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|  <p>Policies and Procedures</p> | <p align="center"><b>Standard Operating Procedure</b></p> | <p>Document #: 4.2.001<br/> Revision: 2<br/> Valid Date: 20Aug2009<br/> Page 1 of 6<br/> Effective Date: 27Aug2009</p> |
| <p align="center"><b>Reviewing Complaints and Grievances</b></p>   |   |  |

**1.0 Purpose**

The purpose of this Standard Operating Procedure is to outline the Foundation for the Accreditation of Cellular Therapy (FACT)’s process for responding to a complaint or grievance.



Situations may arise when FACT receives a complaint or grievance related to its business of accreditation. To ensure adequate, appropriate, and objective review of the complaint or grievance, the steps in this SOP must be followed. It is FACT’s goal to conduct investigations, derive conclusions, and enact remedial steps in a respectful and confidential manner to both the complainant and the subject of the complaint or grievance.

**2.0 Scope**

FACT will only review complaints and grievances that are specific to the Cellular Therapy Standards; the Cord Blood Standards; the FACT accreditation process; and/or FACT Board of Directors, committee members, inspectors, and/or staff. FACT does not address grievances related to the individual management of a patient unless it directly relates to a standard. FACT does not review any complaints related to unaccredited organizations.

This procedure is applicable to all FACT staff and volunteers when involved in a complaint or grievance. It is meant to be a descriptive outline of the review process. Due to the unique nature of complaints and grievances, it is not intended to be prescriptive regarding which avenues to explore during the review process. The goal of the procedure is to ensure adequate, objective review through the appropriate chains of command.

This procedure is not applicable to legal issues, in which case FACT’s legal counsel will direct the organization on which steps to take, if any.

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| <p><b><u>Document Approvals</u></b></p>   |   |
|  <p><b>Linda Miller – Chief Operating Officer, FACT</b><br/> Date: 20Aug2009</p> |  <p><b>Jill Hempel – Quality Assurance Coordinator</b><br/> Date: 20Aug2009</p> |

### 3.0 Responsibility

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

- 3.1.1 All staff and appropriate committee members are adequately trained and have access to this SOP.
- 3.1.2 All complaints and grievances are kept confidential.
- 3.1.3 The guidelines described herein are followed.

3.2 This procedure is formally carried out by the Grievance Committee, with input from other committees, volunteers, and staff as necessary to carry out the procedure.

3.2.1 The Grievance Committee is comprised of, but not limited to, the following:

- 3.2.1.1 FACT Grievance Committee Chair.
- 3.2.1.2 FACT Training & Development Committee representative.
- 3.2.1.3 FACT Program Relations Committee representative.
- 3.2.1.4 FACT Standards Development Committee representative.
- 3.2.1.5 FACT BMT Program Quality Management Committee representative.
- 3.2.1.6 FACT Inspectorate representative.
- 3.2.1.7 FACT Office Committee Liaison (“Grievance Committee Liaison”).

### 4.0 References

- 4.1 Duality of Interest and Statement of Compliance, 2.1.001
- 4.2 Confidentiality and Statement of Compliance, 2.1.002
- 4.3 Complaint Acknowledgement Letter, 4.2.001 Form 1
- 4.4 Grievance Acknowledgement Letter, 4.2.001 Form 2
- 4.5 Complaint Outcome Letter, 4.2.001 Form 3
- 4.6 Grievance Outcome Letter, 4.2.001 Form 4
- 4.7 Complaint and Grievance Log, 4.2.001 Form 5
- 4.8 Complaint and Grievance Submission Form, 4.2.001 Form 6
- 4.9 FACT Inspector Qualifications Standard Operating Procedure, 7.1.001
- 4.10 FACT Accreditation Status Granted to Cellular Therapy Programs, 6.2.002
- 4.11 UNMC Corrective and Disciplinary Action Policy, Policy #1098

### 5.0 Definitions

- 5.1 **Complaint:** A written or verbal objection related to the FACT Board of Directors, committee members, inspectors, staff, and/or the accreditation process.
- 5.2 **Grievance:** A formal request for review of a perceived wrong at a FACT accredited or applied organization or an unsatisfactorily resolved complaint.
- 5.3 **Complainant:** The individual or entity submitting a complaint or grievance.
- 5.4 **Subject:** The focus of a complaint and/or grievance. The subject may be an individual or an idea (e.g. an inspector or a standard).

### 6.0 Procedure

6.1 Receiving complaints and grievances.

6.1.1 Methods for reporting a complaint or grievance include:

- 6.1.1.1 Complaint and grievance submission form.
- 6.1.1.2 Inspection evaluation forms.
- 6.1.1.3 Written or electronic complaint or grievance.
- 6.1.1.4 Verbal complaint or grievance.

