HEMATOPOIETIC CELLULAR THERAPY PRODUCT COLLECTION, PROCESSING, AND ADMINISTRATION

DOCUMENT SUBMISSION REQUIREMENTS

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

FACT-JACIE International Standards for Hematopoietic Cellular Therapy Product Collection, Processing and Administration

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HEMATOPOIETIC CELLULAR THERAPY
DOCUMENT SUBMISSION REQUIREMENTS

Copies of the following items are required prior to the on-site inspection, and must be uploaded via the online Compliance Application within the FACT Accreditation Portal. For additional information, see the referenced standard and the accompanying information in the Accreditation Manual.

Do not use patient names on the documents submitted. All submitted documents, policies, and procedures must be in English unless otherwise specified. If your facility utilizes electronic records, hard copies of the primary source data must be assembled and flagged before the inspection, and must be ready for inspector review on-site. Those items not provided for inspector review by the end of the on-site inspection will be marked as a deficiency.

The documents listed in the following pages are only a subset of what inspectors will need to review. Documentation of compliance with each standard must be readily available to the inspectors during the on-site inspection. See the Applicant Guidelines on the FACT website at www.factwebsite.org for tips on how to prepare on-site documentation.

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CLINICAL PROGRAM DOCUMENTATION

Clinical Program Director(s)

☐ Copy of current license or certificate to practice medicine in the jurisdiction in which the program is located for each Program Director. If the license or certificate is in a language other than English, include a general description in English. [B3.1.1]

☐ Copy(ies) of specialty certification(s) for each Clinical Program Director. Documentation of specialty certification in the U.S. can be accessed from ABIM, ABMS, ABP, and AOA. If the documentation is in a language other than English, include a general description in English. [B3.1.1]

or

Physicians who received all or part of their medical and specialty training outside of the United States or Canada must submit documentation of training and experience and a copy of any registration or certification in a relevant specialty. Documentation should describe the specifics of the training received, and may be submitted in the form of curriculum vitaes, letters from the directors of the referenced training programs or current department chair, or other similar information. If the documentation is in a language other than English, include a general description in English. [B3.1.1]

☐ Curriculum vitae for each Clinical Program Director. If one individual serves as a director for multiple facilities, submit this individual's curriculum vitae whenever applicable. If the documentation is in a language other than English, include a summary in English. [B3.1.2]

☐ Documentation of at least ten (10) hours of participation per year for each Clinical Program Director in educational activities related to cellular therapy, including hematopoietic progenitor cell (HPC) transplantation, since the previous date of accreditation. Complete and upload the Educational Activities Form (Appendix A) or submit other documentation that contains the equivalent information for each activity: [B3.1.6]

- ☐ Date of activity
- ☐ Title of activity
- ☐ Type of activity (for example, webinar, meeting, grand round, etc.)
- ☐ Topic of activity (for example, hematology, cell transplantation, etc.)
- ☐ Approximate number of hours of activity

☐ Complete and upload the HCT Training and Competency Form (Appendix B) or submit the following for each Clinical Program Director: [B3.3]

- ☐ Documentation of specific training and competency in the skills listed in Standard B3.3.3.
- ☐ For programs requesting accreditation for allogeneic transplantation, documentation of specific training and competency in each of the skills listed in Standard B3.3.4.
- ☐ Documentation of knowledge in the skills listed in Standard B3.3.5.

Attending Physicians (specify adult and pediatric programs if applicable):

☐ Copy of current license or certificate to practice medicine in the jurisdiction in which the program is located for each attending physician. If the license or certificate is in a language other than English, include a general description in English. [B3.2.1]

☐ Copy(ies) of specialty certification(s) for each attending physician, if appropriate. Documentation of specialty certification in the U.S. can be accessed from ABIM, ABMS, ABP, and AOA. If the documentation is in a language other than English, include a general description in English. [B3.2.1]

or

Physicians who received all or part of their medical and specialty training outside of the United States or Canada must submit documentation of training and experience and a copy of any registration or certification in a relevant specialty. Documentation should describe the specifics of the training received, and may be submitted in the form of curriculum vitaes, letters from the directors of the referenced training programs or current department chair, or other similar information. If the documentation is in a language other than English, include a general description in English. [B3.2.1]

☐ Documentation of at least ten (10) hours of participation per year for each attending physician in educational activities related to cellular therapy, including HPC transplantation, since the previous accreditation date. Complete and upload the Educational Activities Form (Appendix A) or submit other documentation that contains the equivalent information for each activity: [B3.2.2]

- ☐ Date of activity
- ☐ Title of activity
- ☐ Type of activity (for example, webinar, meeting, grand round, etc.)
- ☐ Topic of activity (for example, hematology, cell transplantation, etc.)
- ☐ Approximate number of hours of activity

☐ Complete and upload the HCT Training and Competency Form (Appendix B) or submit the following for each attending physician: [B3.3]

- ☐ Documentation of specific training and competency in the skills listed in Standard B3.3.3.
- ☐ For programs requesting accreditation for allogeneic transplantation, documentation of specific training and competency in each of the skills listed in Standard B3.3.4.
- ☐ Documentation of knowledge in the skills listed in Standard B3.3.5.

Physicians-in-Training

☐ If physicians-in-training are receiving their training within a program accredited by the Accreditation Council for Graduate Medical Education (ACGME) or equivalent, documentation that physicians-in-training are residents or fellows in an accredited graduate medical education program. [B3.4.2]

☐ For physicians-in-training not in an accredited graduate medical education program, copy of current license or certificate to practice medicine in the jurisdiction in which the program is located for each physician-in-training. If the license or certificate is in a language other than English, include a general description in English. [B3.4.1]

☐ For physicians-in-training not in an accredited graduate medical education program, complete and upload the HCT Training and Competency Form (Appendix B) or submit the following for each physician-in-training: [B3.4.2]

- ☐ Documentation of specific training and competency development in the skills listed in Standard B3.3.3.
- ☐ For programs requesting accreditation for allogeneic transplantation, documentation of specific training and competency development in each of the skills listed in Standard B3.3.4.

