

_____

_____

## You must attach reports and provide the dates:

☐ **Attach a brief summary of the patient's medical history**

☐ **Attach a copy of the reports from all relevant imaging studies**

**Please note that failure to submit results of previous diagnostic tests may delay the review of the application.**

List all relevant imaging studies
1. Date of: _____/_____/_____ ☐CT ☐US ☐MRI
YYYY MM DD
2. Date of: _____/_____/_____ ☐CT ☐US ☐MRI
YYYY MM DD
3. Date of: _____/_____/_____ ☐CT ☐US ☐MRI
YYYY MM DD
4. Date of: _____/_____/_____ ☐CT ☐US ☐MRI
YYYY MM DD
5. Date of: _____/_____/_____ ☐CT ☐US ☐MRI
YYYY MM DD

**Please fax this form, the patient consent form and any additional documents in support of a PET scan to Provider Services Branch at (613) 536-3184.**

**Should you have any questions about this form or the program, please call 1-888-359-8807.**

# Ontario PET SCAN Access Program Request – Patient Consent

**TO BE COMPLETED & SIGNED BY THE PATIENT or PARENT/GUARDIAN**

## Patient Consent

*(To be completed and signed by the patient)*

I, _____, consent to my physician disclosing personal health information to the Ministry of Health and Long-Term Care relevant to my medical condition that might qualify me for a diagnostic assessment using Positron Emission Tomography (PET). My medical information will be reviewed by an expert panel to determine whether I qualify for one of the current clinical studies or PET registry studies and if not, whether a PET scan would be potentially helpful in the management of my medical condition.

_____ _____

**Signature of patient** **Date**

## Patient Consent for minor child

*(To be completed and signed by parent/legal guardian of patient)*

I, _____, (name of parent/guardian) am the parent/ legal guardian of _____ (name of child). I consent to the above-named physician disclosing personal health information to the Ministry of Health and Long-Term Care relevant to the medical condition that might qualify my child for a diagnostic assessment using Positron Emission Tomography (PET). My child's medical information will be reviewed by an expert panel to determine whether he/she qualifies for one of the current clinical studies or PET registry studies and if not, whether a PET scan would be potentially helpful in the management of his/her medical condition.

_____ _____

**Name of parent/guardian** **Signature of parent/guardian or patient**

_____

**Date**