SWOG http://swog.org

Policy Memorandum No. 27

Subject: Bone Marrow and Stem Cell Transplantation

Guidelines for Institution Approval

Departments Affected: All

Page 1 of 1 pages

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BONE MARROW AND STEM CELL TRANSPLANTATION GUIDELINES FOR INSTITUTION APPROVAL

Transplant facilities must have approval from SWOG and the Bone Marrow and Stem Cell Transplantation (BMSCT) Committee for performing bone marrow and stem cell transplants as part of protocol therapy for patients on Group treatment studies. Approval is granted for allogeneic transplant only, autologous transplant only, or both. To receive approval, the transplant facility must be accredited by the Foundation for the Accreditation of Cellular Therapy (FACT). Information about guidelines and procedures for accreditation may be obtained via the internet from the FACT website at http://www.factwebsite.org/ or from FACT at the following address:

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

A transplant facility must apply for SWOG bone marrow transplant facility approval in the form of a letter from the Principal Investigator (PI) of the institution to the Chairman of the BMSCT Committee (with a copy to the Operations Office). This letter should include a copy of the FACT letter granting the institution accreditation, and/or, preferably, a copy of the FACT accreditation certificate, and state whether approval is requested for allogeneic transplantation, autologous transplantation, or both. If the transplant facility is an Affiliate of the Group, an additional letter from the PI of the member institution must be submitted stating that the member institution is aware of their Affiliate's activities and approves of their request to be an approved BMT site. Upon receipt of the application letter, the BMSCT Committee Chair will grant approval and either the BMSCT Committee Chair or the Operations Office will communicate back to the Principal Investigator and the facility.

It is the goal of the BMSCT Committee to have all SWOG BMT centers FACT certified. As of 2000, all SWOG BMT centers that are not FACT certified should have at least applied for FACT inspection and accreditation in order to maintain the cooperative group transplant facility status.

3. To maintain approval, the transplant facility should maintain its FACT accreditation and perform at least 10 transplants per calendar year in the category approved (i.e., 10 allogeneic or 10 autologous) or a combined total of at least 20 for both forms of transplantation. Beginning with the first complete calendar year after receiving approval, the transplant facility should provide protocol treatment to at least five patients registered on SWOG bone marrow and stem cell transplant studies.