Advanced Practice Providers/Professionals (APPs)

☐ Copy of current license or certificate to practice as required in the jurisdiction in which the program is located for each APP. If the license or certificate is in a language other than English, include a general description in English. [B3.5.1]

☐ Complete and upload the HCT Training and Competency Form (Appendix B) or submit the following for each APP in the transplant-related cognitive and procedural skills that he/she routinely practices: [B3.5.2]

- ☐ Documentation of specific training and competency in the skills listed in Standard B3.3.3 for each APP as applicable.
- ☐ For programs requesting accreditation for allogeneic transplantation, documentation of specific training and competency in each of the skills listed in Standard B3.3.4 for each APP as applicable.

☐ Documentation of at least ten (10) hours of participation per year for each APP in educational activities related to cellular therapy, including HPC transplantation, since the previous accreditation date. Complete and upload the Educational Activities Form (Appendix A) or submit other documentation that contains the equivalent information for each activity: [B3.5.3]

- ☐ Date of activity
- ☐ Title of activity
- ☐ Type of activity (for example, webinar, meeting, grand round, etc.)
- ☐ Topic of activity (for example, hematology, cell transplantation, etc.)
- ☐ Approximate number of hours of activity

Nurses

☐ Submit a description of the processes for nursing orientation, training, and competency assessment in the field of cellular therapy, including HPC transplantation. [B3.7.3]

Pharmacists

☐ Copy of current license or certificate to practice as required in the jurisdiction in which the program is located for each designated blood and marrow transplant (BMT) pharmacist. If the license or certificate is in a language other than English, include a general description in English. [B3.8.1]

☐ Documentation of at least ten (10) hours of participation per year for each BMT-designated pharmacist in educational activities related to cellular therapy, including HPC transplantation, since the previous accreditation date. Complete and upload the Educational Activities Form (Appendix A) or submit other documentation that contains the equivalent information for each activity: [B3.8.4]

- ☐ Date of activity
- ☐ Title of activity
- ☐ Type of activity (for example, webinar, meeting, grand round, etc.)
- ☐ Topic of activity (for example, hematology, cell transplantation, etc.)
- ☐ Approximate number of hours of activity

Consulting Physicians

Submit a photocopy of board certification or documentation of training and experience for at least one (1) specialist in each specialty field. For programs that perform pediatric transplantation, documentation of specialist certification or training for consultants qualified to manage pediatric patients must be submitted. Documentation of specialty certification in the U.S. can be accessed from ABIM, ABMS, ABP, ABPN, the ABR, the ABA, and AOA. If the documentation is in a language other than English, include a general description in English. [B3.7]

Peds	Adult		Peds	Adult	
☐	☐	Surgery [B3.9.1.1]	☐	☐	Pulmonary Medicine [B3.9.1.2]
☐	☐	Intensive Care [B3.9.1.3]	☐	☐	Gastroenterology [B3.9.1.4]
☐	☐	Nephrology [B3.9.1.5]	☐	☐	Infectious Disease [B3.9.1.6]
☐	☐	Cardiology [B3.9.1.7]	☐	☐	Pathology [B3.9.1.8]
☐	☐	Psychiatry [B3.9.1.9]	☐	☐	Radiology [B3.9.1.10]
☐	☐	Radiation Oncology [B3.9.1.11]	☐	☐	Transfusion Medicine* [B3.9.1.12]
☐	☐	Neurology [B3.9.1.13]	☐	☐	Ophthalmology [B3.9.1.14]
☐	☐	Obstetrics/Gynecology [B3.9.1.15]	☐	☐	Dermatology [B3.9.1.16]
			☐	☐	Palliative and end of life care [B3.9.1.17]

**The transfusion medicine requirement is separate from the pathology requirement.*

Clinical Quality Manager

☐ Documentation of at least ten (10) hours of participation per year for each Clinical Quality Manager in educational activities related to cellular therapy and/or quality management, including HPC transplantation, since the previous accreditation date. Complete and upload the Educational Activities Form (Appendix A) or submit other documentation that contains the equivalent information for each activity: [B3.10.2]

- ☐ Date of activity
- ☐ Title of activity
- ☐ Type of activity (for example, webinar, meeting, grand round, etc.)
- ☐ Topic of activity (for example, hematology, cell transplantation, etc.)
- ☐ Approximate number of hours of activity

Other Clinical Documentation

☐ A completed Clinical Facility Grid. For initial accreditation, enter data for the previous 12 months. For renewal accreditation, enter data from the start of the current accreditation cycle. [B1.1]

☐ General physical floor plan of all program facilities (clinical, marrow collection, apheresis collection, processing). Label all floors of the building(s) that are used for transplant activities. If the floor plan or diagram is labeled in a language other than English, include a general description of the floor plan or diagram in English. [B1.1]

☐ A map of the overall organization that includes all facilities. If the map is labeled in a language other than English, include a general description of the floor plan or diagram in English. [B1.1]

☐ If cellular therapy products are received directly by the Clinical Program from a third-party provider, an example or template of a written agreement that defines the following responsibilities at a minimum for each applicable cellular therapy product: [B1.2.1]

- ☐ Traceability and chain of custody of cellular therapy products. [B1.2.1.1]
- ☐ Cellular therapy product storage and distribution. [B1.2.1.2]
- ☐ Verification of cellular therapy product identity. [B1.2.1.3]

☐ A copy of the certificate for each licensure, registration, or accreditation required by the appropriate governmental authorities. Include, as appropriate, certificates for accreditation of in-patient facilities such as the Joint Commission, American Osteopathic Association, Det Norske Veritas Healthcare, Australian Council on Healthcare Standards, Canadian Council on Health Services Accreditation, or other certification required by the appropriate governmental authority. If the licensure, registration, or accreditation is in a language other than English, include a general description of the document in English. [B1.3.1]

