Immune Effector Cells

DOCUMENT SUBMISSION REQUIREMENTS

FACT Standards for Immune Effector Cells

First Edition
March 2018
Version 1.1

FACT ACCREDITATION OFFICE
University of Nebraska Medical Center
986065 Nebraska Medical Center
Omaha, NE 68198-6065, USA
Tel: (402) 559-1950
Fax: (402) 559-1951
www.factwebsite.org
IMMUNE效应细胞
文档提交要求

前言

提供以下项目的副本并要求在实地检查前提交并上传到FACT认证平台的合规性应用程序。有关更多信息，请参见引用的标准和附件的准确性。

切勿在提交的文件中使用患者姓名。所有提交的文件、政策和程序都必须以英文提交，除非另有说明。如果您的机构使用电子记录，硬拷贝的原始数据文件必须在实地检查前组装并标记，必须准备好供现场审查。

以下列出的文件仅为审查员需要审查的文件子集。每个标准的符合性文件必须在实地检查期间供审查员可随时查阅。详细信息，请参见网站上的申请指南。

目录

临床项目文档

第1页至4页

临床项目主任

第5页

主任医师

第5页

实习生

第6页

高级实践提供者/专业人士（APP）

第6页

护士

第7页

药剂师

第7页

顾问

第8页

临床质量经理

第8页

其他临床文档

第11页

收集文档

第11页

收集活动的主任

第11页

收集质量经理

第11页

其他收集文档

第11页

电子记录系统

第14页

6.6.008 Form 19, Immune Effector Cells 1.1
Document Submission Requirements, R1, 30Jul2018  Page 2 of 17
CLINICAL PROGRAM DOCUMENTATION

Clinical Program Director(s)

☐ Copy of the 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. 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 registrations or certifications in the therapeutic disease area. Documentation should describe the specifics of the training received, and may be submitted in the form of curriculum vitaeas, 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 curriculum vitae is in a language other than English, include a summary in English. [B3.1.2]

☐ Documentation of at least ten (10) hours of participation in the previous year for each Clinical Program Director in educational activities related to cellular therapy in the previous year. 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 rounds)
☐ Topic of activity (e.g., hematology, cell administration)
☐ Approximate number of hours of activity

☐ Complete and upload the Immune Effector Cells Standards Training and Competency Form or submit the following for each Clinical Program Director: [B3.3]

☐ Documentation of specific training and competency in the skills listed in Standard B3.3.2.

☐ For programs requesting accreditation for allogeneic cell therapy, documentation of specific training and competency in each of the skills listed in Standard B3.3.3.

☐ Documentation of knowledge in the skills listed in Standard B3.3.4.

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

☐ Copy of the 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. 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 registrations or certifications 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. [B3.2.1]

☐ Documentation of at least ten (10) hours of participation in the previous year for each attending physician in educational activities related to cellular therapy. Complete and upload the Educational Activities Form or submit other documentation that contains the equivalent information for each activity: [B3.2.2]
☐ Date of activity
☐ Title of activity
☐ Type of activity (e.g., webinar, meeting, grand rounds)
☐ Topic of activity (e.g., hematology, cell administration)
☐ Approximate number of hours of activity

☐ Complete and upload the Immune Effector Cells Standards Training and Competency Form or submit the following for each attending physician: [B3.3]
☐ Documentation of specific training and competency in the skills listed in Standard B3.3.2.
☐ For programs requesting accreditation for allogeneic cell therapy, documentation of specific training and competency in each of the skills listed in Standard B3.3.3.
☐ Documentation of knowledge in the skills listed in Standard B3.3.4.

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 the 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 Immune Effector Cells Standards Training and Competency Form 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 B3.3.2.
- For programs requesting accreditation for allogeneic cell therapy, documentation of specific training and competency development in each of the skills listed in Standard B3.3.3.

Advanced Practice Providers/Professionals (APPs)

- Copy of the 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 Immune Effector Cells Standards Training and Competency Form or submit the following for each APP in the therapeutic-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 B3.3.2 for each APP as applicable.
  - For programs requesting accreditation for allogeneic cellular therapy, documentation of specific training and competency in each of the skills listed in Standard B3.3.3 for each APP as applicable.

