FACT Common Standards for Cellular Therapies

Second Edition
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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, refer to the referenced standard in the Common Standards for Cellular Therapies, Second Edition.

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. Refer to the Applicant Guidelines on the FACT website at http://www.factwebsite.org/CTLibrary/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 translation or 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 the therapeutic disease area. Documentation should describe the specifics of the training received, and may be submitted in the form of curriculum vitae, 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 the documentation is in a language other than English, include a summary in English. [B3.1.2]

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

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

☐ Complete and upload the Common Standards Training and Competency Form or submit the following for each Clinical Program Director: [B3.2.4]

☐ Documentation of specific training and competency in the skills listed in Standard B3.2.4.

☐ For programs requesting accreditation for allogeneic cell therapy, documentation of specific training and competency in each of the skills listed in Standard B3.2.5.

☐ Documentation of knowledge in the skills listed in Standard B3.2.6.

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 translation or 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 the therapeutic disease area. 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, B3.2.2]

Documentation of at least ten (10) hours per year for each attending physician of participation in educational activities related to cellular therapy since the previous accreditation date. Complete and upload the Educational Activities Form or submit other documentation that contains the equivalent information for each activity: [B3.2.3]

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

Complete and upload the Common Standards Training and Competency Form or submit the following for each attending physician: [B3.2.4]

- Documentation of specific training and competency in the skills listed in Standard B3.2.4.
- For programs requesting accreditation for allogeneic cell therapy, documentation of specific training and competency in each of the skills listed in Standard B3.2.5.
- Documentation of knowledge in the skills listed in Standard B3.2.6.

**Physicians-in-Training** (specify adult and pediatric programs if applicable):

- 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. [B3.3.1]

- 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 translation or general description in English. [B3.3.1]

- For physicians-in-training not in an accredited graduate medical education program, complete and upload the Common Standards Training and Competency Form or submit documentation of specific training and competency development in the skills listed in Standard B3.2.4 and B3.2.5 (for allogeneic accreditation, if applicable).
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 translation or general description in English. [B3.4.1]

☐ Complete and upload the Common Standards Training and Competency Form or submit the following for each APP in the management, and the skills related to the therapeutic disease areas that he/she routinely practices, included within but not limited to those listed in B3.2.4 and B3.2.5. [B3.4.1]

☐ Documentation of at least ten (10) hours per year for each APP of participation in educational activities related to cellular therapy since the previous accreditation date. Complete and upload the Educational Activities Form or submit other documentation that contains the equivalent information for each activity: [B3.4.3]
  ☐ Date of activity
  ☐ Title of activity
  ☐ Type of activity (e.g., webinar, meeting, grand round)
  ☐ Topic of activity (e.g., hematology, cell administration)
  ☐ Approximate number of hours of activity

Nurses

☐ Description of the processes for nursing orientation, training, and competency assessment in the field of cellular therapy. [B3.6.4]

Pharmacists

☐ Copy of current license to practice as required in the jurisdiction in which the program is located for each designated pharmacist. If the license is in a language other than English, include a translation or general description in English. [B3.7.1]

☐ Documentation of training and knowledge including an overview of the process of cellular therapy and pharmacological management of expected complications. [B3.7.2]

Consulting Specialists

☐ List of the defined certified or trained consulting specialists or specialist groups from key disciplines capable of assisting in the management of recipients or donors requiring medical care. [B3.8.1]

☐ Copy of board certification or documentation of training and experience for at least one (1) specialist in each specialty field in the submitted list. For programs that treat pediatric patients, documentation of specialist certification or training for consultants qualified to manage pediatric patients must be submitted. For programs that treat adult patients, documentation of specialist certification or training for consultants qualified to manage adult patients must be submitted. If the documentation is in a language other than English, include a general description in English. [B3.8.1, B3.8.2, B3.8.3]
Clinical Quality Manager

☐ Documentation of at least ten (10) hours per year for each Clinical Quality Manager of participation in educational activities related to cellular therapy and quality management since the previous accreditation date. Complete and upload the Educational Activities Form or submit other documentation that contains the equivalent information for each activity: [B3.9.3]
☐ Date of activity
☐ Title of activity
☐ Type of activity (e.g., webinar, meeting, grand round)
☐ Topic of activity (e.g., hematology, cell administration)
☐ Approximate number of hours of activity

Other Clinical Documentation

☐ Completed Clinical Facility Grid, which includes new patient numbers. 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 and B1.5].

