FOUNDATION FOR THE ACCREDITATION OF CELLULAR THERAPY
AT THE UNIVERSITY OF NEBRASKA MEDICAL CENTER

FACT APPLICANT GUIDELINES
Information for Hematopoietic Cellular Therapy Applicants

COMPLETING THE COMPLIANCE APPLICATION

- ❑ Review the Compliance Application. Assign someone to complete each section.
  - ❑ Generate required SOPs if not previously written.
  - ❑ Address the areas where you cannot document that you meet the Standard. Ensure that new protocols or procedures are written or existing protocols/procedures are revised to document compliance.

- ❑ The Compliance Application requires document uploads for some standards. Upload the required documents when requested. The *Document Submission Requirements form (6.6.008 Form 1)* lists the documents that must be uploaded.

- ❑ For each standard in the Compliance Application, a checkbox titled "Not Complete" is available to assist you with tracking which standards need additional evidence entered. You may keep a checkmark in this box until all required information has been entered.

- ❑ The Compliance Application cannot be submitted unless all questions have been answered, all required documents are uploaded, all "Not Complete" boxes have been unchecked, and the application has been signed by the Program Director (or Facility Director for facilities applying independently of a Clinical Program).

- ❑ Requests for information (RFIs) are generated by your assigned FACT coordinator or inspectors when additional information or documents are required.

- ❑ When the Compliance Application is considered complete by the FACT staff, you will be contacted for potential inspection dates. Please be prepared to give several sets of consecutive dates when all key personnel will be available for the inspection.

- ❑ Organizations applying for accreditation for the first time are given 12 months after submitting their online Eligibility Application to arrange their documentation, adjust processes to comply with the FACT Standards, and submit their Compliance Application. Organizations in the process of renewal accreditation should submit their Compliance Application 10 months prior to accreditation expiration. Timely responses are critical to achieve FACT accreditation.

PREPARING DATA MANAGEMENT DOCUMENTATION

- ☐ Programs audited by CIBMTR must submit [B9.1]:
  - ☐ CIBMTR Audit Results report from the most recent CIBMTR data audit performed.
  - ☐ Error rates for the last three (3) CIBMTR Data Audits [Critical Field Error Rate (CER), Random Field Error Rate, and Overall Error Rate] if not included in the most recent CIBMTR Audit Results report.
  - ☐ Corrective Action Plan (CAP) submitted at the last CIBMTR audit (including CAP related to systemic errors, even if the CER is ≤ 3.0%), if applicable.
    - ☐ Progress on implementation of the CAP, if applicable.
    - ☐ Internal audit addressing the effectiveness of the CAP, if applicable.
  - ☐ Continuous Process Improvement (CPI) letters from the past three (3) trimesters.

- ☐ Programs not audited by CIBMTR [B9.1]:
  - ☐ Programs with no B9 deficiencies for the last three (3) FACT on-site inspections submit internal data audits for the last three (3) years. Requirements will be sent to the program for preparation of a minor on-site data audit to be performed by a FACT clinical inspector.
  - ☐ Programs with B9 deficiencies provide dates of the last three (3) on-site FACT inspections and deficiencies received under B9 and submit the following:
    - ☐ CAP that FACT accepted to grant accreditation.
    - ☐ Evidence of implementation of CAP.
    - ☐ Most recent internal audit of data management to demonstrate improvement.
    - ☐ If the internal audit is determined to be sufficient, requirements will be sent to the program for preparation of a minor on-site data audit to be performed by a FACT clinical inspector.
    - ☐ If the CAP was not implemented or if the internal audit failed to demonstrate appropriate improvement, requirements will be sent to the program for preparation of a comprehensive on-site data audit to be performed by a FACT clinical inspector.
  - ☐ Programs applying for initial accreditation submit their most recent internal audit of data management.
    - ☐ If the internal audit is determined to be sufficient, requirements will be sent to the program for preparation of a minor on-site data audit to be performed by a FACT clinical inspector.
    - ☐ If the internal audit is not sufficient, requirements will be sent to the program for preparation of a comprehensive on-site data audit to be performed by a FACT clinical inspector.

BEFORE THE ON-SITE INSPECTION

- ❑ Schedule the on-site inspection for a date when ALL KEY PERSONNEL will be available. At a minimum, this includes the Program Director, the Collection Facility Director and Medical Director, and the Processing Facility Director and Medical Director. In addition, there must be designated personnel available throughout the day to accompany each of the inspectors and assist as needed, and at least one person familiar with charts and data to assist with chart review.

- ❑ Schedule the on-site inspection on a day that is acceptable for all sites (e.g., hospitals, off-site storage facilities, etc.). The inspectors MUST visit each site to be included in the accredited organization and talk to key personnel at each of these sites. This may require clearance from an administrator, Director of Nursing, etc.

- ❑ If inspector travel costs exceed historical averages, your organization may be assessed a travel surcharge.

- ❑ Provide the FACT Office with the name of a convenient reasonable hotel.

- ❑ The Program Director or designee should communicate the following information to the Team Leader:
  - ❑ Provide inspectors information about how to get to the facility. It is acceptable to arrange to pick up the inspectors at their hotel. If this is not possible, provide them information about available transportation and estimate the time that will be required to reach your facility.
  - ❑ Inform the team of where you want them to meet upon arrival at your facility.

