	<b>Policy</b>	Document #: 7.1.002 Revision: 2 Publication Date: 9/7/2017 Page 1 of 6 Effective Date: 9/7/2017
<b>Inspector Status</b>		

## 1.0 Purpose

- 1.1 The purpose of this policy is to outline inspector status classifications.

## 2.0 Scope

- 2.1 This policy is applicable to all FACT inspectors and FACT staff involved in classifying the status of an inspector and scheduling on-site FACT inspections.

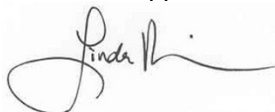
## 3.0 Responsibility

- 3.1 It is the responsibility of the Quality Manager to ensure FACT staff and FACT inspectors have access to this policy.
- 3.2 It is the responsibility of the Education and Training Coordinator to ensure that all FACT staff are adequately trained on this policy.
- 3.2.1 The guidelines described herein are followed.
- 3.3 It is the responsibility of the Education and Training Coordinator, Business Manager, and Quality Manager to perform the tasks herein or delegate tasks to trained staff members when necessary.

## 4.0 References

- 4.1 Travel Guidelines and Expense Reimbursement Policy, 1.1.004
- 4.2 Privacy and Security Policy, 1.2.002
- 4.3 Duality of Interest and Statement of Compliance, 2.1.001
- 4.4 Confidentiality and Statement of Compliance, 2.1.002
- 4.5 Hearsay Evidence, 4.1.001
- 4.6 Reviewing Complaints and Grievances, 4.2.001
- 4.7 Reviewing Complaints and Grievances, 4.2.001 Form 6
- 4.8 Accreditation Process, 6.1.001
- 4.9 Accreditation of HRSA National Cord Blood Inventory Contractors, 6.1.004
- 4.10 Initial FACT Inspector Qualifications, 7.1.001
- 4.11 Training Inspection Tracking Sheet, 7.1.002 Form 1
- 4.12 Review of Inspector Performance, 7.1.003
- 4.13 Inspector Handbook, 7.2.001
- 4.14 Inspector Training Program, 7.2.002
- 4.15 Approving Inspector Applications, 7.6.001

### Document Approvals



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## 5.0 Definitions:

**Qualifying FACT Committee:** A FACT committee with responsibilities directly linked to the inspection and accreditation process for which membership requires current knowledge of FACT requirements. This includes the Cellular Therapy Accreditation Committee, Cord Blood Accreditation Committee, Standards Committees, and Education Committee.

## 6.0 Policy

6.1 FACT inspectors are classified as one of the following:

- 6.1.1 Trainee inspector.
- 6.1.2 Active inspector.
- 6.1.3 Inactive inspector.
- 6.1.4 Cancelled inspector.

### 6.2 Trainee Inspector

- 6.2.1 A trainee inspector is one whose application has been approved and is in the process of completing the inspector training program.
- 6.2.2 When a trainee satisfactorily completes the training inspection within the timelines outlined in *Inspector Training Program, 7.2.002*, the trainee's status is changed to "active."

### 6.3 Active Inspector

- 6.3.1 An active inspector is an individual who can be scheduled to perform on-site FACT inspections.
- 6.3.2 An active inspector is one who:
  - 6.3.2.1 Has completed the inspector training program. Active inspectors must complete their first active inspection within 12 months of the training inspection.
  - 6.3.2.2 Has current credentials, contact information, and compliance with *Duality of Interest and Statement of Compliance, 2.1.001* and *Confidentiality and Statement of Compliance, 2.1.002*.
  - 6.3.2.3 Participates in or views one FACT educational session annually.
  - 6.3.2.4 Completes applicable inspector tests for each new edition with a minimum score of 90 percent correct. This satisfies 6.3.2.3.
  - 6.3.2.5 Ideally performs a minimum of two inspections per twelve-month period.
  - 6.3.2.6 Follows the policies and procedures of FACT as applicable to inspector responsibilities.
    - Travel Guidelines and Expense Reimbursement Policy, 1.1.004
    - Privacy and Security Policy, 1.2.002
    - Duality of Interest and Statement of Compliance, 2.1.001
    - Confidentiality and Statement of Compliance, 2.1.002
    - Accreditation Process, 6.1.001