- 6.1.2 Upon receipt of complaint or grievance, the initial recipient at the FACT Office forwards the information to the Grievance Committee Liaison within 24 hours of receipt.
  - 6.1.3 If necessary, the initial recipient assists the complainant with providing the information. This may include, but is not limited, to:
    - 6.1.3.1 Providing the complainant with the email address and/or telephone number of the committee liaison.
    - 6.1.3.2 Instructing the complainant to complete the appropriate evaluation or submission form.
    - 6.1.3.3 Obtaining the complainant's contact information to forward to the Grievance Committee Liaison.
  - 6.1.4 The Grievance Committee Liaison documents the complaint or grievance in the Complaint and Grievance Log. Refer to 4.2.001, Form 5.
  - 6.1.5 If applicable, the Grievance Committee Liaison compiles additional data related to the complaint or grievance. This information may include:
    - 6.1.5.1 Source documents (e.g., letters, electronic messages, etc.)
    - 6.1.5.2 Inspection reports
    - 6.1.5.3 Inspection evaluations
  - 6.1.6 If additional information is requested from the complainant, the information must be provided in 30 days or the complaint or grievance will be closed.
- 6.2 For complaints related to the FACT Board of Directors, committee members, inspectors, staff, and/or the accreditation process:
- 6.2.1 The Grievance Committee Liaison forwards complaints and additional data (if applicable) to the liaison of the appropriate FACT committee within three days of original receipt.
    - 6.2.1.1 Complaints specific to office procedures are forwarded to the FACT Chief Operating Officer.
  - 6.2.2 The liaison to the appropriate FACT committee notifies the applicable Committee Chair within 10 days of original receipt.
  - 6.2.3 The applicable Committee Chair responds to the complainant in writing or electronically within 30 days of original receipt to acknowledge the complaint and explain the process for reviewing it. Refer to 4.2.001 Form 1 for further details.
  - 6.2.4 The applicable Committee Chair (or COO) determines if the complaint can be addressed by FACT office staff.
  - 6.2.5 If appropriate, the applicable Committee Chair convenes a committee meeting to address the issue.
    - 6.2.5.1 The appropriate FACT committee meets within 60 days of original receipt.
- 6.3 For grievances related to a perceived wrong at a FACT accredited or applied organization or an unsatisfactorily resolved complaint:
- 6.3.1 For grievances related to the services of a FACT accredited or applied program or bank, the complainant will be instructed to first file a complaint with the program or bank.
    - 6.3.1.1 The complainant will be given information for how to file a subsequent grievance to FACT if the complainant is not satisfied by the program's or bank's resolution of the grievance.
  - 6.3.2 The Grievance Committee Liaison forwards the grievance and additional data to the Grievance Committee Chair within 10 days of original receipt.

- 6.3.2.1 If the Chair needs to be recused because of bias or conflict of interest, he/she shall appoint another Grievance Committee member to contact the complainant.
- 6.3.2.2 If a grievance contains material evidence of violation of laws or regulations, the Chair will request legal review and consultation from FACT's attorney.
- 6.3.3 The Grievance Committee Chair acknowledges the complainant in writing or electronically within 30 days of original receipt to acknowledge the grievance and explain the process for reviewing it. Refer to 4.2.001 Form 2 for further details.
  - 6.3.3.1 For grievances related to patient care filed by a complainant other than the patient, the Chair will ask that the patient endorse the grievance if appropriate. If appropriate and the patient refuses to endorse the grievance, FACT will close the grievance.
  - 6.3.3.2 If the Chair determines the grievance does not relate directly to the FACT Standards or accreditation process, he/she will notify the complainant that the grievance is not within the scope of FACT.
- 6.3.4 The Grievance Committee Chair calls a committee meeting to address the issue.
- 6.3.5 The information is forwarded to the Grievance Committee.
- 6.3.6 Depending on the nature of the complaint or grievance, the Grievance Committee may request input from additional staff and volunteers as necessary to conduct a thorough review.
- 6.3.7 Grievance Committee members are recused if potential or actual bias or conflict of interest exists.
- 6.3.8 The Grievance Committee convenes to discuss the information and determine if additional investigation is necessary.
  - 6.3.8.1 The Grievance Committee meets within 60 days of original receipt.

#### 6.4 Investigating complaints and grievances.

- 6.4.1 For grievances related to the services of a FACT accredited or applied program or bank, the program or bank will be notified and provided an opportunity to comment on the grievance.
- 6.4.2 Potential avenues for investigation include, but are not limited to:
  - 6.4.2.1 Source documents.
  - 6.4.2.2 Inspection reports.
  - 6.4.2.3 Inspection evaluations.
  - 6.4.2.4 Accreditation Coordinator(s) interview.
  - 6.4.2.5 Inspector(s) interview.
  - 6.4.2.6 Facility representative(s) interview.
  - 6.4.2.7 Standards and Guidance materials.
  - 6.4.2.8 Previous performance.
  - 6.4.2.9 Legal Review.
- 6.4.3 Upon completion of investigation (during initial meeting or after subsequent meetings), the committee arrives to a conclusion.
  - 6.4.3.1 Inconclusive or controversial investigations are elevated first to the Grievance Committee (if applicable) and then to the FACT Board of Directors.

