

Initial FACT Inspector Qualifications

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 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 All personnel and inspectors have access to this policy.
- 3.1.2 Guidelines described herein are followed.

4.0 Reference

- 4.1** Duality of Interest Policy, 2.1.001
- 4.2** Confidentiality Policy, 2.1.002
- 4.3** Inspector Status Classifications, 7.1.002

5.0 Policy

5.1 Initial Inspector Qualifications

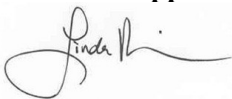
5.1.1 General qualifications for an inspector:

5.1.1.1 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 5.1.2 to 5.1.9), as determined by the FACT Board of Directors.

5.1.1.2 Is affiliated with a FACT accredited or applicant organization.

- A hematopoietic cellular therapy 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.

Document approval:



Linda Miller
Chief Executive Officer
Date Approved: 7/25/2019



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Date Approved: 7/25/2019

- A 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 or for up to two years while his/her affiliated bank is an applicant for FACT accreditation of cord blood banking.
 - 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.
- 5.1.1.3 Is an individual member of ISCT, ASBMT, ASFA, CBA, or is a member of a professional society relevant to immune effector cells.
- 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 CBA only, 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.
- 5.1.1.4 Has submitted a complete inspector application, including required documents.
- 5.1.1.5 Has agreed to comply with FACT's policies on *Duality of Interest (2.1.001)* and *Confidentiality (2.1.002)*.
- 5.1.2 Clinical Program Inspector
- 5.1.2.1 Is a licensed physician (medical degree).
- 5.1.2.2 An HPC inspector has at least two years experience in hematopoietic progenitor cell transplantation.
- 5.1.2.3 An immune effector cell inspector has experience in cellular therapy product administration, including experience with immune effector cell protocols.
- 5.1.2.4 A translational cellular therapy inspector has experience in cellular therapy product administration, including experience with investigational new drug (IND) or clinical research protocols.
- 5.1.3 Marrow Collection Inspector
- 5.1.3.1 Is a licensed physician (medical degree).
- 5.1.3.2 Has completed formal fellowship training in marrow collection or at least one year experience in marrow collection as a director or physician.
- 5.1.4 Apheresis Collection Inspector
- 5.1.4.1 Has a relevant doctoral (M.D. or Ph.D.), nursing, or biological science degree.

- 5.1.4.2 Has completed formal fellowship training in apheresis or at least one year experience in cell collection by apheresis as one of the following: director, physician or individual with direct supervision of apheresis personnel.
- 5.1.5 Processing: minimal manipulation of HPC
 - 5.1.5.1 Has a relevant doctoral (M.D. or Ph.D.), biological science, or medical technologist degree.
 - 5.1.5.2 Has at least two years experience as director or medical director of a cell processing facility or as an individual with direct supervision of processing personnel.
- 5.1.6 Processing: more than minimal manipulation of any cell type
 - 5.1.6.1 Has a relevant doctoral (M.D. or Ph.D.), biological science, or medical technologist degree.
 - 5.1.6.2 Has at least two years experience as director or medical director of a cell processing facility or as an individual with direct supervision of processing personnel.
 - 5.1.6.3 Has experience processing cellular therapy products with more than minimal manipulation under IND or equivalent requirements.
- 5.1.7 Cord Blood Bank Inspector
 - 5.1.7.1 Has a relevant doctoral (M.D. or Ph.D.) degree.
 - 5.1.7.2 Has at least two years experience in cord blood banking and/or transplantation.
- 5.1.8 Cord Blood Bank Collection Inspector
 - 5.1.8.1 Has a relevant doctoral (M.D. or Ph.D.), nursing, or biological science degree.
 - 5.1.8.2 Has at least one year experience as cord blood bank director or individual with direct supervision of cord blood collection personnel.
- 5.1.9 Cord Blood Bank Processing Inspector
 - 5.1.9.1 Has a relevant doctoral (M.D. or Ph.D.), biological science, or medical technologist degree.
 - 5.1.9.2 Has at least two years experience as a director or medical director of a cord blood bank cell processing facility or as an individual with direct supervision of cord blood bank, cord blood processing, or cellular therapy product processing personnel.
- 5.2** To determine the classification of an inspector after the initial inspector qualifications have been met, refer to FACT's policy on *Inspector Status (7.1.002)*.