☐ A complete recipient list, in Excel or similar format, since the date of your previous accreditation (renewal applicants) or from the twelve months preceding submission of the Compliance Application (initial applicants). Include unique patient identifier, date of transplant, diagnosis, source of cells (marrow, peripheral blood, cord blood), type of transplant (autologous, allogeneic), type of recipient (adult, pediatric), and CIBMTR ID (if applicable). Per United States HIPAA guidelines, do not include any direct identifiers including patient names. [B1.5]

- ☐ For programs requesting allogeneic transplantation accreditation, submit a copy of the HLA laboratory's current ASHI, EFI, or other appropriate accreditation certificate, including documentation of certification for DNA-based typing. [B2.11]
  - ☐ For ASHI accreditation:
    - ☐ Include the accreditation letter in addition to the certificate
    - ☐ If the laboratory is not ASHI-accredited for HSC/BM transplantation, include documentation of HLA expertise available within the Clinical Program for selecting the best matched donor for the recipient.

- ☐ For programs requesting allogeneic transplantation accreditation, submit a copy of the certificate of laboratory accreditation for techniques used in chimerism testing. [B2.12]

- ☐ Copy of the Clinical Program's Quality Management Plan that includes all requirements listed in B4. [B4.2]

- ☐ Copy of the organizational chart of key positions and functions within the cellular therapy program, including clinical, collection, and processing. [B4.3]

- ☐ Standard operating procedure for development, approval, implementation, review, revision, and archival of all critical documents. [B4.5.1]

- ☐ Standard operating procedure(s) that outlines a standardized format for policies, procedures, worksheets, and forms and required elements of each procedure. [B4.5.3.1 and B5.3]

- ☐ Evidence of a completed outcome analysis, such as a report of conclusions, meeting minutes, or completed forms. [B4.7]

- ☐ Corrective action plan in response to clinical outcomes below expected ranges, if applicable:
  - ☐ 100-day survival that does not meet center-defined benchmarks. [B4.7.3.2]
  - ☐ One-year survival that does not meet the expected range when compared to national or international outcome data. Programs in the U.S. must assess one-year survival using the CIBMTR Transplant Center Survival Report. Programs in other regions must define what data it uses for comparison. [B4.7.5.1]

- ☐ Schedule of audits that includes dates and subjects of audits already performed and audits planned for the future. At a minimum, the audits listed under B4.8.3 must be included. [B4.8]

- ☐ The policy or procedure for qualification of critical reagents, supplies, equipment, and facilities used for the marrow collection procedure. [B4.13]

- ☐ The policy or procedure for validation and/or verification of the marrow collection procedure. [B4.13]

- ☐ A validation and/or verification of the marrow collection procedure that includes: [B4.13]
  - ☐ A summary of the validation and/or verification plan
  - ☐ Number of data points used
  - ☐ Acceptance criteria
  - ☐ Summary of results and conclusion
  - ☐ Review and approval of the plan, results, and conclusion

- ☐ Table of Contents from the Clinical Program Standard Operating Procedures Manual that includes the title, identifier, and version for each policy and procedure. [B5.2]

- ☐ Unsigned samples of all allogeneic and autologous donor consent forms and the procedure for consenting to be a cellular therapy product donor that contains all required elements. [B6.2]

- ☐ Unsigned samples of recipient consent forms and the procedure for consenting to receive cellular therapy. [B7.1]

- ☐ Policy for determining the appropriate volume and the appropriate dose of red blood cells, cryoprotectants, and other additives. [B7. 6.1]

- ☐ Policy or procedure for preparing cord blood units for administration. [B7.6.3]

- ☐ Policy or procedure addressing the administration of immune effector cells and management of complications. [B7.10]

- ☐ Data management [B9]:
  - ☐ Programs audited by CIBMTR:
    - ☐ Error rates for the last three (3) CIBMTR Data Audits: Critical Field Error Rate (CER), Random Field Error Rate, and Overall Error Rate
      - ☐ Corrective Action Plan (CAP) submitted at the last CIBMTR audit, if applicable (including CAPs related to systemic errors even if the CER is ≤3.0%)
      - ☐ Progress on implementation of the CAP, if applicable
      - ☐ Internal audit addressing the effectiveness of the CAP, if applicable
    - ☐ Continuous Process Improvement rates for the past three (3) trimesters

- ☐ Programs not audited by CIBMTR [B9]:
  - ☐ 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 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 the deficiencies received under B9.
    - ☐ Submit a CAP that FACT accepted to grant accreditation.
    - ☐ Submit evidence of implementation of CAP.
    - ☐ Submit most recent internal audit of data management to demonstrate improvement.
    - ☐ If the internal audit is determined to be sufficient, requirements will be sent to programs 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 programs for preparation of a comprehensive on-site data audit to be performed by a FACT clinical inspector.
  - ☐ Programs applying for initial accreditation
    - ☐ Submit most recent internal audit of data management to demonstrate improvement.
    - ☐ If the internal audit is determined to be sufficient, requirements will be sent to programs 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 programs for preparation of a comprehensive on-site data audit to be performed by a FACT clinical inspector.