☐ General physical floor plan of all program facilities (clinical, collection, processing). Label all floors of the building(s) that are used for cellular therapy 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]

☐ Map of the overall organization that includes all facilities (clinical, collection, processing). If the map is labeled in a language other than English, include a general description of the map in English. [B1.1]

☐ If the Clinical Program or intermediary facility receives cellular therapy products directly 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] If the documentation is in a language other than English, include a general description in English.
☐ 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]
☐ Review and verification of product specifications provided by the manufacturer, if applicable. [B1.2.1.4]
☐ Readily available access to a summary of documents used to determine allogeneic donor eligibility. [B1.2.1.5]
☐ Documented evidence of allogeneic donor eligibility screening and testing in accordance with Applicable Law. [B1.2.1.6]
☐ 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]

☐ For programs requesting accreditation of allogeneic cellular therapies requiring HLA matching, submit a copy of the HLA laboratory's current ASHI, EFI, or other appropriate accreditation certificate, including documentation of certification for DNA-based typing. For ASHI accreditation, include the accreditation letter in addition to the certificate. If the certificate is in a language other than English, include a general description of the document in English. [B2.6]

☐ For programs requesting accreditation of allogeneic cellular therapies, submit a copy of the certificate of laboratory accreditation for techniques used in chimerism testing or the results of the validation of techniques used. [B2.7]

☐ Clinical Program’s Quality Management Plan that includes all requirements listed in B4. [B4.2]

☐ Organizational chart of key positions and functions within the cellular therapy program, including clinical, collection, and processing, as applicable. [B4.3]

☐ Policies or Standard Operating Procedures for development, approval, implementation, distribution, review, revision, and archival of all critical documents. [B4.5.2]

☐ Submit a document control system policy for all controlled documents that addresses all required elements. [B4.5.3 - B4.5.3.8 and B5.3]

☐ Evidence of a completed outcome analysis, e.g., a report of conclusions, meeting minutes, or completed forms. [B4.7]

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

☐ Submit an audit report of an audit performed within the past 12 months. Refer to the Data Management Resource Center for information on the minimal requirements of an audit report and examples of audit templates. [B4.8]

☐ Policy or Standard Operating Procedure for qualification of critical equipment, supplies, reagents, and facilities. [B4.13.1]

☐ Policy or Standard Operating Procedure for validation or verification of critical procedures. [B4.14]
Validation of a critical procedure (e.g., collection procedures, labeling, storage, or distribution) that includes: [B4.14.2]
- An approved validation plan, including conditions to be validated
- Acceptance criteria
- Data collection
- Evaluation of Data
- Summary of results
- References, if applicable
- Review and approval of the plan, results, and conclusion by the Medical Director of collection activities or designee and the Quality Manager or designee

Detailed list of all controlled documents, including the title and identifier for the Clinical Program. [B5.2]

Unsigned samples of all allogeneic and autologous donor consent forms. [B6.2]

Standard Operating Procedure for consenting a cellular therapy product donor that contains all required elements. [B6.2]

Unsigned samples of recipient consent forms and the Standard Operating Procedure for consenting to receive cellular therapy. [B5.1.3, B7.1]

Policies or Standard Operating Procedures that address appropriate follow-up of recipients after administration of cellular therapy products. [B7.5.7]

Report of a recent data accuracy audit. Ensure the audit report contains the minimum elements of an audit report, assesses accuracy of critical data fields, and identifies the underlying cause of errors detected and appropriate corrective actions. Include documentation that corrective actions have been implemented. Refer to the Data Management Resource Center for submission guidelines, templates, examples and education resources. [B9]

Submit documentation of educational activities for each data management staff responsible for collecting and reporting data since the previous date of accreditation. Complete and upload the Educational Activities Form or submit other documentation that contains the equivalent information for each activity: [B3.9.3]
- Date of activity
- Title of activity
- Type of activity (e.g., webinar, meeting, grand round)
- Topic of activity (e.g., hematology, cell administration)
- Approximate number of hours of activity
Electronic Record Systems:

