

	<b>Policy</b>	Document #: 2.1.001 Revision: 8 Publication Date: 09/07/2017 Page 1 of 4 Effective Date: 09/07/2017
<b>Duality of Interest and Statement of Compliance</b>		

**1.0 Purpose**



The Foundation for the Accreditation of Cellular Therapy (“FACT”) is a not-for-profit professional association founded to establish high quality standards in cellular therapy and to develop and implement a voluntary program of inspection and accreditation in collection, processing, and administration of cellular therapy products and in cord blood collection, banking, and release for administration.

Volunteers and staff of FACT carry out the mission of the Foundation through service on the Board of Directors, as members of various committees and task forces, as inspectors and reviewers in the accreditation process, and as liaisons to other organizations. Their activities in FACT have far-reaching implications, including the development of consensus standards for the field, determination of the accreditation status of applicants, and representation of FACT to outside individuals and organizations. FACT is well served when its volunteers and staff have diverse interests and participate in activities outside of FACT. These outside interests and participations enhance the experience and expertise that volunteers and staff bring to their various roles in serving, governing, or representing FACT.

Situations occasionally arise in which an individual serving FACT as a staff member or in an elected or appointed position has a duality of interest that may be, or could be, perceived as a relevant duality of interest or even a conflict of interest.

It is not the intent of this policy to prohibit or discourage anyone from participation in the activities of FACT or other outside interests. Closely related dualities of interest are not inherently wrong or forbidden, but FACT must be made aware of such interests in order to be able to evaluate fully their impact on its mission and activities.

A key element in monitoring relevant dualities of interest and in avoiding potential conflicts of interest is a system by which those serving FACT disclose these interests. This permits FACT to determine if a duality of interest is relevant and the steps necessary to minimize the likelihood that a conflict would arise.

<u>Document Approvals</u>	
 Linda Miller Chief Executive Officer, FACT Date: 6Sep2017	 Heather J. Conway Quality Manager Date: 6Sep2017

## **2.0 Scope**

- 2.1 The following individuals are required to disclose to FACT any dualities that may be relevant to the work of FACT:
  - 2.1.1 Officers
  - 2.1.2 Members of the Board of Directors
  - 2.1.3 Committee and task force members
  - 2.1.4 Inspectors and inspector trainees
  - 2.1.5 FACT personnel

## **3.0 Responsibility**

- 3.1 It will be the responsibility of the FACT Quality Manager to ensure that:
  - 3.1.1 All Board Members, Officers, committee and task force members, inspectors, inspector trainees, and FACT personnel have access to this policy.
  - 3.1.2 The guidelines described herein are followed.
  - 3.1.3 The statement of compliance is made available to all persons covered by the policy upon initial association with FACT and annually thereafter.

## **4.0 References**

- 4.1 *Copyright Assignment, Confidentiality, Duality of Interest, and Professional History, 2.1.005 Form 1*

## **5.0 Definitions - N/A**

## **6.0 Policy**

- 6.1 Generally, a relevant duality of interest exists when volunteers or staff members have material interests outside of FACT that could influence them, or could be perceived as influencing them, to act contrary to the interests of FACT or its applicant and accredited organizations, and for their own personal benefit or that of a family member or a business associate. Most often, a relevant duality of interest is financial, such as when an individual has an employment relationship, a stock ownership interest, or a consultative or advisory arrangement, or receives a grant or stipend. A conflict of interest may also exist in situations of current, past, or future employment, prior on-site inspection experiences, or other situations that do not arise out of financial considerations.
  - 6.1.1 Types of dual interests subject to disclosure to FACT are detailed on *Copyright Assignment, Confidentiality, Duality of Interest, and Professional History Form, 2.1.005 Form 1*.
- 6.2 Reporting Process
  - 6.2.1 Volunteers and staff who are subject to this policy must complete and submit the *Copyright Assignment, Confidentiality, Duality of Interest, and Professional History Form, 2.1.005 Form 1*, at the time they are nominated, appointed, employed, or become officially associated with an activity of FACT.
  - 6.2.2 In addition, those required to submit the statement are expected to notify FACT in writing if there are any material changes since the last statement was submitted.