MARROW COLLECTION FACILITY DOCUMENTATION

Marrow Collection Facility Medical Director

☐ Copy of current license or certificate to practice medicine in the jurisdiction in which the program is located for each Marrow Collection Facility Medical Director. If the license or certificate is in a language other than English, include a general description in English. [CM3.1.1]

☐ Curriculum vitae for each Marrow Collection Facility Medical Director. If one individual serves as a director for multiple facilities, submit this individual's curriculum vitae whenever applicable. If the documentation is in a language other than English, include a summary in English. [CM 3.1.1 and CM3.1.3]

☐ Documentation of at least ten (10) hours of participation per year for each Marrow Collection Facility Medical Director in educational activities related to cellular therapy, including HPC transplantation and marrow collection, since the previous accreditation date. Complete and upload the Educational Activities Form (Appendix A) or submit other documentation that contains the equivalent information for each activity: [CM3.1.5]

- ☐ Date of activity
- ☐ Title of activity
- ☐ Type of activity (for example, webinar, meeting, grand round, etc.)
- ☐ Topic of activity (for example, hematology, apheresis, etc.)
- ☐ Approximate number of hours of activity

Marrow Collection Facility Quality Manager

☐ Documentation of at least ten (10) hours of participation per year for each Marrow Collection Facility Quality Manager in educational activities related to cellular therapy, cell collection, and/or quality management, including HPC transplantation, since the previous accreditation date. Complete and upload the Educational Activities Form (Appendix A) or submit other documentation that contains the equivalent information for each activity: [CM3.2.2]

- ☐ Date of activity
- ☐ Title of activity
- ☐ Type of activity (for example, webinar, meeting, grand round, etc.)
- ☐ Topic of activity (for example, hematology, apheresis, etc.)
- ☐ Approximate number of hours of activity

Other Marrow Documentation

☐ A completed Collection Facility/Location Grid. For initial accreditation, enter data for the previous 12 months. For renewal accreditation, enter data from the start of the current accreditation cycle. [CM1.1]

☐ A map of the overall organization that includes all facilities. If the map is labeled in a language other than English, include a general description of the floor plan or diagram in English. [CM1.1]

☐ A physical floor plan of all facilities. Label all floors of the building(s) that are used for cellular therapy related activities. If the floor plan or diagram is labeled in a language other than English, include a general description of the floor plan or diagram in English. [CM1.1]

☐ Certificate of licensure, registration, or accreditation required by the appropriate governmental authority for the activities performed. Include, as appropriate, certificates for accreditation of in-patient facilities such as the Joint Commission, American Osteopathic Association, Det Norske Veritas Healthcare, Australian Council on Healthcare Standards, Canadian Council on Health Services Accreditation, or other certification required by the appropriate governmental authority. If the licensure, registration, or accreditation is in a language other than English, include a general description of the document in English. [CM1.3.1]

☐ If the Marrow Collection Facility operates independently of the clinical program: [CM4.1 and CM5.2]

- ☐ Copy of the Quality Management Plan that includes all requirements listed in B4. [B4.2]
- ☐ Copy of the organizational chart of key positions and functions within the organization. [B4.3]
- ☐ Standard operating procedure for development, approval, implementation, review, revision, and archival of all critical documents and procedure that outlines a standardized format for policies, procedures, worksheets, and forms. [B4.5.1 and B4.5.3.1]
- ☐ Schedule of audits that includes dates and subjects of audits already performed and audits planned for the future. [B4.8]
- ☐ The policy or procedure for qualification of critical reagents, supplies, equipment, and facilities used for the marrow collection procedure. [B4.13]
- ☐ The policy or procedure for the validation and/or verification of bone marrow collection. [B4.13]

- ☐ A validation and/or verification of the marrow collection procedure that includes [B4.13]:
  - ☐ A summary of the validation and/or verification plan
  - ☐ Number of data points used
  - ☐ Acceptance criteria
  - ☐ Summary of results and outcomes
  - ☐ Review and approval of the plan, results, and conclusion

- ☐ Table of Contents from the Marrow Collection Facility Standard Operating Procedures Manual that includes the title, identifier, and version for each policy and procedure. [B5.2]

- ☐ Standard operating procedure(s) that outlines required elements of each procedure. [CM5.3]

- ☐ Unsigned samples of all allogeneic and autologous donor consent forms and the procedure for consenting for the marrow collection procedure that contains all required elements. [CM6.2]

- ☐ Completed examples of each type of label used by the Marrow Collection Facility. Do not use any direct patient identifiers. Mock identifiers and names must be used. If the labels are in a language other than English, include a general description of the label elements in English. [CM7.4.1]
  - ☐ Primary collection container label, applied on completion of collection of products for allogeneic use. [Cellular Therapy Standards Appendix II]
  - ☐ Primary collection container label applied on completion of collection of products for autologous use. [Cellular Therapy Standards Appendix II]
  - ☐ Any partial labels applied by the Collection Facility. [Cellular Therapy Standards Appendix II]
  - ☐ Labels applied to inner and outer shipping containers for products shipped or transported on public roads. [Cellular Therapy Standards Appendix III]

- ☐ An SOP for labeling that includes when biohazard and/or warning labels are used, including: [CM7.4.2, Cellular Therapy Standards Appendix II]
  - ☐ Biohazard legend
  - ☐ Statement "NOT EVALUATED FOR INFECTIOUS SUBSTANCES"
  - ☐ Statement "WARNING: Advise Patient of Communicable Disease Risks"
  - ☐ Statement "WARNING: Reactive Test Results for [name of disease agent or disease]"
  - ☐ Statement "FOR AUTOLOGOUS USE ONLY"

- ☐ Documentation that accompanies the cellular therapy product at distribution and a policy or procedure that discusses the documentation that is distributed with the product. [CM7.4.4, Cellular Therapy Appendix IV]

□ Where cellular therapy products are distributed directly from the Marrow Collection Facility to the Clinical Program If the labels are in a language other than English, include a general description of the label elements in English. [CM12.1]:

- □ Completed examples of autologous and allogeneic labels attached to the product prior to distribution. Do not use any direct patient identifiers. Mock identifiers and names must be used. [Cellular Therapy Standards Appendix II]
- □ Completed examples of labels applied to inner and outer containers for products shipped or transported on public roads. Do not use any direct patient identifiers. Mock identifiers and names must be used. [Cellular Therapy Standards Appendix III]
- □ Documentation that accompanies the cellular therapy product at distribution. [D7.4.5, D11.1.4 and Cellular Therapy Standards Appendix IV]

