Transplant & Cellular Therapy Center
The region’s elite resource for the latest approaches in transplant, CAR T and other cell therapies

Roswell Park is home to **New York State’s first cell and gene therapy hub** focused on discovery and production of life-saving cell therapies.

We are a **high-volume center**, providing allogeneic and autologous stem cell transplant to patients of any age.

**What Sets Us Apart**

- **CAR T-cell therapies.** We offer Kymriah, Yescarta, Tecartus, Breyanzi, Ábecma, and Carvykti.

- **Tumor infiltrating lymphocyte (TIL) therapy.** We have ongoing trials of TIL therapy for cervical and non-small cell lung cancer and will offer it for other indications once approved.

- **Gene therapy.** We will soon offer Casgevy™ (exagamglogene autotemcel, exa-cel) for sickle cell disease.

- **Strategies for better transplant outcomes.** We have specific expertise in technologies to reduce complications, including graft-versus-host disease (GVHD), and enhance quality of life.

- **Outpatient therapy.** We offer safe, effective, and convenient outpatient CAR T and autologous stem cell transplantation for eligible patients.

- **Clinical trials of next-generation cell therapies,** including options for solid tumor cancers, and with transplant to prevent disease relapse and GVHD.
We offer the full range of FDA-approved cell, gene, and transplant therapies. Highlights of our program include:

**EXPERTISE** to improve outcomes and quality of life

We use technologies and practices to substantially reduce risks of transplant-related complications, like clinically relevant or life-threatening acute and chronic GVHD. This allows us to efficiently find young, unrelated stem cell donors to improve outcomes and reduce risks after transplantation.

**A ONE-STOP Shop**

Our team includes specialists in transplant, hematology, pediatrics, radiation medicine, infectious disease, cardiology and gastroenterology, plus oncology nurses trained in care of immunocompromised patients. We integrate other disciplines and services — dental care, physical and pulmonary therapy, nutrition, psychologists, social workers, child life specialists and more — into the care pathway for all.

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**Conditions We Treat**

Roswell Park offers transplant and cellular therapies to eligible patients with the following conditions:

- Leukemia
- Lymphoma
- Multiple myeloma
- Aplastic anemia and other marrow failure syndromes
- Amyloidosis
- Hemoglobinopathies, including sickle cell disease and thalassemias
- Myelodysplastic syndrome
- Myeloproliferative neoplasms
- Selected solid tumors such as testicular cancer
- Graft-versus-Host Disease

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Roswell Park was one of the first centers in the world to routinely offer blood and bone marrow transplantation to cancer patients. Since 1977, we have performed more than 3,450 transplants and have continually striven to refine the treatment, improve outcomes, reduce complications, and make transplant available to more patients.
OUTPATIENT Transplant or Cell Therapy

Our beautiful, MODERN facility

The state-of-the-art Bill and Jane Greene Transplant & Cellular Therapy Center opened in 2021 on the 6th floor of the hospital. Our outpatient clinic features 12 large rooms to support outpatient services and procedures, increased infusion space, and enhanced privacy in shared and common areas.

Long-term SURVIVORSHIP Clinic

We provide specialized survivorship care that focuses on patients’ well-being and includes expert cancer monitoring and screening, managing any new or continuing symptoms or side effects, mental and social support, nutrition and lifestyle guidance, and other assistance — for life.

- Clinical recommendations and referrals for unique symptoms that can occur after treatment, such as:
  - Skin changes, alopecia
  - Side effects of corticosteroid use
  - Cardiac or pulmonary problems
  - Thyroid changes
  - Cataracts
- Bone density surveillance
- Re-immunization tracking
- Routine cancer screening

This annual event at Roswell Park brings together survivors and the TCT clinical team for a day of hope, comradery, and celebration!
HEMATOPOIETIC Cell Transplantation (HCT)

Our transplant team will partner with you to find the very best option for your patient. We will provide consultation to determine whether transplant is appropriate, and which technique would benefit your patient most.

These strategies include:

- Prioritizing age <40 for donor selection, even if it means going to an unrelated matched or mismatched donor.
- GVHD prophylaxis with post-transplant cyclophosphamide-based regimens. Our goal is to initiate taper of systemic immune suppression by day +60.
- Early discharge post-transplant

We offer customized HCT for patients of any age, including:

- Autologous
- Allogeneic, including expertise in HLA-mismatched transplant
- Haplo-identical
- Gene therapy
- Reduced intensity
- Myeloablative

Improved outcomes for stem cell transplant

We use the latest strategies and technologies for:

- Optimizing survival and cure rates
- Decreasing complications and relapse
- Monitoring immune response
- Reducing duration of immune suppression
- Shortening inpatient stays
- Improving quality of life and patient experience

“These new methods make grade III-IV acute GVHD and severe chronic GVHD rare, allow long term immune tolerance off systemic prophylaxis, reduce toxicity and improve outcomes post-transplant.”

