ELIGIBILITY CRITERIA EXAMPLES

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Example 1: (MR Imaging study)

Patient Eligibility

1.1 Prior histologic diagnosis of prostate cancer and scheduled for radiotherapy treatment.

1.2 Patients must be >18 years old.

1.3 There is no any contraindication for MRI such as pacemaker or other non-MR compatible implanted device.

1.4 Patients must be able to lie still for MRI. Their girth and weight must be suitable to enter the MRI.

1.5 Patients must be able to understand and sign an informed consent indicating that they are aware of the investigational nature of this study, in keeping with the policies of the cancer center.

Example 2: (PET Imaging study)

Inclusion criteria:

1. Clinical and radiological diagnosis of a lung tumor (including primary lung tumors and metastases) who have not yet received treatment. Also patients with previously diagnosed and treated lung, who are now progressing, prior to starting a new line of therapy.

2. Age 18-82 years at the time of the PET scan.

3. Good general condition.

4. Patient agrees to sign the Informed Consent form for this study.

Exclusion criteria:

1. Terminal illness, with life expectancy of less than 6 months, where further diagnostic studies are not expected to change management or outcome.

2. Pregnancy.

3. Recent (within 1 month) tumor resection, chemotherapy or radiotherapy.

Example 3: (Immunotherapy study with T cell infusion)

4.0 ELIGIBILITY

4.1 Metastatic Breast Cancer. Women with histologically documented breast cancer and histologically or clinically documented MBC of all histological types that have recurred (defined below) after the most recent line (first, second or third) of chemotherapy in the metastatic setting are eligible. Recurrence is defined as:

(a) progression on the most recent line (first, second or third) of chemotherapy.

and

(b) patient is planned to receive, or already received within 1 month, of subsequent line of chemotherapy.

Patients are required to have at least one measurable lesion that has not been irradiated.

4.2 HER2/*neu* Expression. Patients with 0-2+ HER2 expression as determined by immunohistochemistry staining and/or FISH ratio $\leq$2.2, with the above pathologic criteria will be eligible. Patients with HER2 overexpression by IHC or overamplification by FISH are not eligible and are defined as follows: IHC staining of 3+ (uniform, intense membrane staining of > 30% of invasive tumor cells), a fluorescent in situ hybridization (FISH) result of more than six HER2 gene copies per nucleus or a FISH ratio (HER2 gene signals to chromosome 17 signals) of more than 2.2.

4.3 Prior or Current Therapy

> **4.3.1 Hormone Therapy.** Patients on prior hormonal therapy are eligible. Hormonal therapy will be stopped 2 weeks prior to leukopheresis.
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> **4.3.2 Chemotherapy:** *All patients who developed metastatic disease who have had prior first, second or third line treatment are eligible.* Patients are ineligible if they had tumor progression on more than three chemoT regimen for metastatic disease. Prior taxanes, anthracyclines, or any other chemoT or biological agents are permitted. Leukopheresis may be done when the lymphocyte count has recovered to 500 cells/mm^3 and there are no residual chemotoxicities that would prevent leukopheresis. Patients who just started second, third or fourth line chemotherapy, within one month, are eligible.
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> **4.3.3 Radiotherapy.** Leukopheresis may be done 4 weeks after radiation to the axial skeleton.

4.4 Measurable or Evaluable Disease. Measurable or evaluable metastatic disease documented by radiograph, CT scan, PET/CT, MRI, bone scan, or physical exam is required. Each patient will be required to have at least one bi-dimensionally measurable lesion that has not been irradiated with a minimum size at least one diameter of ≥ 20 mm for liver lesions and ≥ 10 mm for lung, skin, and lymph node metastases. Biopsy of recurrent site(s) is not required. Biopsy of accessible sites before and after armed ATC is part of this study.

4.5 Age. ≥18 years.

4.6 Performance Status. Karnofsky ≥ 70%

4.7 Life Expectancy. Life Expectancy ≥ 3 months

4.8 Other Malignancies. Women with a history of another malignancy within 5 years of study entry are not eligible (except basal cell skin carcinoma and carcinoma-in-situ of the cervix).

4.9 Nonpregnant: Negative serum test for pregnancy, for pre-menopausal women, unless prior hysterectomy.

4.10 No serious illness. No serious medical or psychiatric illness which prevents informed consent or intensive treatment is allowed.

4.11 Cardiac Status. Patients will be ineligible for treatment on this protocol if:

4.11.1 There is a history of a recent myocardial infarction (within one year)

4.11.2 There is a history of a past myocardial infarction (more than one year ago) along with current coronary symptoms requiring medications and/or evidence of depressed left ventricular function (LVEF < 45% by MUGA or ECHO)

4.11.3 There is a current history of angina/coronary symptoms requiring medications and/or evidence of depressed left ventricular function (LVEF < 45% by MUGA or ECHO)

4.11.4 There is clinical evidence of congestive heart failure requiring medical management (irrespective of MUGA or ECHO results)

4.11.5 If the systolic BP is consistently ≥140 or their diastolic BP is consistently ≥90, patients must have their BP controlled by anti-hypertensive medications for at least 7 days prior to the first armed ATC infusion.

4.12 No evidence of central nervous system (CNS) metastases. Patients with treated brain metastases (*i.e.* those who have received definitive radiation, chemotherapy, and/or underwent surgical resection) are eligible for therapy on this protocol. Patients with clinical evidence of active CNS metastases are ineligible for therapy on this protocol.

4.13 Required initial laboratory data:

Granulocytes $\geq$ 1,000/mm^3
Platelet count $\geq$ 50,000/µl
Hemoglobin 8 gm/dl,
BUN $\leq$ 1.5 times normal
Serum creatinine < 1.8 mg/dl
Creatinine Cl ≥60 ml/mm
Bilirubin < 1.5 times normal
ALT, AST and alkaline phosphatase < 5 times upper normal
No active HIV, Hepatitis B or Hepatitis C infections
LVEF ≥ 45% at rest (MUGA or ECHO)

PFT-FEV_1, DLCO, and FVC ≥ 50% of predicted

4.14 Informed consent. Each patient must be aware of the nature of her disease and must willingly consent to treatment after being informed of alternatives, potential benefits, side effects, and risks.