APHERESIS COLLECTION FACILITY DOCUMENTATION

Apheresis Collection Facility Director

☐ Curriculum vitae for each Apheresis Collection Facility Director. If one individual serves as a director for multiple facilities, submit this individual's curriculum vitae whenever applicable. If the documentation is in a language other than English, include a summary in English. [C3.1.1]

☐ Documentation of at least ten (10) hours of participation per year for each Apheresis Collection Facility Director in educational activities related to cellular therapy, including HPC transplantation and apheresis, since the previous accreditation date. Complete and upload the Educational Activities Form (Appendix A) or submit other documentation that contains the equivalent information for each activity: [C3.1.5]

- ☐ Date of activity
- ☐ Title of activity
- ☐ Type of activity (for example, webinar, meeting, grand round, etc.)
- ☐ Topic of activity (for example, hematology, apheresis, etc.)
- ☐ Approximate number of hours of activity

Apheresis Collection Facility Medical Director

☐ Copy of current license or certificate to practice medicine in the jurisdiction in which the program is located for each Apheresis Collection Facility Medical Director. If the license or certificate is in a language other than English, include a general description in English. [C3.2.1]

☐ Curriculum vitae for each Apheresis Collection Facility Medical Director. If one individual serves as a director for multiple facilities, submit this individual's curriculum vitae whenever applicable. If the documentation is in a language other than English, include a summary in English. [C3.2.1 and C3.2.3]

☐ Documentation of at least ten (10) hours of participation per year for each Apheresis Collection Facility Medical Director in educational activities related to cellular therapy, including HPC transplantation and apheresis, since the previous accreditation date. Complete and upload the Educational Activities Form (Appendix A) or submit other documentation that contains the equivalent information for each activity: [C3.2.5]

- ☐ Date of activity
- ☐ Title of activity
- ☐ Type of activity (for example, webinar, meeting, grand round, etc.)
- ☐ Topic of activity (for example, hematology, apheresis, etc.)
- ☐ Approximate number of hours of activity

Apheresis Quality Manager

☐ Documentation of at least ten (10) hours of participation per year for each Apheresis Collection Facility Quality Manager in educational activities related to cellular therapy, cell collection, and/or quality management, including HPC transplantation, since the previous accreditation date. Complete and upload the Educational Activities Form (Appendix A) or submit other documentation that contains the equivalent information for each activity: [C3.3.2]

- ☐ Date of activity
- ☐ Title of activity
- ☐ Type of activity (for example, webinar, meeting, grand round, etc.)
- ☐ Topic of activity (for example, hematology, apheresis, etc.)
- ☐ Approximate number of hours of activity

Other Apheresis Documentation

☐ A completed Collection Facility/Location Grid. For initial accreditation, enter data for the previous 12 months. For renewal accreditation, enter data from the start of the current accreditation cycle. [C1.1]

☐ A map of the overall organization that includes all facilities. If the map is labeled in a language other than English, include a general description of the floor plan or diagram in English. [C1.1]

☐ Physical floor plans of all facilities. Label all floors of the building(s) that are used for cellular therapy related activities. If the floor plan(s) or diagram is labeled in a language other than English, include a general description of the floor plan or diagram in English. [C1.1]

☐ Certificate of licensure, registration, or accreditation required by the appropriate governmental authority for the activities performed. U.S. facilities must submit a copy of the validated FDA registration for Human Cells, Tissues, and Cellular and Tissue Based Products (Form 3356). Facilities in other countries must submit certification required by the appropriate governmental authority. If the licensure, registration, or accreditation is in a language other than English, include a general description of the document in English. [C1.3.1]

☐ Copy of the Apheresis Collection Facility's Quality Management Plan that includes all requirements listed in C4. [C4.2]

☐ Copy of the organizational chart of key personnel and functions within the Apheresis Collection Facility [C4.3].

☐ Standard operating procedure for development, approval, implementation, review, revision, and archival of all policies and procedures. [C4.5.1]

- ☐ Standard operating procedure(s) that outlines a standardized format for policies, procedures, worksheets, forms, and labels and required elements of each individual procedure. [C4.5.3.1 and C5.3]

- ☐ Evidence of a completed outcome analysis, such as a report of conclusions, meeting minutes, or completed forms. [C4.7]

- ☐ Schedule of audits that includes dates and subjects of audits already performed and audits planned for the future. At a minimum, the audits listed in C4.8.3 must be included. [C4.8]

- ☐ The policy or procedure for qualification of critical reagents, supplies, equipment, and facilities used for critical procedures. [C4.13]

- ☐ The policy or procedure for the validation and/or verification of critical procedures. [C4.14]

- ☐ A summary of one completed validation or verification study of a critical procedure of the Apheresis Collection Facility that includes: [C4.14]
  - ☐ A summary of the validation and/or verification plan
  - ☐ Number of data points to be used
  - ☐ Acceptance criteria
  - ☐ Summary of results and conclusions
  - ☐ Review and approval of the plan, results, and conclusion

- ☐ Table of Contents from the Apheresis Collection Facility Standard Operating Procedures Manual that includes the title, identifier, and version for each policy and procedure. [C5.2]

- ☐ Unsigned samples of all allogeneic and autologous donor consent forms and the procedure for consenting for the apheresis collection procedure that contains all required elements. [C6.2]

- ☐ Completed examples of each type of label used by the Apheresis Collection Facility. <u>Do not use any direct patient identifiers.</u> Mock identifiers and names must be used. If the labels are in a language other than English, include a general description of the label elements in English. [C7.4.1, Cellular Therapy Standards Appendix II]
  - ☐ Primary collection container label, applied on completion of collection of products for allogeneic use [Cellular Therapy Standards Appendix II]
  - ☐ Primary collection container label applied on completion of collection of products for autologous use [Cellular Therapy Standards Appendix II]
  - ☐ Any partial labels applied by the Collection Facility [Cellular Therapy Standards Appendix II]
  - ☐ Labels applied to inner and outer shipping containers for products shipped or transported on public roads. [Cellular Therapy Standards Appendix III]