- Documentation of at least ten (10) hours of participation in the previous year for each APP in educational activities related to cellular therapy. Complete and upload the Educational Activities Form or submit other documentation that contains the equivalent information for each activity. [B3.5.3]
  - Date of activity
  - Title of activity
  - Type of activity (e.g., webinar, meeting, grand rounds)
  - Topic of activity (e.g., hematology, cell administration)
  - Approximate number of hours of activity

Nurses

- Submit a description of the processes for nursing training and competency assessment in the field of cellular therapy. [B3.7.3]

Pharmacists

- Copy of the current license or certificate to practice as required in the jurisdiction in which the program is located for each designated 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 designated pharmacist in educational activities, including cytokine release syndrome and neurological toxicities resulting from cellular therapies, since the previous accreditation date. Complete and upload the Educational Activities Form or submit other documentation that contains the equivalent information for each activity: [B3.8.4]

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

Consulting Specialists

Submit a copy of board certification or documentation of training and experience for at least one (1) specialist in each specialty field. For programs that treat pediatric patients, 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]

<table>
<thead>
<tr>
<th>Peds</th>
<th>Adult</th>
<th>Peds</th>
<th>Adult</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐</td>
<td>Surgery [B3.9.1.1]</td>
<td>☐</td>
<td>Pulmonary Medicine [B3.9.1.2]</td>
</tr>
<tr>
<td>☐</td>
<td>Intensive Care [B3.9.1.3]</td>
<td>☐</td>
<td>Gastroenterology [B3.9.1.4]</td>
</tr>
<tr>
<td>☐</td>
<td>Nephrology [B3.9.1.5]</td>
<td>☐</td>
<td>Infectious Disease [B3.9.1.6]</td>
</tr>
<tr>
<td>☐</td>
<td>Cardiology [B3.9.1.7]</td>
<td>☐</td>
<td>Pathology [B3.9.1.8]</td>
</tr>
<tr>
<td>☐</td>
<td>Psychiatry [B3.9.1.9]</td>
<td>☐</td>
<td>Radiology [B3.9.1.10]</td>
</tr>
<tr>
<td>☐</td>
<td>Radiation Therapy [B3.9.1.11]</td>
<td>☐</td>
<td>Transfusion Medicine* [B3.9.1.12]</td>
</tr>
<tr>
<td>☐</td>
<td>Obstetrics/Gynecology [B3.9.1.15]</td>
<td>☐</td>
<td>Dermatology [B3.9.1.16]</td>
</tr>
</tbody>
</table>

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

Clinical Quality Manager

Documentation of at least ten (10) hours of participation in the previous year for each Clinical Quality Manager in educational activities related to cellular therapy and/or quality management in the previous twelve (12) months. Complete and upload the Educational Activities Form or submit other documentation that contains the equivalent information for each activity: [B3.10.3]

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

☐ A 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]

☐ Complete and upload the EC List. [B1.1]

☐ 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]

☐ 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 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: [B1.2.1.1]
  ☐ Traceability and chain of custody of cellular therapy products. [B1.2.1.1.1]
  ☐ 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 donor eligibility screening and testing in accordance with applicable laws and regulations. [B1.2.1.6]

☐ 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 from the previous twelve months. Include unique patient identifier, date of cellular therapy, diagnosis, source of cells (marrow, peripheral blood, cord blood, etc.), type of donor (autologous, allogeneic), type of recipient (adult, pediatric), and CIBMTR ID (if applicable). Per United States HIPAA guidelines, do not include protected health information (PHI), such as patient names, medical record numbers, birth date, or others. [B1.5]
For programs requesting allogeneic accreditation of 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. [B2.9]

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]

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]

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]

List of all policies and procedures in the Clinical Program Standard Operating Procedures Manual, including 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. [B6.1.2 through B6.1.11]

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

Policies or procedures for addressing appropriate follow-up of recipients after administration of preparative regimens and cellular therapy products. [B7.6]

Policy or procedure addressing the administration of immune effector cells and management of complications. [B7.7]
Data management [B9]:

Programs audited by CIBMTR:
- The most recent CIBMTR Audit Results Report, including Appendix D.
- Corrective Action Plan (CAP) submitted at the last CIBMTR audit, if applicable. CAPs related to systemic errors even if the CER is ≤3.0% are required. CAPs related to consent issues or missing documentation are not required.
- Summary of current progress on implementation of the CAP.
- An audit report from a recent internal audit (performed within the last 12 months on current data) addressing the effectiveness of the CAP.
- CIBMTR Continuous Process Improvement Status letters from 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.
- An audit report from a recent internal audit (performed within the past 12 months on current data). Requirements will be sent to program for preparation of an on-site data audit to be performed by a FACT clinical inspector.

Programs with B9 deficiencies.
- Dates of the last three (3) on-site FACT inspections and the deficiencies received under B9.1.
- Corrective Action Plan (CAP) submitted at the most recent inspection that FACT accepted to grant accreditation.
- Summary of current progress on implementation of the CAP.
- An audit report from a recent internal audit (performed within the past 12 months on current data) addressing the effectiveness of the CAP.
- Requirements will be sent to programs for preparation of an on-site data audit to be performed by a FACT clinical inspector.

Programs applying for initial accreditation
- An audit report from a recent internal audit (performed within the past 12 months on current data) addressing the effectiveness of the CAP.
- Requirements will be sent to programs for preparation of an on-site data audit to be performed by a FACT clinical inspector.

