

 <p>FOUNDATION FOR THE ACCREDITATION OF CELLULAR THERAPY Policies and Procedures</p>	<p>Policy</p>	<p>Document #: INS.7.1.001 Revision: 13 Approval Date: 03/21/2023 Page 1 of 3 Effective Date: 03/21/2023</p>
<p>Initial FACT Inspector Qualifications</p>		

1.0 Purpose

This policy outlines initial qualifications for individuals applying to become a FACT Inspector.

2.0 Scope

This policy applies to individuals applying to become a FACT inspector and to FACT personnel involved in approving FACT inspector applications.

3.0 Responsibility

- 3.1 It is the responsibility of FACT to ensure that:
- 3.1.1 FACT personnel and volunteers have access to this policy.
 - 3.1.2 This policy is followed.

4.0 Reference

- 4.1 [Conflict of Interest Policy](#), CMP.15.1.008
- 4.2 [Confidentiality Policy](#), CMP.15.1.009
- 4.3 [Copyright Policy](#), CMP.15.1.007
- 4.4 [Inspector Status](#), INS.7.1.002

5.0 Definitions and Abbreviations - NA

6.0 Policy

6.1 Initial Inspector Qualifications

6.1.1 General qualifications for an inspector:

6.1.1.1 Meets educational and professional qualifications and has the appropriate work experience related to his/her area(s) of expertise. Some of the experience should be within the most recent 10 years (refer to 6.1.2 to 6.1.9), as determined by the FACT Board of Directors.

6.1.1.2 Is affiliated with a FACT accredited or applicant organization.

- A hematopoietic cellular therapy or cord blood bank inspector applicant may matriculate through the inspector training program and will be eligible to serve as an active inspector when his/her affiliated organization achieves FACT accreditation.
- An immune effector cell or regenerative medicine clinical inspector applicant may be approved and initiate inspector training prior to program application for accreditation. Inspectors may matriculate through the inspector training program and are eligible to serve as an active inspector when his/her affiliated organization achieves FACT accreditation or for up to two years while his/her affiliated program is an applicant for FACT accreditation of immune effector cellular therapy accreditation.
- An inspector applicant recommended by the Global Affairs Committee to serve on one of its initiatives may be approved and initiate inspector

training. Inspectors may matriculate through the inspector training program and are eligible to serve as an active inspector when his/her affiliated organization achieves FACT accreditation or for up to two years while his/her affiliated program is an applicant for FACT accreditation. An inspector is approved to perform inspections only for programs seeking certification or accreditation at the same level of the inspector's affiliated program (e.g., Step 1 of the FACT- JACIE Stepwise Accreditation Program).

6.1.1.3 Is an individual member of ISCT, ASTCT, ASFA, AABB, CBA, WMDA, or is a member of a professional society relevant to cord blood banking or immune effector cells as approved by the FACT Chief Medical Officer.

- If the individual is a member of ASFA only, he/she is limited to conducting inspections of apheresis facilities.
- If the individual is a member of AABB only, he/she is limited to conducting inspections of apheresis or cell processing facilities.
- If the individual is a member only of CBA, WMDA, or a professional society relevant to cord blood banking, he/she is limited to conducting inspections of cord blood banks.
- If the individual is a member only of a professional society relevant to immune effector cells, he/she is limited to conducting inspections of immune effector cellular therapy programs.

6.1.1.4 Has submitted a complete inspector application, including required documents.

6.1.1.5 Has agreed to comply with FACT's policies on [Conflict of Interest Policy](#), [Confidentiality Policy](#), and [Copyright Policy](#).

6.1.2 Clinical Program Inspector

6.1.2.1 Is a licensed physician.

6.1.2.2 An HPC inspector has at least two years experience in hematopoietic progenitor cell transplantation.

6.1.2.3 An immune effector cell inspector has experience in cellular therapy product administration, including experience with immune effector cell protocols.

6.1.2.4 A translational cellular therapy inspector has experience in cellular therapy product administration, including experience with investigational new drug (IND) or clinical research protocols.

6.1.3 Marrow Collection Inspector

6.1.3.1 Is a licensed physician.

6.1.3.2 Has completed formal fellowship training that includes marrow collection or has at least one year experience as a marrow collection physician.

6.1.4 Apheresis Collection Inspector

6.1.4.1 Has a relevant doctoral (M.D. or equivalent, or Ph.D.), nursing, or biological science degree.

6.1.4.2 Has completed formal fellowship training in apheresis or at least one year experience in cellular therapy product collection by apheresis as one of the following: director, physician, or individual with direct supervision of apheresis personnel.

- 6.1.5 Cell Processing: minimal manipulation of HPC
 - 6.1.5.1 Has a relevant doctoral (M.D. or equivalent, or Ph.D.) , biological science, or medical technologist degree.
 - 6.1.5.2 Has at least two years experience as director or medical director of a cell processing facility or as an individual with direct supervision of cellular therapy product processing personnel.
- 6.1.6 Cell Processing: more than minimal manipulation of any cell type
 - 6.1.6.1 Has a relevant doctoral (M.D. or equivalent, or Ph.D.), biological science, or medical technologist degree.
 - 6.1.6.2 Has at least two years experience as director or medical director of a cell processing facility or as an individual with direct supervision of cellular therapy product processing personnel.
 - 6.1.6.3 Has experience processing cellular therapy products with more than minimal manipulation under IND or equivalent requirements, or as the director, medical director, or direct supervisor of personnel in such a facility.
- 6.1.7 Cord Blood Bank Inspector
 - 6.1.7.1 Has a relevant doctoral (M.D. or equivalent, or Ph.D.) degree or if not serving as a FACT Inspection Team Leader, a relevant biological science degree with sufficient experience.
 - 6.1.7.2 Has at least two years experience in cord blood banking and/or transplantation.
- 6.1.8 Cord Blood Bank Collection Inspector
 - 6.1.8.1 Has a relevant doctoral (M.D. or equivalent, or Ph.D.) , nursing, or biological science degree.
 - 6.1.8.2 Has at least one year experience as cord blood bank director or individual with direct supervision of cord blood collection personnel.
- 6.1.9 Cord Blood Bank Processing Inspector
 - 6.1.9.1 Has a relevant doctoral (M.D. or equivalent, or Ph.D.) , biological science, or medical technologist degree.
 - 6.1.9.2 Has at least two years experience as a director or medical director of a cord blood processing or cellular therapy product processing facility or as an individual with direct supervision of cord blood bank, cord blood processing, or cellular therapy product processing personnel.
- 6.2 To determine the classification of an inspector after the initial inspector qualifications have been met, refer to FACT's policy on [*Inspector Status*](#).

Approved by (date):

Heather Conway (Quality Manager) (03/21/2023), Linda Miller (Chief Operating Officer) (03/21/2023), Phyllis Warkentin (Chief Medical Officer) (01/24/2023)