



*This list of clinical research protocols relating to high-dose therapy is compiled for your convenience.*

*For more information on these protocols, please call PDQ, a service of the National Cancer Institute, at 1-800-4-CANCER. The PDQ Web site is accessible at [http://www.cancer.gov/clinical\\_trials](http://www.cancer.gov/clinical_trials).*

*A searchable Web site developed by the National Library of Medicine is also available at <http://clinicaltrials.gov>.*

## SELECTED CLINICAL RESEARCH PROTOCOLS FOR HIGH-DOSE THERAPY

### Phase I/II

**HCRC-1586.00, NCI-H01-0080** Phase I/II Study of a Non-myeloablative Conditioning Regimen Comprising Fludarabine and Total Body Irradiation Followed by Allogeneic Peripheral Blood Stem Cell or Bone Marrow Transplantation in Patients With High-Risk Acute Lymphoblastic Leukemia in Complete Remission

Chairperson: Brenda Sandmaier, MD. Telephone: 206-667-4961. Lead organization: Fred Hutchinson Cancer Research Center. Age range: 75 and under.

**FHCRC-1409.00, NCI-G00-1776** Phase I/II Study of Autologous Peripheral Blood Stem Cell (PBSC) Transplantation Followed by Nonmyeloablative Allogeneic PBSC Transplantation in Patients With Refractory or Relapsed Non-Hodgkin's Lymphoma

Chairperson: David Maloney, MD, PhD. Telephone: 206-667-5616. Lead organization: Fred Hutchinson Cancer Research Center. Age range: 65 and under.

**FHCRC-1495.00, NCI-G00-1790** Phase I/II Study of HLA-Matched Allogeneic Peripheral Blood Stem Cell Transplantation After Nonmyeloablative Conditioning Therapy in Patients With Metastatic Renal Cell Carcinoma

Chairperson: Brenda Sandmaier, MD. Telephone: 206-667-4961. Lead organization: Fred Hutchinson Cancer Research Center. Age range: under 75.

**NHLBI-97-H-0196** Phase I/II Study of HLA-Matched Nonmye-

loablative Peripheral Blood Stem Cell Transplantation Followed by Allogeneic T-Cell Infusion as Adoptive Immunotherapy in Patients With Metastatic Renal Cell Carcinoma

Chairperson: Richard W. Childs. Telephone: 301-594-8013. Lead organization: National Heart, Lung, and Blood Institute. Age range: 18 to 80.

**JHOC-J0115, JHOC-01011706, JHOC-K0007, NCI-G01-2020** Phase I/II Study of Induction Chemotherapy Followed by Autologous Tumor Cell Vaccine and Autologous Peripheral Blood Stem Cell Transplantation in Patients With Multiple Myeloma

Chairperson: Ivan Borrello, MD. Telephone: 410-955-8964. Lead organization: Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins. Age range: 18 to 70.

**FHCRC-1596.00, NCI-H01-0068** Phase I/II Study of Low-Dose Radiotherapy and Fludarabine Followed by Allogeneic Peripheral Blood Stem Cell Transplantation, Mycophenolate Mofetil, and Cyclosporine in Patients With Hematologic Malignancies

Chairperson: David Maloney, MD, PhD. Telephone: 206-667-5616. Lead organization: Fred Hutchinson Cancer Research Center. Age range: under 75.

**FHCRC-1641.00, NCI-H01-0081** Phase I/II Study of Low-Dose Total-Body Irradiation and Fludarabine Followed by Unrelated Donor Peripheral Blood Stem Cell Transplantation Using Enhanced Post-Grafting Immunosuppression in

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Patients With Hematologic Malignancies or Renal Cell Carcinoma

Chairperson: Michael Maris, MD. Telephone: 206-667-2480. Lead organization: Fred Hutchinson Cancer Research Center. Age range: any age.

## Phase II

**FHCRC-1209.00, NCI-G97-1359** Phase II Pilot Study of Fludarabine, Low-Dose Total Body Irradiation, and Allogeneic Peripheral Blood Stem Cell Transplantation Followed by Immunosuppression With Cyclosporine and Mycophenolate Mofetil and Donor Lymphocyte Infusion for Induction of Mixed Hematopoietic Chimerism in Older Patients With Chronic or Accelerated Phase Chronic Myeloid Leukemia

Chairperson: Brenda Sandmaier, MD. Telephone: 206-667-4961. Lead organization: Fred Hutchinson Cancer Research Center. Age range: 66 to 74.

**CWRU-4Y97, NCI-G98-1429** Phase II Pilot Study of Unrelated Umbilical Cord Blood Transplantation in Patients With High Risk Hematologic Malignancies

Chairperson: Mary J. Laughlin, MD. Telephone: 216-844-8609; 1-800-641-2422. Lead organization: Ireland Cancer Center. Age range: under 55.

**NCI-99-C-0138, NCI-NMOB-9902, NCI-T99-0075** Phase II Randomized Pilot Study of p53 Peptide Vaccine and Low-Dose Interleukin-2 in Patients With Stage IV, Recurrent, or Progressive Adenocarcinoma of the Breast

Chairperson: Robert Behrens, MD. Telephone: 301-435-5407. Lead organization: Center for Cancer Research. Age range: 18 and over.

