

 <p>FOUNDATION FOR THE ACCREDITATION OF CELLULAR THERAPY AT THE UNIVERSITY OF NEBRASKA MEDICAL CENTER Policies and Procedures</p>	<p>Policy</p>	<p>Document #: 7.1.003 Revision: 0 Publication Date: 9/7/2017 Page 1 of 4 Effective Date: 9/7/2017</p>
<p>Review of Inspector Performance</p>		

1.0 Purpose

- 1.1 The purpose of this document is to define FACT’s policy for management of active inspector performance.

2.0 Scope

- 2.1 This policy is applicable to all FACT active and trainee inspectors, volunteers, and FACT staff.

3.0 Responsibility

- 3.1 It is the responsibility of the FACT Education and Training Coordinator to ensure that:
 - 3.1.1 All FACT personnel and inspectors have access to this policy.
 - 3.1.2 The guidelines described herein are followed.

4.0 References

- 4.1 Hearsay Evidence, 4.1.001
- 4.2 Reviewing Complaints and Grievances, 4.2.001
- 4.3 Inspector Status, 7.1.002
- 4.4 Inspector Training Program, 7.2.002
- 4.5 Documenting and Facilitating the FACT Inspector Training Program, 7.6.002

5.0 Definitions – N/A

6.0 Procedure

- 6.1 FACT inspectors are volunteer experts in the field who are expected to maintain their professional credentials and conscientiously perform objective on-site inspections of applicant facilities in a timely, professional, unbiased, and confidential manner according to FACT policies and procedures.
- 6.2 Specific inspector requirements are listed in the *Inspector Status policy (7.1.002)*, *Inspector Training Program policy (7.2.002)*, and *Documenting and Facilitating the FACT Inspector Training Program procedure (7.6.002)*.
- 6.3 The FACT Education Committee has oversight of training and education requirements and opportunities for the FACT inspectorate and of inspector performance (both collectively and individually).

<p><u>Document Approvals</u></p>	
 <p>Linda Miller CEO Date: 06Sep2017</p>	 <p>Heather J. Conway Quality Manager Date: 31Aug2017</p>

- 6.4 The FACT Education Committee regularly reviews feedback regarding inspector performance during on-site inspections. Such feedback may be received from other inspectors, the applicant facility personnel, FACT coordinators, or other sources.
 - 6.4.1 The FACT Quality Manager and Education and Training Coordinator are responsible for review of evaluations from all on-site inspections and for the preparation of data for the Education Committee.
 - 6.4.2 Trends of aggregate data are identified and necessary improvements will be made to the FACT education and training program. Data includes, but is not limited to, the number of inspection evaluations received, sources of evaluations (e.g., applicants, inspectors, trainees), and number of evaluations that include complaints, compliments, suggestions, or other comments.
 - 6.4.3 Inspectors who are the subject of specific, positive evaluations will receive a letter of acknowledgement from the FACT Office on behalf of the Education Committee and Chair.
 - 6.4.4 Management of unfavorable comments is described below.
- 6.5 FACT may receive adverse inspector information in a variety of ways, including but not limited to evaluations, in-person communication, telephone discussion, email, or inspection audit results.
- 6.6 Upon receipt of any adverse information, the initial recipient at the FACT Office forwards the information to the FACT Quality Manager and the FACT Education and Training Coordinator.
- 6.7 The name of the inspector remains confidential with the exception of the Chair of the Education Committee and FACT personnel.
- 6.8 The FACT Education and Training Coordinator assesses the information and determines what (if any) further investigation is necessary.
 - 6.8.1 The inspector may not be scheduled for any new on-site inspections during this process if the initial determination suggests the incident warrants action.
 - 6.8.2 The extent of further investigation depends upon many factors, including but not limited to:
 - 6.8.2.1 Severity of the complaint.
 - 6.8.2.2 Prior complaints related to the same individual.
 - 6.8.2.3 Experience of the inspector, including frequency of inspections performed.
 - 6.8.2.4 Extenuating circumstances (such as high profile complaint, public dissemination of complaint, etc.).
 - 6.8.2.5 Any other relevant factors.

- 6.9 The FACT Education and Training Coordinator compiles additional data related to the performance issue and the specific inspection. This information may include but is not limited to:
- 6.9.1 Source documents.
 - 6.9.2 Inspection reports.
 - 6.9.3 Inspection evaluations.
 - 6.9.4 Coordinator assessments.
 - 6.9.5 Prior information about the inspector (for example, experience, number of prior inspections, and number of previous complaints of which he/she was the subject).
 - 6.9.6 Previous information about the complainant (length of time the program has been accredited, previous complaints, etc.).
- 6.10 Complaints deemed to have little or no merit or lack significance are filed, the issue is closed, and the inspector may continue to perform on-site inspections.
- 6.11 Complaints unrelated to performance as a FACT inspector (such as issues in the press or at the inspector's home institution) are handled on a case by case basis by the FACT Chief Medical Officer, FACT Education and Training Coordinator, FACT Quality Manager, Attorney, or others as appropriate. Refer to *Hearsay Evidence, 4.1.001* or *Reviewing Complaints and Grievances, 4.2.001*.
- 6.12 Complaints related to inspector performance in relation to FACT business, including the results of the investigation to date, are forwarded by the FACT Education and Training Coordinator to the Chair of the FACT Education Committee.
- 6.13 The Chair of the Education Committee may request additional information.
- 6.14 The Chair of the Education Committee contacts the inspector to identify additional factors relevant to the complaint, and follow up with the FACT Education and Training Coordinator to determine what (if any) remedial or corrective action is required. The FACT Chief Medical Officer is informed as this process progresses.
- 6.15 If it is determined that the complaint lacks merit, the complaint is closed and filed, and the inspector is notified that the complaint has been closed.
- 6.16 If it is determined that the inspector in some manner did not fulfill his/her responsibilities in the conduct of the inspection process, remedial actions may be required depending in part upon severity, number of prior occurrences, and other factors. Potential remedial actions include but are not limited to:
- 6.16.1 Email acknowledgement of the issue and further guidance.
 - 6.16.2 Telephone discussion of the issue and further guidance.
 - 6.16.3 Additional reading, review of standards, or an exam on standards.
 - 6.16.4 Participation in an additional training workshop or trainee inspection.

- 6.16.5 Disqualification of inspector from further inspections for a specified or unspecified period of time.
- 6.17 The Chair of the Education Committee or the FACT Education and Training Coordinator coordinates completion of the required corrective and preventive actions with the inspector, the timeline for completion, and the repercussions of failure to complete these requirements and to demonstrate improvement.
- 6.18 Upon completion of the corrective and preventive actions, the inspector may resume on-site inspections.
- 6.19 If the inspector does not show improvement or is the subject of additional performance complaints, the Chair of the Education Committee and Chief Medical Officer determine the appropriate action(s) to follow, based on the number and severity of performance issues, up to removal of the individual from the FACT inspectorate.
- 6.19.1 Inspectors with repeated unsatisfactory performance reports may not be assigned additional on-site inspection responsibilities.
- 6.20 At any time, a volunteer inspector may appeal the decisions made by the FACT Education and Training Coordinator, the Chair of the Education Committee, or the Education Committee.
- 6.20.1 The first appeal is sent to the FACT Chief Medical Officer. If the issues cannot be resolved at this level, the FACT Chief Medical Officer forwards the issue to the Grievance Committee.

7.0 Revision History

Date	Revision #	Author/Requestor	Changes	Justification
31Aug2017	0	Education Committee	New Document	New Document