

 <p>Policies and Procedures</p>	<p>Policy</p>	<p>Document #: 7.2.002 Revision: 0 Valid Date: 17Nov2011 Page 1 of 3 Effective Date: 24Nov2011</p>
<p>Inspector Training Program</p>		

1.0 Purpose

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

2.0 Scope

2.1 This policy is applicable to all FACT office personnel.

3.0 Responsibility

3.1 It will be the responsibility of the FACT QA Manager to ensure that:

- 3.1.1 All FACT personnel and trainee inspectors have access to this SOP.
- 3.1.2 The guidelines described herein are followed.

3.2 The Administrative Staff is comprised of the Business Manager who will be responsible for the “Administrative Staff” duties described herein.

3.3 The Accreditation Coordinators are responsible for the “Coordinator” duties described herein.

4.0 References

- 4.1 Updating the Members Only Database and Accredited Programs Sections on the FACT Website, 1.6.002
- 4.2 Duality of Interest and Statement of Compliance, 2.1.001
- 4.3 Confidentiality and Statement of Compliance, 2.1.002
- 4.4 Initial FACT Inspector Qualifications, 7.1.001
- 4.5 Inspector Status, 7.1.002
- 4.6 Documenting and Facilitating the Inspector Training Program, 7.6.002
- 4.7 Trainee/Mentor guide: Cellular Therapy Program, 7.2.002 Form 1
- 4.8 Trainee/Mentor guide: Cord Blood Bank, 7.2.002 Form 2

5.0 Definitions – N/A

<p><u>Document Approvals</u></p> <p>Chief Operating Officer Approval Granted: <u>17Nov2011</u></p> <p>Issued as Controlled Document by Quality Assurance: <u>17Nov2011</u></p>

6.0 Policy

- 6.1 Upon approval of the inspector application (7.6.002), the trainee inspector is 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 at a CT and/or CB inspection and accreditation workshop 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 one and one half years after completion of the requirements in 6.1.1. If FACT is unable to place the trainee with a suitable on-site inspection within one and one half years, 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 of the inspection checklist and the inspection report; submission of the checklist, report, and notes to the FACT office; and submission of the Inspection Evaluation (Trainee) online.
 - 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, etc.).
 - 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.

6.2.1.7 Agrees to train inspectors.

6.3 Post-Training Inspection Evaluation

6.3.1 The trainee inspector is required to submit to the mentor and the FACT office, 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 to the FACT office the Inspection Evaluation (Trainee).

6.3.2 Within two weeks of the inspection, the mentor is to review the trainee's report, provide feedback to the trainee, complete the Inspection Evaluation (Mentor), including a summary of the feedback to the trainee, and submit all documents to the FACT office.

6.3.3 The trainee inspector and/or mentor will not be reimbursed for expenses until all documentation has been submitted.

6.3.4 Once all of 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 Accreditation Coordinator assigned to the organization will notify the trainee inspector of the decision concerning active inspector status.

6.4 Maintaining Active Status

6.4.1 To maintain active status, inspectors must complete annual requirements outlined in the Inspector Status Policy, 7.1.002