- ❑ Reserve a room for the inspectors for the entire day where they can review charts, procedure manuals, and documents. In addition, for the initial meeting and the exit interview, reserve a room that is adequate in size to accommodate the entire inspection team, key personnel, and others the applicant wishes to invite.

- ❑ Arrange to provide a modest business lunch for the inspection team. Most teams will want to utilize the lunch hour, at least in part, as a working lunch.

- ❑ Arrange for a computer(s) with internet access that inspectors can use throughout the inspection day, or, at a minimum, during the lunch hour. Notify the inspection team of the computer arrangements that have been made prior to the inspection.

PREPARING ON-SITE DOCUMENTATION

- ❑ Compile documents and shadow records that support compliance for each FACT standard.

- ❑ Organize the documents and records by standard. Label the documents with the standard they address.

- ❑ Create a crosswalk between each standard and the document(s) that supports it for the inspector to reference while onsite. The *HCT Self-Assessment Tool (6.6.008 Form 6)* may be useful for documenting the crosswalk. This will promote inspection efficiency.

- ❑ Review the FACT website for additional information regarding preparation for the inspection day. Though not required, two specific webinars are suggested: *Quality Organization Virtual Roundtable* and *Organizational Self-Assessments*.

DURING THE ON-SITE INSPECTION

- ❑ The initial interview should include all key personnel of the cellular therapy program and members of the inspection team.

- ❑ The Program Director should plan to introduce the members of the cellular therapy program to the inspectors, and present information to the inspection team about the program that may be helpful, especially information that was not required on the Compliance Application. It is helpful to review the structure of the organization and the location of the applicant sites, particularly if these issues are complex and/or there are any off-site locations. This presentation should not exceed 10-15 minutes.

- ❑ A knowledgeable personnel member must be available to the inspector at all times to answer questions, find documents or procedures, assist with chart navigation, etc. Appropriate individuals would include a data manager, collection center nurse supervisor, and laboratory supervisor.

- ❑ The following documents should be immediately available for the inspectors to review:
  - ❑ Quality assessment and improvement documents, including internal audits performed by the organization.
  - ❑ SOPs for the clinical, collection, and processing areas.
  - ❑ Documentation of physician and staff training and continued competency; including documentation of current license(s), contracts, and other documents that have expired between time of submission and the inspection date.
  - ❑ Documentation of proficiency testing.
  - ❑ Documents demonstrating quality improvement and assessment including audits and validations.
  - ❑ IRB approval documentation, if appropriate.
  - ❑ Validation of computer system if the system is within the control of the facility requesting accreditation and is considered a critical electronic record system (Apheresis and Processing Facilities).

- ❑ The Inspection Team Leader will provide a schedule for the on-site inspection. If you do not have a detailed schedule one week before the on-site inspection, the Program Director should contact the Team Leader and/or the FACT Office to obtain it. The Program Director is responsible for disseminating the inspection agenda to all key personnel within the program. The Program Director may contact the Team Leader at any time to discuss the schedule or specifics of the inspection.
  - ❑ Be prepared to have someone escort the inspectors to each of the sites. If there are distant sites, be prepared to transport the inspectors there and accompany them at those sites.
  - ❑ Inspectors will need to talk to key personnel at each of the sites. Be certain that they will be available during the scheduled time of the visit for each of the sites. For example, in the Clinical Program, the nurse supervisor, social worker, pharmacy staff, and any additional personnel who are needed to answer specific questions on the checklist need to be available.

- ❑ Be prepared to gather additional documentation as requested by the team during the time that they are present in your facility.

- ❑ Assume that the inspectors will want some closed-session time during the lunch hour, but they may also wish to use a portion of this time to communicate with the applicant. Be available. Be sure to check with the inspection team for questions or concerns related to completing the inspection visit before you leave for your own lunch break.

- ❑ At the end of the inspection, the inspectors may wish to meet privately with the Program Director and/or designated directors if there are issues to be raised that may be of a sensitive or confidential nature. Be available for this meeting.

- ❑ The purpose of the Exit Interview is to allow the inspectors to summarize their major findings and to outline the remainder of the accreditation process. Not all citations are discussed at the Exit Interview. Remember, citations are reviewed by the FACT Accreditation Coordinators and the Accreditation Committee, and the final decision on accreditation status will be determined by the Board of Directors. The inspectors have specifically been instructed not to speculate on the accreditation status your organization will attain after Accreditation Committee review.

- ❑ The Program Director and other individuals authorized on your Compliance Application are notified by email when an Accreditation Committee decision has been reached. Consult the timeline for these processes, and feel free to contact the FACT Office if you have questions or need information.

- ❑ Additional documentation cannot be submitted until the Accreditation Committee has reviewed your organization's application and a request for information has been initiated in the Accreditation Portal.

AFTER THE ON-SITE INSPECTION

- ❑ Your program will receive a final inspection summary including the accreditation decision. All citations must be adequately addressed prior to accreditation; some citations contain multiple items that need to be summarized.

- ❑ Do not make any changes to your organization until you have received the final inspection summary.

- ❑ If you have any questions regarding a citation, request clarification from your FACT Accreditation Coordinator.

- ❑ Please complete the evaluations from the FACT Office regarding the inspection process. Your comments, suggestions, and observations are important for continued improvement in the inspection and accreditation processes.