

 <p>Policies and Procedures</p>	<p>Policy</p>	<p>Document #: INS.7.1.004 Revision: 2 Approval Date: 31/March/2023 Page 1 of 3 Effective Date: 31/March/2023</p>
<p>Inspector Training Program</p>		

1.0 Purpose

The purpose of this policy is to define the FACT inspector training program.

2.0 Scope

This policy applies to all FACT personnel, inspectors, inspector trainees, and volunteers.

3.0 Responsibility

- 3.1 The FACT Quality Manager ensures that all FACT personnel, inspectors, inspector trainees, and volunteers have access to this policy.
- 3.2 The Education and Training Coordinator is responsible for the overseeing the process and ensuring the guidelines described herein are followed

4.0 References

- 4.1 [Conflict of Interest Policy](#) , CON.2.1.001
- 4.2 [Confidentiality Policy](#) , CON.2.1.002
- 4.3 [Mentor Training Inspection Evaluation](#), INS.FRM.7.009
- 4.4 [Trainee Training Inspection Evaluation](#), INS.FRM.7.010
- 4.5 [Initial FACT Inspector Qualifications](#), INS.7.1.001
- 4.6 [Inspector Status](#), INS.7.1.002

5.0 Definitions and Abbreviations – N/A

6.0 Policy

- 6.1 Approved trainee inspectors are notified of the following requirements:
 - 6.1.1 Trainee inspectors must complete the following requirements within 12 months of application approval:
 - 6.1.1.1 Attendance of a CT and/or CB Inspector Training Course as applicable.
 - 6.1.1.2 Completion of the current CT and/or CB Inspector Test as applicable with a minimum score of 90 percent correct. Trainee inspectors who do not score a 90 percent correct may submit a re-completed test one additional time.

- 6.1.1.3 Viewing of the Professional Inspections webinar recording.
- 6.1.1.4 Viewing of the Training Inspections tutorial.
- 6.1.2 After completion of the initial inspector training program, the trainee must participate in a training inspection.
 - 6.1.2.1 The trainee must complete a training inspection within 18 months after completion of the requirements in 6.1.1. If FACT is unable to place the trainee with a suitable on-site inspection within 18 months, the timeframe for completing this requirement will be extended.
 - 6.1.2.2 The inspection shall be at FACT expense.
 - 6.1.2.3 Insurance as it applies to inspectors shall apply to the trainee.
 - 6.1.2.4 The trainee must satisfactorily complete all training inspection requirements, which include completion, review, and submission of the inspection checklist and the inspection report, and submission of the Inspection Evaluation.
 - 6.1.2.5 The trainee must receive a satisfactory evaluation from his/her mentor indicating that the trainee is able to perform the duties required.

6.2 Qualified Mentors

- 6.2.1 An inspector is qualified to serve as a mentor to train an inspector trainee if he/she meets the following qualifications:
 - 6.2.1.1 Is currently an active inspector.
 - 6.2.1.2 For cellular therapy program inspectors, he/she must satisfactorily perform at least two inspections as an active inspector of cellular therapy programs prior to training an inspector candidate.
 - 6.2.1.3 For cord blood bank inspectors, he/she must satisfactorily perform at least one inspection as an active inspector of a cord blood bank prior to training an inspector candidate.
 - 6.2.1.4 Must be paired with a trainee inspector of the same inspector category (i.e., has the same area of technical expertise as the trainee inspector, such as collection, processing)
 - 6.2.1.5 Must be able to subjectively evaluate the trainee inspector and provide a timely report to FACT regarding his/her assessment of the trainee's ability to effectively perform independent inspections.
 - 6.2.1.6 Must not have any unresolved unsatisfactory evaluations from programs, Accreditation Coordinators, other inspectors, or others.

6.3 Post-Training Inspection Evaluation

- 6.3.1 The trainee inspector is required to submit, within three days of the inspection, his/her completed checklist, report, and notes. In addition, within two weeks of the inspection the trainee must complete and submit the [Trainee Training Inspection Evaluation](#).
- 6.3.2 Within two weeks of the inspection, the mentor is to review the trainee's report, provide feedback to the trainee, and complete the [Mentor Training Inspection Evaluation](#), including a summary of the feedback to the trainee.
- 6.3.3 The trainee inspector and/or mentor will not be reimbursed for expenses until all documentation has been submitted.
- 6.3.4 After the required documents from the mentor and the trainee are determined to be adequate, the trainee inspector will be granted active inspector status.
- 6.3.5 The Education and Training Coordinator will notify the trainee inspector of the decision concerning active inspector status.

6.4 Maintaining active status, inspectors must complete annual requirements outlined in the [Inspector Status](#).

Approved by (date):

Heather Conway (Quality Manager) (31/March/2023), Linda Miller (Chief Operating Officer) (30/March/2023)