— Brian Betts, MD
COLLABORATIVE Care

While many aspects of transplant and cell therapy care will be managed at Roswell Park during the first 1-3 months, we aim to have patients back with their referring oncologists after 30 days post autologous transplantation or CAR T, or after 60-100 days following allogeneic transplantation. We will continue to see patients for comprehensive response assessments at 3 months, 6 months, 1 year, and 2 years post-transplant.

Timeline for Collaborative alloHCT

1. **STEP ONE**: Referring Oncologist schedules appointment with patient for transplant.
2. **STEP TWO**: Within 2 weeks of referral, patient attends TRANSPLANT ORIENTATION with nurse coordinator.
3. **STEP THREE**: Patient is admitted to Roswell Park TCT Center.
4. **STEP FOUR**: Stem cell infusion day.
5. **STEP FIVE**: GvHD prophylaxis infusions on day 0, DAY 3, & DAY 4. Patient is discharged from hospital care. Patient returns to primary oncologist for maintenance chemotherapy.
6. **STEP SIX**: 2-year anniversary.
7. **STEP SEVEN**: Goal is for patient to be in complete remission.

**GvHD prophylaxis**: Infusions on day 0, DAY 3, & DAY 4.

**DONOR SELECTION PRIORITY 1**
- Matched
- Related
- Age <40

**DONOR SELECTION PRIORITY 2**
- Matched
- Unrelated
- Age <40

**DONOR SELECTION PRIORITY 3**
- 6-7/8 Mismatched
- Unrelated
- Age <40

**DONOR SELECTION PRIORITY 4**
- Haplo donor
- Age <40

**COLLABORATIVE Care**

The joint program provides transplant and cellular therapies to pediatric patients of all ages for the following diagnoses:

- Aplastic anemia, Fanconi anemia and other narrow failure syndromes
- Hemophagocytic lymphohistiocytosis
- Leukemia
- Lymphoma
- Malignant brain tumors
- Myelodysplastic and myeloproliferative disorders
- Neuroblastoma
- Sickle cell disease
- Thalassemia
- Immunodeficiency disorders

**Referring Oncologist**

We partner with referring physicians to reduce inpatient duration and return patient to care of primary oncologist sooner.

**Pediatric Transplant Program**

Pediatric patients are cared for through a joint venture between Roswell Park and John R. Oishei Children’s Hospital of Buffalo.

**CANCER AND BLOOD DISORDERS PROGRAM**

This unique partnership allows our youngest patients to receive cutting-edge oncology care, transplant, and cellular therapies along with the pediatric care and subspecialties of a freestanding children’s hospital, while remaining close to home.
Tumor-Infiltrating Lymphocyte (TIL) THERAPY

A cutting-edge cell therapy, TIL treatment offers a promising strategy for the treatment of advanced solid tumor cancers. Using each patient’s own T cells — collected from within their own tumor tissue — TIL therapy multiplies these cells and returns them to the patients. These cells need no engineering. They already know how to find and infiltrate the tumor.

Roswell Park currently offers TIL therapy through clinical trials for eligible patients with:

- cervical carcinoma
- non-small cell lung cancer

The first FDA approval of a TIL therapy to be used in patients with metastatic melanoma is expected in the coming months and Roswell Park will offer this as well.

**TIMELINE for TIL therapy**

Receiving TIL therapy is a multi-step process that involves:

- **Surgery to remove the tumor or metastatic lesions.** T cells are retrieved and multiplied into millions.
- **Non-myeloablative chemotherapy** given over 7 days.
- **TIL infusion.** Receiving TIL therapy is a one-time intravenous (IV) infusion.
- **High dose interleukin 2 (IL-2) therapy.** Up to 6 doses over 3 days to stimulate T cell and other immune cell growth.

CAR T-cell therapies, made from a patient’s own T cell lymphocytes, offer new hope and potentially curative options for patients with relapsed or refractory disease, including:

- Large B cell lymphoma
- Mantle cell lymphoma
- Follicular lymphoma
- Acute lymphoblastic leukemia
- Multiple myeloma

With CAR T-cell therapies, the patient’s T cells are collected, genetically modified to recognize and attack cancer cells, multiplied into the millions, and infused back into the patient.

Diagnosed with aggressive and treatment resistant infantile ALL, Chasity underwent CAR T-cell therapy followed by stem cell transplant at age 7 months.

Today she is thriving.
GENE-EDITED Cellular Therapy
A breakthrough treatment for sickle cell disease

Casgevy™ (Exagamglogene autotemcel or exa-cel), alters the genes of patients’ own hematopoietic stem cells to produce higher levels of fetal hemoglobin in red blood cells. This elevation has been shown to reduce painful and debilitating sickle cell crises and alleviate the need for transfusions in patients with beta thalassemia.

Patients’ own hematopoietic stem cells and progenitor cells are collected from peripheral blood, sent to the lab for gene editing, and the edited cells (exa-cel) are returned to the patient as an autologous stem cell transplant.