- Current list of critical electronic record systems under the control of the Clinical Program, including a description of the purpose of each system and how it is used. Complete and upload the Critical Electronic Record Systems form (Appendix II) or submit other documentation that contains the equivalent information for each critical record system. [B10.4.1]

For all critical electronic record systems, 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: [B10.4.9]
  - Training and continued competency of personnel in systems use. [B10.4.9.1]
  - Monitoring of data integrity. [B10.4.9.2]
  - Back-up of the electronic records system on a regular schedule. [B10.4.9.3]
  - System assignment of unique identifiers. [B10.4.9.4]
COLLECTION DOCUMENTATION

Medical Director of Collection Activities

☐ Copy of current license or certificate to practice medicine in the jurisdiction in which the program is located for each Medical Director. If the license or certificate is in a language other than English, include a translation or general description in English. [C3.1.1]

☐ Curriculum vitae for each Medical Director. 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 per year for each Medical Director of participation in educational activities related to cellular therapy or the therapeutic disease area since the previous accreditation date. Complete and upload the Educational Activities Form or submit other documentation that contains the equivalent information for each activity: [C3.1.4]
  ☐ Date of activity
  ☐ Title of activity
  ☐ Type of activity (e.g., webinar, meeting, grand round)
  ☐ Topic of activity (e.g., cell collection)
  ☐ Approximate number of hours of activity

Collection Quality Manager

☐ Documentation of at least ten (10) hours per year for each Collection Quality Manager of participation in educational activities related to cellular therapy, cell collection, and/or quality management since the previous accreditation date. Complete and upload the Educational Activities Form or submit other documentation that contains the equivalent information for each activity: [C3.2.3]
  ☐ Date of activity
  ☐ Title of activity
  ☐ Type of activity (e.g., webinar, meeting, grand round)
  ☐ Topic of activity (e.g., cell collection)
  ☐ Approximate number of hours of activity

Other Collection Documentation

☐ Completed Collection 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. [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]

☐ 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 map 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. 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]

Submit instructions sent to collection staff with collection kits. If the instructions are in a language other than English, submit at a minimum a summary of instructions in English. [C2.2]

Quality Management Plan that includes all requirements listed in C4. [C4.2]

Organizational chart of key positions and functions required for collection. [C4.3]

Policies or Standard Operating Procedure(s) for development, approval, implementation, distribution, review, revision, and archival of all critical documents. [C4.5.1.2]

Submit a document control system policy for all controlled documents that addresses all required elements. [C4.5.3.1-C4.5.3.8 and C5.3]

Evidence of a completed outcome analysis, e.g., 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]

Submit a report of an audit performed within the past 12 months. Refer to the Data Management Resource Center for information on the minimal requirements of an audit report and examples of audit templates. [C4.8]

Policy or Standard Operating Procedure for qualification of critical manufacturers, vendors, equipment, supplies, reagents, facilities, and services. [C4.13]

Policy or Standard Operating Procedure for the validation or verification of critical procedures. [C4.14]

Summary of one completed validation study of a critical procedure of the Collection Facility (e.g., collection, testing, labeling, storage, distribution) that includes: [C4.14.1, C4.14.2]
  - An approved validation plan, including conditions to be validated
  - Acceptance criteria
  - Data collection
  - Evaluation of Data
  - Summary of results
  - References, if applicable
  - Review and approval of the validation plan, results, and conclusion by the Medical Director of collection activities or designee and the Quality Manager or designee.