☐ An SOP for labeling that includes when biohazard and/or warning labels are used, including: [C7.4.2, Cellular Therapy Standards Appendix II]
- ☐ Biohazard legend
- ☐ Statement "NOT EVALUATED FOR INFECTIOUS SUBSTANCES"
- ☐ Statement "WARNING: Advise Patient of Communicable Disease Risks"
- ☐ Statement "WARNING: Reactive Test Results for [name of disease agent or disease]"
- ☐ Statement "FOR AUTOLOGOUS USE ONLY"]

☐ Documentation that accompanies the cellular therapy product at distribution and a policy or procedure that discusses the documentation that is distributed with the product. [C7.4.4, Cellular Therapy Standards Appendix IV]

☐ Current list of critical electronic record systems under the control of the Apheresis Collection Facility. Complete and upload the Critical Electronic Record Systems form (Appendix C) or submit other documentation that contains the equivalent information for each critical record system. [C11.6.1]

☐ Where cellular therapy products are distributed directly from the Apheresis Collection Facility to the Clinical Program: If the labels are in a language other than English, include a general description of the label elements in English. [C12.1]
- ☐ Completed examples of autologous and allogeneic labels attached to the product prior to distribution. Do not use any direct patient identifiers. Mock identifiers and names must be used. [Cellular Therapy Standards Appendix II]
- ☐ Completed examples of labels applied prior to transport or shipping of cellular therapy products, including inner and outer container labels. Do not use any direct patient identifiers. Mock identifiers and names must be used. [Cellular Therapy Standards Appendix III]
- ☐ Documentation that accompanies the cellular therapy product at distribution. [D7.4.5, D11.1.4, and Cellular Therapy Standards Appendix IV]

Electronic Record Systems:

For critical electronic record systems used for record keeping, documentation of validation of the systems must be available on-site as well as a qualified individual to review the documentation with the inspector. Documentation should demonstrate compliance with the following Standards:

☐ Validated procedures for and documentation of: [C11.6.9]
- ☐ Training and continued competency of personnel in systems use [C11.6.9.1]
- ☐ Monitoring of data integrity [C11.6.9.2]
- ☐ Back-up of the electronic records system on a regular schedule [C11.6.9.3]
- ☐ System assignment of unique identifiers [C11.6.9.4]

PROCESSING FACILITY DOCUMENTATION

Processing Facility Director

☐ Curriculum vitae for each Processing Facility Director. If one individual serves as a director for multiple facilities, submit this individual's curriculum vitae whenever applicable. If the documentation is in a language other than English, include a summary in English. [D3.1.1]

☐ Documentation of at least ten (10) hours of participation per year for each Processing Facility Director in educational activities related to cellular therapy, including HPC transplantation and processing, since the previous date of accreditation. Complete and upload the Educational Activities Form (Appendix A) or submit other documentation that contains the equivalent information for each activity: [D3.1.3]

- ☐ Date of activity
- ☐ Title of activity
- ☐ Type of activity (for example, webinar, meeting, grand round, etc.)
- ☐ Topic of activity (for example, hematology, cell processing, etc.)
- ☐ Approximate number of hours of activity

Processing Facility Medical Director

☐ Copy of current license or certificate to practice medicine in the jurisdiction in which the program is located for each Processing Facility Medical Director. If the license or certificate is in a language other than English, include a general description in English. [D3.2.1]

☐ Curriculum vitae for each Processing Facility Medical Director. If one individual serves as a director for multiple facilities, submit this individual's curriculum vitae whenever applicable. If the documentation is in a language other than English, include a summary in English. [D3.2.1]

☐ Documentation of at least ten (10) hours of participation per year for each Processing Facility Medical Director in educational activities related to cellular therapy, including HPC transplantation and processing, since the previous accreditation date. Complete and upload the Educational Activities Form (Appendix A) or submit other documentation that contains the equivalent information for each activity: [D3.2.3]

- ☐ Date of activity
- ☐ Title of activity
- ☐ Type of activity (for example, webinar, meeting, grand round, etc.)
- ☐ Topic of activity (for example, hematology, cell processing, etc.)
- ☐ Approximate number of hours of activity

Processing Facility Quality Manager

☐ Documentation of at least ten (10) hours of participation per year for each Quality Manager in educational activities related to cellular therapy processing and/or quality management, including HPC transplantation, since the previous accreditation date. Complete and upload the Educational Activities Form (Appendix A) or submit other documentation that contains the equivalent information for each activity: [D3.3.2]

- ☐ Date of activity
- ☐ Title of activity
- ☐ Type of activity (for example, webinar, meeting, grand round, etc.)
- ☐ Topic of activity (for example, hematology, cell processing, etc.)
- ☐ Approximate number of hours of activity

Other Processing Documentation

☐ A completed Processing Facility Grid. For initial accreditation, enter data for the previous 12 months. For renewal accreditation, enter data from the start of the current accreditation cycle. [D1.1]

☐ A map of the overall organization that includes all facilities. If the map is labeled in a language other than English, include a general description of the floor plan or diagram in English. [D1.1]

☐ Physical floor plans of all facilities. Label all floors of the building(s) that are used for cellular therapy related activities. If the floor plan(s) or diagram is labeled in a language other than English, include a general description of the floor plan or diagram in English. [D1.1]

☐ Documentation of licensure, registration, and/or accreditation required by the appropriate governmental authority for the activities performed. U.S. facilities must submit a copy of the validated FDA registration for Human Cells, Tissues, and Cellular and Tissue Based Products (Form 3356). Facilities in other countries must submit certification required by the appropriate governmental authority. If the licensure, registration, or accreditation is in a language other than English, include a general description of the document in English. [D1.2.1]