- Accreditation of HRSA National Cord Blood Inventory Contractors, 6.1.004
  - Initial FACT Inspector Qualifications, 7.1.001
  - Review of Inspector Performance, 7.1.003
  - Inspector Handbook, 7.2.001
  - Inspector Training Program, 7.2.002
- 6.3.3 Membership: An active inspector must maintain membership with ISCT, ASBMT, ASFA, or a professional society relevant to immune effector cells, or continue affiliation with a bank that is a member of NetCord.
- 6.3.3.1 Inspectors may be limited to inspector categories related to their memberships per *Initial FACT Inspector Qualifications, 7.1.001*.
- 6.3.4 An active cellular therapy inspector must currently be affiliated with an accredited organization or a qualifying FACT committee.
- 6.3.5 An active cord blood inspector must currently be affiliated with an applicant or accredited organization or a qualifying FACT committee.
- 6.3.5.1 Cord blood inspectors are eligible to serve as an active inspector for two years while affiliated with an applicant bank. If the applicant bank is not accredited at the end of the two years, the Business Manager places the inspector in inactive status until his/her bank is accredited.
- 6.3.6 If an active inspector is no longer affiliated with an applicant or accredited organization or a qualifying FACT committee, that inspector may request continuance of active inspector status for up to two years if the following conditions are met:
- 6.3.6.1 The individual has completed the entire inspector training program and achieved active inspector status prior to leaving the applicant or accredited organization.
- 6.3.6.2 The individual must submit a current CV and job description.
- 6.3.6.3 The individual is not currently employed by another organization that accredits cellular therapy activities or cord blood banking.
- 6.3.6.4 The individual is not acting as a quality assurance, accreditation, or certification consultant in cellular therapy or cord blood banking as the primary source of income.
- 6.3.6.5 The individual's new employment position does not pose an unacceptable conflict of interest with FACT.
- 6.3.6.6 The individual is covered by professional liability insurance.
- 6.3.6.7 The individual signs and submits new statements confirming compliance with *Duality of Interest and Statement of Compliance, 2.1.001* and *Confidentiality and Statement of Compliance, 2.1.002*.
- 6.3.6.8 The Education and Training Coordinator ensures these inspectors meet the above conditions.

## 6.4 Inactive Inspector

- 6.4.1 An inactive inspector is an individual who cannot be scheduled to perform on-site FACT inspections.
- 6.4.1.1 If an inactive status exceeds two (2) years, the inspector may be required to repeat training requirements (e.g., attend a workshop, retake the inspector test, or complete other requirements) as directed by the Education Committee to remain a FACT inspector.
- 6.4.1.2 The inactive inspector must meet the conditions outlined in 6.3 before active status can be reinstated.
- 6.4.1.3 The Education and Training Coordinator, Business Manager, or Quality Manager places inspectors in inactive status, updates the inspector's profile, and notes the change in status on the *Training Inspection Tracking Sheet, 7.1.002 Form 1*.
- 6.4.2 An inactive inspector is one who:
- 6.4.2.1 Has requested to be put on reserve for a specific amount of time
- The Business Manager reviews this request, places the inspector in inactive status, and returns the inspector to active status at the appropriate time.
- 6.4.2.2 Has unresolved performance or behavior issues. Refer to *Review of Inspector Performance, 7.1.003*.
- The Education and Training Coordinator or Quality Manager places the inspector in inactive status, and returns the inspector to active status after issues have been resolved.
- 6.4.2.3 Has missed the deadline for the Inspector Test and/or annual compliance update.
- The Education and Training Coordinator, Quality Manager, or Business Manager places the inspector in inactive status, and returns the inspector to active status upon receipt of completed test or update.
- 6.4.2.4 Is affiliated with a suspended organization.
- The Business Manager places the inspector in inactive status, and returns the inspector back to active status once the organization's accreditation has been reinstated.
- 6.4.2.5 Does not return emails or calls, has left his/her organization with no forwarding information, or has not performed an inspection in the previous two years.
- Such inspectors are notified by email or written letter from the Education and Training Coordinator requesting a response with intent to continue FACT inspections within 30 days. The FACT Education and Training coordinator places the inspector in inactive status upon sending the notification.
  - If a response is not received after 30 days, the Education and Training Coordinator changes the inspector's status to cancelled.
  - If a response is received, refer to 6.4.1.1.