#### 6.5 Remedial actions.

- 6.5.1 A remedial action, if any, is set in accordance with the conclusion agreed upon by the Grievance Committee, appropriate FACT committee, FACT Board of Directors, or designee, as applicable.

- 6.5.2 Potential remedial actions include, but are not limited to:
  - 6.5.2.1 Process improvement.
  - 6.5.2.2 Education and training.
  - 6.5.2.3 Termination or probation of active inspector status. Refer to 7.1.001 for further details.
  - 6.5.2.4 Termination or probation of accreditation. Refer to 6.2.002 for further details.
  - 6.5.2.5 Personnel actions according to the UNMC policy, Corrective and Disciplinary Action, Policy #1098.
- 6.5.3 Remedial actions that result in termination or probation of accreditation must be approved by the FACT Board of Directors.
- 6.5.4 Upon decision of remedial action, if any, the subject of the complaint or grievance is notified of the complaint or grievance (when applicable and if has not been already), the avenues taken during the investigation, conclusions, and remedial actions.

## 6.6 Outcome

- 6.6.1 After the review is complete, the complainant is notified that the review is complete. Refer to 4.2.001 Forms 3 and 4 for further details.
  - 6.6.1.1 Specific information related to the investigation of the complaint or grievance is confidential and will not be disclosed to the complainant.
  - 6.6.1.2 As appropriate, de-identified and summarized complaint or grievance information is shared with the appropriate FACT committees for continuous improvement of the inspection and accreditation process.

## 6.7 Appeals

- 6.7.1 The complainant and/or the subject of a complaint or grievance has the right to one appeal of the outcome of a review.
- 6.7.2 A written appeal must be received by the FACT office within 30 days of being notified of the completion of the review.
  - 6.7.2.1 The written request shall provide complete details of the reasons for appeal including all supporting documentation.
- 6.7.3 Appeals regarding complaints will be reviewed by the FACT Grievance Committee.
- 6.7.4 Appeals regarding grievances will be reviewed by the FACT Board of Directors.
- 6.7.5 The FACT Board of Directors or Grievance Committee, as applicable, will notify the complainant and/or subject of the complaint or grievance of its decision.

## 6.8 Document Control

- 6.8.1 All documents related to a specific complaint or grievance file are managed and confidentially controlled in the FACT office by the Grievance Committee Liaison.
  - 6.8.1.1 Protected Health Information (PHI) is redacted from source documents before distribution to the appropriate individuals unless the PHI is needed to address the issue.
  - 6.8.1.2 PHI is distributed only to organizations with a Business Associate Agreement in effect with FACT or individuals conducting business on behalf of FACT with a signed Confidentiality Statement of Compliance.

6.8.2 The FACT Office shall retain all documents related to a complaint or grievance for 10 years.

6.8.2.1 The Grievance Committee shall be instructed to destroy all documents related to a complaint or grievance when it is determined these documents are no longer needed to manage the complaint or grievance.

## 7.0 Revision History

| Date      | Revision # | Author/Requestor                 | Changes   | Justification  |
|-----------|------------|----------------------------------|---|--|
| 22May2008 | 0          | FACT Board                       | New Document  | New Document   |
| 19Mar2009 | 1          | Grievance Committee              | <ol style="list-style-type: none"> <li>1. Revise Grievance Committee composition.</li> <li>2. Add complaint and grievance letters, and log.</li> <li>3. Include separate sections in procedure for complaints and grievances.</li> <li>4. Include Grievance Committee Liaison duties.</li> <li>5. Include Outcomes and Document Control sections.</li> </ol>  | <ol style="list-style-type: none"> <li>1. The Grievance Committee includes chairs of all relevant committees.</li> <li>2. No previous documents existed for execution of the complaint/grievance procedure.</li> <li>3. Complaints are distinct from grievances, and are thus handled differently as they pertain to this procedure.</li> <li>4. Liaison duties not previously included in procedure.</li> <li>5. Sections are essential for execution and follow-up of all complaint and grievance activities.</li> </ol> |
| 20Aug2009 | 2          | Grievance Committee/Legal Review | <ol style="list-style-type: none"> <li>1. Revise scope to limit investigations to FACT related activities.</li> <li>2. Add complaint and grievance submission form.</li> <li>3. Include requirements for submitting grievances related to programs/banks.</li> <li>4. Add Board approval for remedial actions resulting in termination or probation of a program/bank .</li> <li>5. Add Appeals section.</li> </ol> | <ol style="list-style-type: none"> <li>1. It is beyond the purview of FACT to become involved in non-FACT related investigations.</li> <li>2. Submission form will help streamline submission process to FACT.</li> <li>3. Complainant must first submit grievance to program/bank prior to FACT's involvement.</li> <li>4. Board approval is required for all termination/probation actions.</li> <li>5. Section details appeals procedure for complainant and/or subject of complaint or grievance.</li> </ol>           |