☐ Copy of the Processing Facility's Quality Management Plan that includes all requirements listed in D4. [D4.2]

☐ Organizational chart of key positions and functions within the Processing Facility. [D4.3;]

☐ Standard operating procedure for development, approval, implementation, review, revision, and archival of all critical documents. [D4.5.1]

☐ Standard operating procedure(s) that outlines a standardized format for policies, procedures, worksheets, forms, and labels and required elements of each procedure. [D4.5.3.1 and D5.3]

☐ Evidence of a completed outcome analysis, such as a report of conclusions, meeting minutes, or completed forms. [D4.7]

☐ Schedule of audits that includes dates and subjects of audits already performed and audits planned for the future. At a minimum, the audits listed in D4.8.3 must be included. [D4.8]

☐ The policy or procedure for qualification of critical reagents, supplies, equipment, manufacturers, vendors, and facilities used for critical procedures. [D4.13]

☐ The policy or procedure for the validation and/or verification of critical procedures. [D4.14]

☐ A validation or verification study of a critical procedure of the Processing Facility that includes [D4.14]:
- ☐ A summary of the validation and/or verification plan
- ☐ Number of data points to be used
- ☐ Acceptance criteria
- ☐ Summary of results and conclusion
- ☐ Review and approval of the plan, results, and conclusion

☐ Complete cryopreservation and thawing SOP(s) that includes the directions for cryopreservation and preparation of the cryoprotectant solution. [D5.1.7]

☐ If the Processing Facility performs processing with more-than-minimal manipulation, an SOP(s) for release and exceptional release. [D5.1.10]

☐ Table of Contents from the Processing Facility Standard Operating Procedures Manual that includes the title, identifier, and version for each policy and procedure. [D5.2]

☐ Completed examples of each type of label used by the Processing Facility. Do not use any direct patient identifiers. Mock identifiers and names must be used. If the labels are in a language other than English, include a general description of the label elements in English. [D7.4.1].
- ☐ Any partial labels applied by the Processing Facility. [Cellular Therapy Standards Appendix II]
- ☐ Labels applied at completion of processing of allogeneic products collected from marrow and allogeneic products collected by apheresis, as applicable. [Cellular Therapy Standards Appendix II]
- ☐ Labels applied at completion of processing of autologous products collected from marrow and autologous products collected by apheresis, as applicable. [Cellular Therapy Standards Appendix II]

- ☐ Labels applied prior to distribution for allogeneic products collected from marrow and allogeneic products collected by apheresis, as applicable. [Cellular Therapy Standards Appendix II]
- ☐ Labels applied prior to distribution for autologous products collected from marrow and autologous products collected by apheresis, as applicable. [Cellular Therapy Standards Appendix II]
- ☐ Labels applied to inner and outer shipping containers for products shipped or transported on public roads. [Cellular Therapy Standards Appendix III]

☐ SOP for labeling that includes when biohazard and/or warning labels are used, including: [D7.4.2, Appendix II]

- ☐ Biohazard legend
- ☐ Statement "NOT EVALUATED FOR INFECTIOUS SUBSTANCES"
- ☐ Statement "WARNING: Advise Patient of Communicable Disease Risks"
- ☐ Statement "WARNING: Reactive Test Results for [name of disease agent or disease]"
- ☐ Statement "FOR AUTOLOGOUS USE ONLY"]

☐ If processing personnel apply labels to cellular therapy products at completion of collection Do not use any direct patient identifiers. Mock identifiers and names must be used. If the labels are in a language other than English, include a general description of the label elements in English. [D7.4.1]

- ☐ Completed example of a primary collection container label applied on completion of allogeneic cellular therapy product collection from marrow or by apheresis, as applicable. [Cellular Therapy Standards Appendix II]
- ☐ Completed example of a primary collection container label applied on completion of autologous cellular therapy product collection from marrow or by apheresis, as applicable. [Cellular Therapy Standards Appendix II]
- ☐ Completed examples of labels applied prior to transport or shipping of cellular therapy products, including inner and outer container labels. [Cellular Therapy Standards Appendix III]

☐ Documentation that accompanies the cellular therapy product at distribution and a policy or procedure that discusses the documentation that is distributed with the product. [D7.4.5, Cellular Therapy Standards Appendix IV]

☐ Policy or procedure for preparing cord blood units for administration. [D8.4.3 and D8.4.4]

☐ If a document other than the current version of the inter-organizational *Circular of Information for the Use of Cellular Therapy Products* is used, submit the document made available to clinical staff containing the following information: [D11.1.4]
  - ☐ Use of the cellular therapy product, indications, contraindications, side effects and hazards, dosage, and administration recommendations. [D11.1.4.1]
  - ☐ Handling the cellular therapy product to minimize the risk of contamination or cross-contamination. [D11.1.4.2]
  - ☐ Appropriate warnings related to the prevention of the transmission or spread of communicable diseases. [D11.1.4.3]

☐ A pre-collection written agreement between the storage facility and the designated recipient or the donor that includes the length of storage, circumstances for disposal, and option to transfer the cellular therapy product to another facility. [D12.1.1 and D12.1.2]

☐ Current list of critical electronic record systems under the control of the Processing Facility. Complete and upload the Critical Electronic Record Systems form (Appendix C) or submit other documentation that contains the equivalent information for each critical record system. [D13.2.1]

Electronic Record System:

If an electronic record system under the control of the facility is used for record keeping, documentation of validation of the system must be available on-site as well as a qualified individual to review the documentation with the inspector. Documentation should demonstrate compliance with the following Standards:

☐ Validated procedures for and documentation of: [D13.2.6]
  - ☐ Systems development [D13.2.6.1]
  - ☐ Numerical designation of system versions if applicable [D13.2.6.2]
  - ☐ Prospective validation of system including hardware, software, and databases [D13.2.6.3]
  - ☐ Installation of the system [D13.2.6.4]
  - ☐ Training and continued competency of personnel in the use of the system [D13.2.6.5]
  - ☐ Monitoring of data integrity [D13.2.6.6]
  - ☐ Back-up of the electronic records system on a regular schedule [D13.2.6.7]
  - ☐ System maintenance and operations [D13.2.6.8]
  - ☐ System assignment of unique identifiers [D13.2.6.9]

APPENDIX A

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

Educational Activities Form

This form is provided as a tool for documenting participation in continuing education. The following information for educational activities completed by key personnel during the current accreditation cycle must be provided to FACT prior to an on-site inspection. A completed form or equivalent documentation is acceptable so long as all information below is included. Specific continuing education requirements for key personnel are listed in the current editions of the applicable FACT Standards.