6.4.2.6 A formal complaint (e.g., *Reviewing Complaints and Grievances, 4.2.001 Form 6*), hearsay or third party information regarding an inspector's qualifications, and/or inspector performance/behavior during an inspection visit has been received by FACT. Refer to *Hearsay Evidence, 4.1.001* and *Reviewing Complaints and Grievances, 4.2.001*.

- The Quality Manager forwards this information to the Chief Medical Officer and/or the Grievance Committee for evaluation.
- The Quality Manager places the inspector in inactive status, and returns the inspector to active status if appropriate based on the evaluation.

6.4.2.7 The inspector is associated in any way with a high profile situation, which would reflect poorly on FACT if the individual were to perform on-site inspections. Refer to *Hearsay Evidence, 4.1.001* and *Reviewing Complaints and Grievances, 4.2.001*.

- The Quality Manager forwards this information to the Chief Medical Officer and/or the Grievance Committee for evaluation.
- The Quality Manager places the inspector in inactive status, and returns the inspector to active status if appropriate based on the evaluation. This decision is at the sole discretion of FACT.

6.4.3 If any of the items in 6.4.2 cannot be resolved, the Education and Training Coordinator may classify the inspector as cancelled with approval by the Education Committee. Refer to section 6.5.

## **6.5 Cancelled Inspector**

6.5.1 A cancelled inspector is an individual who cannot be scheduled to perform on-site FACT inspections.

6.5.1.1 The Education Committee must approve removal of the individual from the FACT inspectorate.

6.5.1.2 The Education and Training Coordinator cancels an individual's inspector status and notifies FACT staff.

6.5.2 A cancelled inspector is one who:

6.5.2.1 Has made a written or verbal request to be removed from the list of active inspectors.

6.5.2.2 Has not responded to requests for intent to continue as a FACT inspector.

6.5.2.3 Is no longer allowed to perform FACT inspections due to a performance, behavior, grievance, and/or hearsay issue at the discretion of FACT.

6.5.2.4 Has been removed from the list of active FACT inspectors at the request of the FACT Board and/or the FACT Chief Medical Officer.

6.5.3 A cancelled inspector may reapply to become a FACT inspector.

6.5.3.1 A reapplication from an individual whose inspector status was cancelled per 6.5.2.3 or 6.5.2.4 must be approved by the Education Committee.

6.5.3.2 If approved, he/she must re-complete the inspector training program.

**6.6** Written notification from FACT to an inspector shall constitute adequate documentation of change of an inspector's status.

## 7.0 Revision History

Date	Revision #	Author/Requestor	Changes	Justification
24Dec2011	0	FACT Board	New Document	New Document
07Jul2014	1	FACT Board	<ol style="list-style-type: none"> <li>1. Add clarification regarding Program or Bank Directors of suspended organizations.</li> <li>2. Update position titles</li> <li>3. Clarify which inspectors can be scheduled for an on-site FACT inspection.</li> </ol>	<ol style="list-style-type: none"> <li>1. Inspector requirements must be included in Policy.</li> <li>2. New position created.</li> <li>3. Clarifies which inspectors can be scheduled for on-site FACT inspections.</li> </ol>
06Sep2017	2	Education and Training Coordinator	<ol style="list-style-type: none"> <li>1. Updated responsibilities and references</li> <li>2. Changed "pending" status to "inactive status"</li> <li>3. Require active inspectors no longer affiliated with an applicant or accredited organization to have professional liability insurance</li> <li>4. Require Education Committee approval: <ol style="list-style-type: none"> <li>a. Cancel an inspector</li> <li>b. Re-application of cancelled inspectors who were cancelled due to performance, behavior, grievance, hearsay, or other significant events.</li> </ol> </li> <li>5. Require inspectors complete training and achieve active status in order to be eligible to inspect 2 years after leaving an applicant or accredited facility.</li> <li>6. Change the requirement for an inspector to complete their first active inspection from 18 months to 12 months.</li> </ol>	<ol style="list-style-type: none"> <li>1. Provide clarity and accuracy</li> <li>2. MatrixMaxx "inactive" status allows FACT staff to quickly identify status of the inspector</li> <li>3. All clinical inspectors must have professional liability insurance.</li> <li>4. Incorporate appropriate review and oversight</li> <li>5. Inspectors must be experienced and active to inspect after leaving an applicant or accredited facility.</li> <li>6. Inspection requirements once active are every 12 months.</li> </ol>