

SWOG
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Policy Memorandum No. 27

Subject: Transplant and Cell Therapies Committee
Guidelines for Institution Approval

Departments Affected: All

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TRANSPLANT AND CELL THERAPIES COMMITTEE
GUIDELINES FOR INSTITUTION APPROVAL

1. Facilities performing hematopoietic cellular therapy as part of SWOG protocol treatment must have approval from SWOG and the Transplant and Cell Therapies Committee. To receive SWOG approval, the facility must maintain current Foundation for the Accreditation of Cellular Therapy (FACT) accreditation applicable to the cellular therapy services provided or demonstrate other credentials acceptable to SWOG and the Committee. For institutions performing only chimeric antigen receptor T-cell therapy (CAR-T), acceptable credentials may include manufacturer authorization or certification for each CAR-T product administered at the facility. Approval may be granted for autologous transplantation, allogeneic transplantation, CAR-T therapy, or an applicable combination. For sites outside the United States, where FACT accreditation may not be appropriate or available, SWOG will consider alternative credentialing bodies on a case-by-case basis.

Information about FACT accreditation requirements is available through the FACT website at <https://learn.factglobal.org/> or from FACT at the following address:

FACT Accreditation Office
University of Nebraska Medical Center
986065 Nebraska Medical Center
Omaha, Nebraska 68198-6065

2. A facility seeking SWOG approval must submit a letter from the institution's Principal Investigator (PI) to the Chair of the Transplant and Cell Therapies Committee, with a copy to the SWOG Network Operations Center. The application must include the facility's current FACT accreditation certificate or letter, or documentation of other credentials acceptable to SWOG and the Committee, and the type of cellular therapy for which approval is requested (autologous transplantation, allogeneic transplantation, CAR-T therapy, or an applicable combination).

If the facility is an Affiliate of a SWOG member institution, the member institution's PI must also provide a letter confirming awareness of and approval for the Affiliate to serve as a SWOG-approved transplant facility. The Transplant and Cell Therapies Committee Chair will communicate the approval decision to the PI and facility.

3. To maintain approval, a facility must keep current the credentials applicable to the cellular therapy services it provides. These may include FACT accreditation for autologous or allogeneic stem cell transplantation or manufacturer-specific authorization or certification for an institutions that performs only CAR-T therapy. The facility should perform at least 20 combined cellular therapy procedures per calendar year, including autologous stem cell transplantation, allogeneic stem cell transplantation, and CAR-T therapy, as applicable.