Detailed list of all controlled documents, including title and identifier for the Collection Activities. [C5.2]
 Unsigned samples of all allogeneic and autologous donor consent forms. [C5.1.2, C6.2]

 Procedure for consenting for the collection procedure that contains all required elements. [C5.1.2, C6.2]

 Completed examples of each type of label used by the Collection Facility on cellular therapy products at the time of collection. Do not include protected health information (PHI), e.g., patient names, medical record numbers, birthdates, or other 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. [C7.3.1, Cellular Therapy Product Labeling table, Appendix I]

 Primary collection container label, applied on completion of collection of products for allogeneic use [Cellular Therapy Product Labeling table, Appendix I]

 Primary collection container label applied on completion of collection of products for autologous use [Cellular Therapy Product Labeling table, Appendix I]

 Any partial labels applied by the collection personnel [Cellular Therapy Product Labeling table, Appendix I]

 Labels applied to inner and outer shipping containers for products shipped or transported on public roads. [Cellular Therapy Product Labels For Shipping And Transport on Public Roads, Appendix II]

 SOP for labeling that includes when biohazard and/or warning labels are used, including: [C7.3.2, Cellular Therapy Product Labeling table, Appendix I]

 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. [C7.3.4, Accompanying Documents At Distribution, Appendix III]

 A policy or procedure that discusses the documentation that is distributed with the product. [C7.3.4, Accompanying Documents At Distribution, Appendix III]

 Completed examples of documentation of the visual examination of supplies and reagents used to collect cellular therapy products. [C8.2.2]

 Sample log of equipment inspection for cleanliness and compliance with the maintenance schedule prior to each use. [C8.3]
Electronic Record Systems:

- Current list of critical electronic record systems under the control of the program performing collection, including a description of the purpose of each system and how it is used. Complete and upload the Critical Electronic Record Systems form (Appendix III) or submit other documentation that contains the equivalent information for each critical record system. [C11.6.1]

For critical electronic record systems, 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]
  - Systems development [C11.6.9.1]
  - Numerical designation of system versions if applicable [C11.6.9.2]
  - Prospective validation of systems, including hardware, software, and databases [C11.6.9.3]
  - Installation of the system [C11.6.9.4]
  - Training and continued competency of personnel in systems use [C11.6.9.5]
  - Monitoring of data integrity [C11.6.9.6]
  - Back-up of the electronic records system on a regular schedule [C11.6.9.7]
  - System maintenance and operations [C11.6.9.8]
  - System assignment of unique identifiers [C11.6.9.9]
PROCESSING FACILITY DOCUMENTATION

Processing Facility Director

☐ Curriculum vitae for each Processing Facility Director. 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 per year for each Processing Facility Director of participation in educational activities related to cellular therapy since the previous accreditation date. Complete and upload the Educational Activities Form (Appendix I) or submit other documentation that contains the equivalent information for each activity: [D3.1.3]

☐ Date of activity
☐ Title of activity
☐ Type of activity (e.g., webinar, meeting, grand round)
☐ Topic of activity (e.g., hematology, cell processing)
☐ 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 processing facility is located for each Processing Facility Medical Director. If the license or certificate is in a language other than English, include a translation or general description in English. [D3.2.1]

☐ Curriculum vitae for each Processing Facility Medical Director. 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 per year for each Processing Facility Medical Director of participation in educational activities related to cellular therapy since the previous accreditation date. Complete and upload the Educational Activities Form (Appendix I) or submit other documentation that contains the equivalent information for each activity: [D3.2.3]

☐ Date of activity
☐ Title of activity
☐ Type of activity (e.g., webinar, meeting, grand round)
☐ Topic of activity (e.g., hematology, cell processing)
☐ Approximate number of hours of activity
Processing Facility Quality Manager

☐ Documentation of at least ten (10) hours per year for each Quality Manager of participation in educational activities related to cellular therapy and quality management since the previous accreditation date. Complete and upload the Educational Activities Form or submit other documentation that contains the equivalent information for each activity: [D3.3.3]
☐ Date of activity
☐ Title of activity
☐ Type of activity (e.g., webinar, meeting, grand round)
☐ Topic of activity (e.g., hematology, cell processing)
☐ Approximate number of hours of activity

Other Processing Documentation

☐ 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]

☐ 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]

☐ 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 map 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. 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]

☐ Instructions sent to collection staff with collection kits. If the instructions are in a language other than English, submit at a minimum a summary of instructions in English. [D2.2]

☐ 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]

☐ Policies or Standard Operating Procedures for development, approval, implementation, distribution, review, revision, and archival of all critical documents. [D4.5.2]

☐ Submit a document control system policy for all controlled documents that addresses all required elements. [D4.5.3.1-D4.5.3.8 and D5.3]

☐ 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]
Submit a report of an audit performed within the past 12 months. Refer to the Data Management Resource Center for information on the minimal requirements of an audit report and examples of audit templates.