Roswell Park expects to begin offering this treatment for eligible patients with sickle cell disease soon.

IN THE PIPELINE
Roswell Park has committed the investment, resources and focus to accelerate the development of next-generation CAR T-cell therapies, and several clinical trials are expected to open in the coming year.

Some highlights of this work include:

- A new CAR T therapy to prevent relapse and GVHD in patients with leukemia.
- Combining CAR T-cell therapy with other immune cells and components of the immune system to improve the treatment’s effectiveness.
- Identifying new antigens to re-engineer the T cells to target other cancer types.
- Breaking down the barriers presented by solid tumors to make this treatment effective for solid tumor cancers, which represent 80% of all cancers.

CLINICAL TRIALS
We have numerous clinical trials evaluating novel approaches for patients undergoing transplant and cell therapies, such as:

- Novel options for conditioning regimens, GVHD prophylaxis, and post-transplant maintenance therapy
- New approaches to prevent bone mineral density loss or infection.
- CAR T-cell therapies for other cancer types, including:
  - acute myeloid leukemia (AML)
  - solid tumors such as breast, lung, prostate and gastrointestinal cancers
- TIL therapy for solid tumor cancers

Scan the QR Code to see all our clinical trials

GMP ENGINEERING & CELL MANUFACTURING Facility

Cell therapy requires the ability to engineer and manufacture therapeutic cells in a sophisticated, dedicated facility built for that purpose. Few centers across the country were involved in cell-based cancer treatments at any level when we opened our Therapeutic Cell Production Facility with one GMP cell production "clean room" in 2010.

Today, our facility includes six cell production clean rooms — and 14 more are under construction now!

Our in-house cell production eliminates the need to rely on external manufacturing partners and helps us to open more clinical trials faster. Patients who need these treatments don’t have time to wait.

Yeong “Christopher” Choi, PhD, MBA, led the first iteration of cell therapy production at Roswell Park with a focus on dendritic cell vaccines and engineered T cell receptors (TCRs). Today, he is expanding the facility to manufacture and test new and emerging cellular therapies.

RoswellPark.org/GMP
We've put together a world class team of physicians and scientists — who were central to recent breakthroughs in cellular therapy — to expand our clinical capacity, further development of next-generation cellular therapies, and speed our ability to bring game-changing emerging treatments to more patients.

Our transplant physicians are members of:

- American Association for Cancer Research (AACR)
- American Society for Transplantation and Cellular Therapy (ASTCT)
- American Society of Clinical Oncology (ASCO)
- American Society of Hematology (ASH)

**WHEN to refer a transplant patient? AT TIME OF DIAGNOSIS.**

The ideal time to refer a patient is at time of diagnosis or induction therapy. Even if your patient is in remission, immediate referral is advised to begin preliminary donor search and stem cell collection.

**REFER A PATIENT**
Call 716-845-RPMD (716-845-7763)

**ROSWELL PARK’S PROGRAM HOLDS THESE DISTINCTIONS:**

- National Marrow Donor Program
- Blue Distinction Center
- FACT Foundation for the Accreditation of Cellular Therapy
- National Comprehensive Cancer Network
- Comprehensive Cancer Center

**Meet the TEAM**

**PEDIATRIC TRANSPLANT TEAM**

- **Kanwaldeep Mallhi, MD**
  Director, Pediatric Transplantation and Cellular Therapy

- **Meghan Higman, MD, PhD**
  Assistant Professor of Oncology

- **Matthew Barth, MD**
  Assistant Professor of Oncology

- **Nataliya Buxbaum, MD**
  Assistant Professor of Oncology

**Our transplant physicians are members of:**

- **Renier Brentjens, MD, PhD**
  Deputy Director
  Chair, Department of Medicine
  Professor of Oncology

- **Marco Davila, MD, PhD**
  Senior Vice President and Associate Director for Translational Research

- **Brian Betts, MD**
  Professor of Oncology
  Vice Chair of Strategic Initiatives

- **Sherman Holman, MD**
  Professor of Oncology
  Chief, Blood and Marrow Transplantation

- **Ehsan Malek, MD**
  Director of Multiple Myeloma Translational Research

- **Anuradha Krishnamurthy, MBBS**
  Associate Director of Early Phase Clinical Trials for Solid Tumor Cell Therapies

- **Maureen Ross, MD, PhD**
  Professor of Oncology

- **Philip McCarthy, MD**
  Professor of Oncology
  Director Emeritus of the Transplant & Cellular Therapy Center

- **Grant Schofield, MD**
  Professor of Oncology

**Kanwaldeep Mallhi, MD**
Director, Pediatric Transplantation and Cellular Therapy

**Meghan Higman, MD, PhD**
Assistant Professor of Oncology

**Matthew Barth, MD**
Assistant Professor of Oncology

**Nataliya Buxbaum, MD**
Assistant Professor of Oncology