6.0 Revision History

Date	Revision #	Author/Requestor	Changes	Justification
07Dec2007	0	FACT Board	New Document	New Document
05May2009	1	FACT Staff	<ol style="list-style-type: none"> 1. Add clarifications on forms for membership requirements. 2. Remove version numbers on referenced documents policies. 3. Add CBB Team Leader qualifications. 	<ol style="list-style-type: none"> 1. Membership requirements need to be aligned with policy requirements. 2. Policy requires adherence to most current version of all referenced documents/policies. 3. CBB Team Leader qualifications need to be explicitly stated in policy.
29May2009	2	Chief Medical Officer	<ol style="list-style-type: none"> 1. Add language 'ideally' to the number of inspections an active inspector performs per year. 2. Include additional Inspector Trainer qualifications. 3. Require 90% accuracy on Inspector Test before applicant may be considered an inspector. 	<ol style="list-style-type: none"> 1. FACT makes every effort to keep inspector base current; however, fully qualified active inspectors may not necessarily be able to conduct 2/year. 2. Additional qualifications part of continuous improvement initiatives. 3. Currently no accuracy requirement.
25Aug2009	3	Chief Medical Officer	<ol style="list-style-type: none"> 1. Add allowance for inspectors to remain qualified for up to two years after service on the Accreditation, Standards, and/or Training and Development Committees. 2. Add the Inspector Tests and Keys as Forms to this SOP. 	<ol style="list-style-type: none"> 1. Some inspectors leave their applied/accredited programs but are still actively involved in FACT committees after two years. Participation in the Accreditation, Standards, and/or Training and Development Committees involves thorough and current knowledge in inspection and accreditation requirements. 2. Ensures review process and maintenance.
30Sep2009	4	Chief Medical Officer	<ol style="list-style-type: none"> 1. Revise Cellular Therapy Test (Form 3) and accompanying Key (Form 4) questions 16, 33, 73, 93. 	<ol style="list-style-type: none"> 1. These questions were confusing to inspectors or applicant inspectors taking the test. The language was revised to clarify certain points in these questions.
01Jan2010	5	Chief Medical Officer	<ol style="list-style-type: none"> 1. Update Cord Blood Test and Key for 4th Edition Standards. 	<ol style="list-style-type: none"> 1. New version of Cord Blood Standards published 01Jan2010.
17Nov2011	6	Manager, Standards Development and Education	<ol style="list-style-type: none"> 1. Changes the SOP to include only the initial qualifications for a person to become a trainee inspector. 2. Moved inspector allowance to remain qualified to Inspector Status (7.1.002) 	<ol style="list-style-type: none"> 1. Policies regarding FACT requirements are separate from work procedures. This <i>policy</i> is to document initial inspector qualifications required by FACT.
16Oct2012	7	Director of Operations	<ol style="list-style-type: none"> 1. Add clarification that some of required experience must be within 10 years. 2. Addition of Category 2 processing inspectors. 	<ol style="list-style-type: none"> 1. Some applicant inspectors obtained experience more than a decade ago; their knowledge may not be current. 2. Category 2 inspectors were added in support of the more than minimal accreditation goal.
14Jul2014	8	Director of Operations	<ol style="list-style-type: none"> 1. Clarified Apheresis Collection Inspector and Marrow Collection Inspector requirements. 	<ol style="list-style-type: none"> 1. Requirements for the Apheresis Collection Inspector and Marrow Collection Inspector was not clear.
05Apr2017	9	Director of Operations	<ol style="list-style-type: none"> 1. Broadened required experience for Category 2 Cellular Therapy Processing Inspectors to include any type of cellular therapy product. 2. Clarified that Clinical Inspectors must have experience with IND products for inspecting translational cellular therapy.. 	<ol style="list-style-type: none"> 1. Category 2 inspectors will be considered eligible to perform inspections under the Common Standards. 2. Requirements for inspectors chosen to inspect under the clinical section of the Common Standards must be outlined.
25Jul2019	10	Strategic Planning Administrator	<ol style="list-style-type: none"> 1. Remove NetCord membership and accreditation requirement. 2. Add CBA individual membership. 3. Change regenerative medicine inspector to "translational cellular therapy inspector." 	<ol style="list-style-type: none"> 1. NetCord is no longer an entity. 2. CBA is current Cord Blood Society. 3. Broader term to encompass all translational therapies.