Policy or Standard Operating Procedure for qualification of critical manufacturers, vendors, equipment, supplies, reagents, facilities, and services. [D4.13]

Policy or Standard Operating Procedure for the validation or verification of critical procedures. [D4.14]

Summary of one completed validation study of a critical procedure of the Processing Facility (e.g., processing techniques, cryopreservation procedures, labeling, storage, distribution) that includes: [D4.14.1, D4.14.2]
- A summary of the validation plan
- Number of data points to be used
- Acceptance criteria
- Data collection
- Evaluation of Data
- Summary of results
- References, if applicable
- Review and approval of the plan, results, and conclusion

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

Standard Operating Procedure(s) for release and exceptional release. [D5.1.10]

Detailed list of all controlled documents, including title and identifier, in the Processing Facility. [D5.2]

Completed examples of documentation of the visual examination of supplies and reagents used to manufacture cellular therapy products. [D6.2.1]

Sample log of equipment inspection for cleanliness and compliance with the maintenance schedule prior to each use. [D6.5]

Completed examples of each type of in-process processing label used by the Processing Facility. Do not include protected health information (PHI), e.g., patient names, medical record numbers, birthdates, or other identifiers. Mock identifiers and names must be used. If the labels are in a language other than English, include a translation of the label elements in English.[D7.3.3]
If processing personnel apply labels to cellular therapy products at completion of collection, submit completed examples of each type of label used by processing personnel at the completion of collection. Do not include protected health information (PHI), e.g., patient names, medical record numbers, birthdates, or other identifiers. Mock identifiers and names must be used. If the labels are in a language other than English, include a translation of the label elements in English. [D7.3.1]

- Completed example of a primary collection container label applied at completion of allogeneic product collection. [Cellular Therapy Product Labeling, Appendix I]
- Completed example of a primary collection container label applied at completion of autologous product collection. [Cellular Therapy Product Labeling, Appendix I]
- Completed examples of labels applied prior to transport or shipment of products, including inner and outer container labels. [Cellular Therapy Product Labels For Shipping And Transport on Public Roads, Appendix II]

Completed examples of each type of label used by the Processing Facility. Do not include protected health information (PHI), e.g., patient names, medical record numbers, birthdates, or other identifiers. Mock identifiers and names must be used. If the labels are in a language other than English, include a translation of the label elements in English. [D7.3.1]

- Labels applied at completion of processing of allogeneic products. [Cellular Therapy Product Labeling table, Appendix II]
- Labels applied at completion of processing of autologous products. [Cellular Therapy Product Labeling table, Appendix II]
- Labels applied prior to distribution for allogeneic products. [Cellular Therapy Product Labeling table, Appendix II]
- Labels applied prior to distribution for autologous products. [Cellular Therapy Product Labeling table, Appendix II]
- Completed examples of each type of partial label used by the Processing Facility. Do not include protected health information (PHI), e.g., patient names, medical record numbers, birthdates, or other identifiers. Mock identifiers and names must be used. If the labels are in a language other than English, include a translation of the label elements in English. [Cellular Therapy Product Labeling table, Appendix I]
- Labels applied to inner and outer shipping containers for products shipped or transported on public roads. [Cellular Therapy Product Labeling table, Appendix II]

Standard Operating Procedure for labeling that includes when biohazard and/or warning labels are used, including: [D7.3.2, 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”

Documentation that accompanies the cellular therapy product at distribution. [D7.3.5, Accompanying Documents At Distribution, Appendix III]

A policy or procedure that discusses the documentation that is distributed with the product. [D7.3.5, Accompanying Documents At Distribution, Appendix III]
Written stability program that evaluates the viability and potency of cryopreserved cellular therapy products, and the results of the last annual assessment. [D9.2.2]

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]
- Instructions for 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]

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]

**Electronic Record System:**

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

If an electronic record system under the control of the facility is used, 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 systems use [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]