Name: _____

Position: _____

Date of Activity	Title of activity	Type of activity (e.g., webinar, meeting, grand round, etc.)	Topic of activity (e.g., hematology, cell transplantation, etc.)	Approximate number of hours of activity

6.6.008 Form 2, Educational Activities Form, Rev. 0 *Page 1 of 1*

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

Hematopoietic Cellular Therapy Training and Competency Form

This form is provided as a tool for documenting training and competency required of Clinical Program Directors, attending physicians, physicians-in-training, and advanced practice providers/professionals (as applicable). Confirmation that training was provided and competency was assessed during the current accreditation cycle in each of the following areas must be provided to FACT prior to an on-site inspection. A completed form or equivalent documentation is acceptable so long as all information below is included.

Name: _____

Position: _____

Topic	Yes	No	N/A	Comment
Specific training and competency in each of the following for both autologous and allogeneic transplantation:				
B3.3.3.1 Indications for HPC transplantation.				
B3.3.3.2 Selection of suitable recipients and appropriate preparative regimens.				
B3.3.3.3 Allogeneic and autologous donor selection, evaluation, and management.				
B3.3.3.4 Donor and recipient informed consent.				
B3.3.3.5 Administration of ABO incompatible cellular therapy products.				
B3.3.3.6 Administration of preparative regimens.				
B3.3.3.7 Administration of growth factors for HPC mobilization and for post-transplant hematopoietic cell reconstitution.				
B3.3.3.8 HPC product infusion and patient management.				
B3.3.3.9 Management of neutropenic fever.				
B3.3.3.10 Diagnosis and management of infectious and non-infectious pulmonary complications of transplantation.				
B3.3.3.11 Diagnosis and management of fungal disease.				
B3.3.3.12 Diagnosis and management of veno-occlusive disease of the liver and other causes of hepatic dysfunction.				
B3.3.3.13 Management of thrombocytopenia and bleeding, including recognition of disseminated intravascular coagulation.				
B3.3.3.14 Management of hemorrhagic cystitis.				
B3.3.3.15 Management of mucositis, nausea, and vomiting.				
B3.3.3.16 Monitoring and management of pain.				
B3.3.3.17 Graft versus host disease.				
B3.3.3.18 Cytokine release syndrome.				
B3.3.3.19 Tumor lysis syndrome.				
B3.3.3.20 Macrophage activation syndrome.				
B3.3.3.21 Cardiac dysfunction.				
B3.3.3.22 Renal dysfunction.				
B3.3.3.23 Respiratory distress.				
B3.3.3.24 Neurologic toxicity.				

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

Hematopoietic Cellular Therapy Training and Competency Form

B3.3.3.25 Anaphylaxis.				
B3.3.3.26 Infectious and noninfectious processes.				
B3.3.3.27 Diagnosis and management of HPC graft failure.				
B3.3.3.28 Evaluation of post-transplant cellular therapy outcomes.				
B3.3.3.29 Evaluation of late effects of allogeneic and autologous transplants, including cellular, pharmacologic, and radiation therapy.				
B3.3.3.30 Documentation and reporting for patients on investigational protocols				
B3.3.3.31 Applicable regulations and reporting responsibilities for adverse events.				
B3.3.3.32 Palliative and end of life care.				
Specific training and clinical competency in each of the following for allogeneic transplantation:				
B3.3.4.1 Identification, evaluation, and selection of HPC source, including use of donor registries.				
B3.3.4.2 Donor eligibility determination.				
B3.3.4.3 Methodology and implications of human leukocyte antigen (HLA) typing.				
B3.3.4.4 Management of patients receiving ABO incompatible HPC products.				
B3.3.4.5 Diagnosis and management of immunodeficiencies and opportunistic infections.				
B3.3.4.6 Diagnosis and management of acute graft versus host disease.				
B3.3.4.7 Diagnosis and management of chronic graft versus host disease.				
Knowledgeable in the following procedures for both autologous and allogeneic transplantation:				
B3.3.5.1 HPC processing.				
B3.3.5.2 HPC cryopreservation.				
B3.3.5.3 Bone marrow harvest procedures.				
B3.3.5.4 Apheresis collection procedures.				
B3.3.5.5 Extracorporeal photopheresis for GVHD.				
B3.3.5.6 Washing and diluting of cellular therapy products.				
B3.3.5.7 Cellular therapy product administration.				

Reviewer Signature and Date (must be signed by someone other than personnel being assessed):

_____ _____

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

Critical Electronic Record Systems

Name of System	Description	Document Type (e.g., Excel, custom software, etc.)	Used in Lieu of Paper	Used to Make Decisions	Used to Perform Calculations	Used to Create and/or Store Information Used in Critical Procedures*
Example: Engraftment Database	*Recording and reporting of cell dose and engraftment data*	*custom software developed in-house*	*No - processing record is official record*	*Yes - used for outcome analysis*	*No*	*No*

*Critical procedures include collection procedures, processing techniques, cryopreservation procedures, labeling, storage conditions, and distribution.