Documentation of participation for each defined data management staff in educational activities. Complete and upload the Educational Activities Form or submit other documentation that contains the equivalent information for each activity: [B9.2.1]
- Date of activity
- Title of activity
- Type of activity (e.g., webinar, meeting, TCT Data Managers Meeting)
- Topic of activity (e.g., disease response, GVHD, neutrophil recovery)
- Approximate number of hours of activity
COLLECTION DOCUMENTATION

Medical Director of Collection Activities

☐ Copy of the 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 general description in English. [C3.1.1]

☐ Curriculum vitae for each Medical Director. If one individual serves as a director for multiple facilities, submit this individual’s curriculum vitae whenever applicable. If the curriculum vitae is in a language other than English, include a summary in English. [C3.1.3]

☐ Documentation of at least ten (10) hours of participation in the previous year for each Medical Director in educational activities related to cellular therapy and/or the therapeutic disease area. 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 rounds)
  ☐ Topic of activity (e.g., cell collection)
  ☐ Approximate number of hours of activity

Collection Quality Manager

☐ Documentation of at least ten (10) hours of participation in the previous year for each Collection Facility Quality Manager in educational activities related to cellular therapy, cell collection, and/or quality management. 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 rounds)
  ☐ Topic of activity (e.g., cell collection)
  ☐ Approximate number of hours of activity

Other Collection Documentation

☐ A 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]

☐ 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 map 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]

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

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

Standard operating procedure for development, approval, implementation, review, revision, and archival of all critical documents. [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 study of a critical collection procedure that includes:
[C4.14]

- A summary of the validation plan
- Number of data points to be used
- Acceptance criteria
- Data collection
- Evaluation of data
- Summary of results and conclusions
- Review and approval of the plan, results, and conclusion

List of all the policies and procedures in the collection Standard Operating Procedures Manual, including 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 collection procedure that contains all required elements. [C6.2]
Completed examples of each type of label used on cellular therapy products at the time of collection. Do not use protected health information (PHI), such as patient names, medical record numbers, birth date, or others. 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, Appendix I, Appendix II]

- Primary collection container label, applied on completion of collection of products for allogeneic use [Appendix I]
- Primary collection container label applied on completion of collection of products for autologous use [Appendix I]
- Partial labels applied by the collection staff [Appendix I]
- Labels applied to inner and outer shipping containers for products shipped or transported on public roads. [Appendix II]

- An SOP for labeling that includes when biohazard and/or warning labels are used, including:
  - 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. [C7.3.4, Appendix III]

- Current list of critical electronic record systems under the control of the program performing collection. Complete and upload the Critical Electronic Record Systems form or submit other documentation that contains the equivalent information for each critical record system. [C11.6.1]

**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 in the previous year for each Processing Facility Director in educational activities related to cellular therapy. Complete and upload the \textit{Educational Activities Form} 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 rounds)
- Topic of activity (e.g., hematology, cell processing)
- Approximate number of hours of activity

Processing Facility Medical Director

☐ Copy of the 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 curriculum vitae is in a language other than English, include a summary in English. [D3.2.1]

☐ Documentation of at least ten (10) hours of participation in the previous year for each Processing Facility Medical Director in educational activities related to cellular therapy. Complete and upload the \textit{Educational Activities Form} 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 rounds)
- 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 of participation in the previous year for each Quality Manager in educational activities related to cellular therapy processing and/or quality management. 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 rounds)
  - Topic of activity (e.g., hematology, cell processing)
  - 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, from the start of the 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 map 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]

- 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 supplies, manufacturers, vendors, reagents, equipment, 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 study of a critical processing procedure that includes: [D4.14]
  ☐ A summary of the validation plan
  ☐ Number of data points to be used
  ☐ Acceptance criteria
  ☐ Data collection
  ☐ Evaluation of data
  ☐ 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, SOP(s) for release and exceptional release. [D5.1.10]

☐ List of all policies and procedures in the Processing Facility Standard Operating Procedures Manual, including 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 protected health information (PHI), such as patient names, medical record numbers, birth date, or others. 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. [D7.3.1, Appendix I, Appendix II].
  ☐ Partial labels applied by the Processing Facility. [Appendix I]
  ☐ Labels applied at completion of processing of allogeneic products. [ Appendix I]
  ☐ Labels applied at completion of processing of autologous products. [ Appendix I]
  ☐ Labels applied prior to distribution for allogeneic products. [ Appendix I]
  ☐ Labels applied prior to distribution for autologous products. [ Appendix I]
  ☐ Labels applied to inner and outer shipping containers for products shipped or transported on public roads. [ Appendix II]

☐ SOP for labeling that includes when biohazard and/or warning labels are used, including: [D7.3.2, 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 and a policy or procedure that discusses the documentation that is distributed with the product. [D7.3.5, Appendix III]
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]

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 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]