

 <p>Policies and Procedures</p>	<p>Policy</p>	<p>Document #: INS.7.1.002 Revision: 3 Approval Date: 10/19/2021 Page 1 of 4 Effective Date: 10/19/2021</p>
<p>Inspector Status</p>		

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 and 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 [Accreditation Process](#), ACC.6.1.001
- 4.2 [Complaint and Grievance Submission Form](#), LGL.FRM.4.001
- 4.3 [Confidentiality Policy](#), CON.2.1.002
- 4.4 [Conflict of Interest Policy](#), CON.2.1.001
- 4.5 [Hearsay Evidence](#), LGL.4.1.001
- 4.6 [Initial FACT Inspector Qualifications](#), INS.7.1.001
- 4.7 [Inspector Handbook](#), INS.7.2.001
- 4.8 [Inspector Training Program](#), INS.7.1.004
- 4.9 [Review of Inspector Performance](#), INS.7.1.003
- 4.10 [Reviewing Complaints and Grievances](#), LGL.4.6.001
- 4.11 [Travel Guidelines and Expense Reimbursement Policy](#), ADM.1.1.004

5.0 Definitions and Abbreviations:

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 Former 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](#), 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 agreement to comply with FACT's policies on [Conflict of Interest](#) and [Confidentiality](#).
 - 6.3.2.3 Participates in or views two hours of FACT education 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 Performs an ideal two inspections annually, but no less than one inspection every 24 months.
 - 6.3.2.6 Follows the policies and procedures of FACT as applicable to inspector responsibilities, including those referenced in 4.0.
- 6.3.3 Membership: An active inspector must maintain membership as outlined in [Initial FACT Inspector Qualifications](#).
- 6.3.4 An active cellular therapy inspector or cord blood inspector must currently be affiliated with an accredited organization.
- 6.3.5 An active immune effector cell or regenerative medicine clinical inspector must currently be affiliated with an applicant or accredited organization.
 - 6.3.5.1 The inspector is eligible to serve as an active inspector for two years while affiliated with an applicant organization.

- 6.3.6 If an active inspector is no longer affiliated with an applicant or accredited organization, that inspector may continue 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 submits a current CV and job description.
 - 6.3.6.3 The individual is not employed by another organization that accredits cellular therapy activities or cord blood banking.
 - 6.3.6.4 The individual is not employed by a company that sells goods or services related to cellular therapy or cord blood banking but is ineligible for FACT accreditation.
 - 6.3.6.5 The individual is not acting as a paid quality assurance, accreditation, or certification consultant in cellular therapy or cord blood banking. If the individual provides consulting services on a voluntary basis to an organization, the individual must not perform the FACT inspection of that organization.
 - 6.3.6.6 The individual is not a member of the FACT Consulting Services Board of Directors or acting as a consultant for FACT Consulting Services.
 - 6.3.6.7 The individual's new employment position does not pose an unacceptable conflict of interest with FACT.
 - 6.3.6.8 The individual is covered by professional liability insurance, if applicable.
 - 6.3.6.9 If the active inspector is not affiliated with an applicant or accredited organization after two years, the individual may request approval to continue as an active inspector status for an additional two years if a member of a qualifying FACT committee.

6.4 Inactive Inspector

- 6.4.1 An inactive inspector is an individual who temporarily cannot be scheduled to perform on-site FACT inspections.
- 6.4.1.1 The inactive inspector must meet the conditions outlined in 6.3 before active status can be reinstated. If an inspection has not been performed in two (2) years, re-completion of the inspector training program in accordance with [Inspector Training Program](#) will be required.
- 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.
 - 6.4.2.2 Has not performed an inspection in two (2) years.
 - 6.4.2.3 Has unresolved performance or behavior issues. Refer to [Review of Inspector Performance](#).
 - 6.4.2.4 Has missed the deadline for the Inspector Test or annual compliance update.
 - 6.4.2.5 Is affiliated with a suspended organization.
 - 6.4.2.6 Does not return emails or calls or has left his/her organization with no forwarding information.

- 6.4.2.7 A formal complaint, hearsay or third-party information regarding an inspector's qualifications or performance/behavior during an inspection visit has been received by FACT. Refer to [Hearsay Evidence](#) and [Reviewing Complaints and Grievances](#).
 - 6.4.2.8 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](#) and [Reviewing Complaints and Grievances](#).
- 6.5 Former Inspector
- 6.5.1 A former inspector is an individual who is no longer a part of the FACT inspectorate and cannot be scheduled to perform on-site FACT inspections.
 - 6.5.1.1 The Chief Medical Officer must approve removal of the individual from the FACT inspectorate.
 - 6.5.2 A former 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 within the defined timeframe.
 - 6.5.2.3 Is no longer eligible due to the requirements listed in 6.3.
 - 6.5.2.4 Is no longer allowed to perform FACT inspections due to a performance, behavior, grievance, and/or hearsay issue at the discretion of FACT.
 - 6.5.2.5 Has been removed from the list of active FACT inspectors at the request of the FACT Board or the FACT Chief Medical Officer.
 - 6.5.3 A former inspector may reapply to become a FACT inspector.
 - 6.5.3.1 A reapplication from a former inspector per 6.5.2.4 or 6.5.2.5 must be approved by the Chief Medical Officer.
 - 6.5.3.2 Individuals who reapply to become an inspector and are approved must re-complete the inspector training program in accordance with [Inspector Training Program](#).
- 6.6 Written notification from FACT to an inspector shall constitute adequate documentation of change of an inspector's status.

Approved by (date):

Heather Conway (Quality Manager) (10/19/2021), Linda Miller (Chief Executive Office) (10/16/2021),
Phyllis Warkentin (Chief Medical Officer) (10/16/2021)