**CHNMC-IRB-98096, CHNMC-PHII-18, NCI-H99-0038** Phase II Randomized Study of Doxorubicin, Cyclophosphamide, and Paclitaxel (ACT) vs Cyclophosphamide, Thiotepa, and Carboplatin (STAMP V) in Patients With High-Risk Primary Breast Cancer

Chairperson: George Somlo, MD. Telephone: 626-359-8111; 1-800-826-4673. Lead organization: Cancer Center and Beckman Research Institute, City of Hope. Age range: physiologic age 60 or under.

**UTSMC-0501228, AMGEN-UTSMC-0501228, IBMTR-SC-00-02.1, NCI-V02-1706, ROCHE-UTSMC-0501228, SPRI-UTSMC-0501228** Phase II Randomized Study of Fludarabine and Total Body Irradiation Versus Cyclophosphamide and Fludarabine Followed by Allogeneic Peripheral Blood Stem Cell Transplantation in Patients With Relapsed Low-Grade Non-Hodgkin's Lymphoma or Chronic Lymphocytic Leukemia

Chairperson: Robert H. Collins, MD. Telephone: 214-648-8689. Lead organization: Simmons Cancer Center - Dallas. Age range: 18 to 75.

**FHCRC-1581.00, NCI-H02-0087** Phase II Study of a Non-Myeloablative Conditioning Regimen Comprising Fludarabine and Total Body Irradiation Followed by Allogeneic Peripheral Blood Stem Cell Transplantation in Patients With Imatinib Mesylate-Responsive Philadelphia Chromosome-Positive Acute

Lymphoblastic Leukemia or Blast Crisis Chronic Myelogenous Leukemia

Chairperson: Michael Maris, MD. Telephone: 206-667-2480. Lead organization: Fred Hutchinson Cancer Research Center. Age range: 70 and under.

**CPMC-IRB-7934, CPMC-CAMP-021, NCI-G00-1899** Phase II Study of Allogeneic Umbilical Cord and Placental Blood Transplantation in Patients With Chronic Myeloid Leukemia, Acute Leukemia, Lymphoma, Myeloma, Myelodysplasia, Aplastic Anemia, Fanconi's Anemia, Histiocytosis, Hereditary Immunodeficiency, or Storage Disorder

Chairperson: David G. Savage, MD. Telephone: 212-305-9327. Lead organization: Herbert Irving Comprehensive Cancer Center. Age range: Under physiologic 60.

**NU-96H3, NCI-G99-1659** Phase II Study of Combination Chemotherapy Followed by Allogeneic or Autologous Bone Marrow Transplantation or Peripheral Blood Stem Cell Transplantation and/or Interferon Alfa and Interleukin-2 Therapy in Patients With Refractory or Stage III or IV Mantle Cell Lymphoma

Chairperson: Leo I. Gordon, MD. Telephone: 312-908-5250. Lead organization: Robert H. Lurie Comprehensive Cancer Center, Northwestern University. Age range: 18 and over.

**CPMC-IRB-7328, CPMC-CAMP-009, NCI-G00-1882** Phase II Study of High-Dose Chemotherapy With Autologous Hematopoietic Stem Cell Support in Patients With

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Multiple Myeloma or Primary Systemic Amyloidosis

Chairperson: Charles Hesdorfer, MD. Telephone: 212-305-9327. Lead organization: Herbert Irving Comprehensive Cancer Center. Age range: 18 and over.

### Phase III

**EORTC-06961** Phase III Randomized Comparison of Autologous Peripheral Blood Stem Cell Transplantation vs Second Intensive Consolidation With High-Dose Cytarabine Following Common Induction and Consolidation in Patients With Poor Prognosis Myelodysplastic Syndromes (MDS) and Acute Myelogenous Leukemia Secondary (sAML) to MDS of More Than 6 Months Duration

Chairperson: Theo De Witte, MD, PhD. Telephone: 024-361-47-62. Lead organization: EORTC Leukemia Group. Age range: 16 to 60.

**E-2993, MRC-LEUK-UKALL-XII, EST-4491** Phase III Randomized Study of Allogeneic Bone Marrow Transplantation (BMT) or Conventional Consolidation and Maintenance Chemotherapy Versus Autologous BMT in Patients With Acute Lymphoblastic Leukemia in First Remission

Chairperson: Jacob Rowe, MD. Telephone: 011-972-4-8542541. Lead organization: Eastern Cooperative Oncology Group. Age range: 15 to 60.

**MSKCC-94076, CLB-99812, E-3894, NCI-T94-0086D, SWOG-9442** Phase III Randomized Study of Bleomycin, Etoposide, and Cis-

platin (BEP) With or Without High-Dose Carboplatin, Etoposide, and Cyclophosphamide Plus Autologous Bone Marrow or Peripheral Blood Stem Cell Transplantation in Male Patients With Previously Untreated Poor- or Intermediate-Risk Germ Cell Tumors

Chairperson: Robert Motzer, MD. Telephone: 646-422-4312. Lead organization: Memorial Sloan-Kettering Cancer Center. Age range: 12 and over.

**HOVON-44/CKVO-2000-06, EU-20042** Phase III Randomized Study of Sequential Chemotherapy With or Without Rituximab Followed by Ablative Chemotherapy and Autologous Peripheral Blood Stem Cell Transplantation in Patients With Relapsed, CD20 Positive, Aggressive B-Cell Non-Hodgkin's Lymphoma

Chairperson: Edo Vellenga, MD. Telephone: 31-50-361-6161. Lead organization: Stichting Hemato-Oncologie voor Volwassenen Nederland. Age range: 18 to 65.