- 6.2.3 The Executive Committee or its designee is responsible for:
  - 6.2.3.1 The reporting and disclosure process to ensure that it is consistent with the purpose of this policy.
  - 6.2.3.2 Regular reports to the Board of Directors to affirm that all appropriate staff and volunteers have submitted compliance statements.
  - 6.2.3.3 Review, approval and monitoring of the process and methods by which there is disclosure of relevant dualities of interest in activities, organizations, and publications.
  - 6.2.3.4 Recommendations or instructions to individuals completing the compliance statement regarding actions that should or must be taken to reduce or eliminate a potential or real conflict.
  - 6.2.3.5 Review of this policy and recommendations for revision whenever appropriate.
  
- 6.3 Participation Process
  - 6.3.1 In addition to reporting potential conflicts of interest, Board members, inspectors, committee or task force members, and FACT personnel are required to follow the following policies of participation:
    - 6.3.1.1 Members of the inspection team are required to recuse themselves if they perceive a conflict of interest exists that would interfere with, or could be perceived as interfering with, the objectivity of the inspection process.
    - 6.3.1.2 A Program Director may request that any proposed inspector be replaced if the Director perceives such a conflict of interest. In this event, a different inspector will be selected.
    - 6.3.1.3 Persons who perform mock inspections to assist an organization with preparation for an on-site FACT inspection shall not participate in the formal inspection process of that organization during that inspection cycle, whether or not the individual is compensated for the mock inspection.
    - 6.3.1.4 An active member of the FACT Board of Directors or the FACT Accreditation Committee and FACT personnel shall not participate in a mock inspection to assist in that organization's preparation for FACT accreditation.
    - 6.3.1.5 Members of the Accreditation Committee are required to recuse themselves if they perceive a conflict that would interfere with, or could be perceived as interfering with the objectivity of the Accreditation Committee review process.
    - 6.3.1.6 An active member of the FACT Board of Directors, any task force, or Chair of the Standards or Accreditation Committees shall not be employed by, serve on the Board of Directors, or participate in standards-setting or accrediting activities of an organization that accredits cellular therapy activities or cord blood banking.
    - 6.3.1.7 Employees or Board members of other organizations that accredit cellular therapy activities or cord blood banking shall not serve on the FACT Board of Directors, task forces, and committees. Employees shall also not serve as FACT inspectors.

## 7.0 Revision History

Date	Rev. #	Author / Requestor	Changes	Justification
17Sep2007	0	FACT Board	New Document	New Document
22Sep2008	1	Kara Wacker	<ol style="list-style-type: none"> <li>1. Include cord blood banks in Purpose section.</li> <li>2. Remove 'hematopoietic' from Purpose section.</li> <li>3. Remove letters sent out with policy.</li> <li>4. Re-number questions in Form 1.</li> </ol>	<ol style="list-style-type: none"> <li>1. Duality if Interest Policy is applicable to all volunteers of FACT.</li> <li>2. The cellular therapy field has expanded.</li> <li>3. Letters no longer used.</li> <li>4. Formatting is more uniform for each question.</li> </ol>
28Sep2009	2	Jill Hempel	<ol style="list-style-type: none"> <li>1. Adjust formatting of form to reduce pages.</li> <li>2. Include "Program" definition.</li> </ol>	<ol style="list-style-type: none"> <li>1. Letterhead is not used when distributing to volunteers.</li> <li>2. The "Program" definition is needed to clarify the inclusion of cellular therapy programs and cord blood banks.</li> </ol>
21Sep2010	3	Jill Hempel	<ol style="list-style-type: none"> <li>1. Create live version of Statement of Compliance</li> <li>2. Change "Program" to "organization"</li> </ol>	<ol style="list-style-type: none"> <li>1. Live form will allow organizations to download and save Statement of Compliance information in FACTWeb.</li> <li>2. Allows for consistency in policy and terminology used in FACTWeb.</li> </ol>
13Aug2012	4	Kara Wacker	<ol style="list-style-type: none"> <li>1. Add additional criteria: <ul style="list-style-type: none"> <li>-The individual is not currently employed by another organization that accredits cellular therapy activities or cord blood banking.</li> <li>- The individual is not acting as a quality assurance, accreditation, or certification consultant in cellular therapy or cord blood banking as a primary source of income.</li> <li>- The individual's new employment position does not pose an unacceptable conflict of interest with FACT.</li> </ul> </li> </ol>	<ol style="list-style-type: none"> <li>1. FACT has many proprietary interests pursued by volunteer committees and task forces, and these interests must be protected.</li> </ol>
05Sep2012	5	FACT Board	Definition of financial interest modified by FACT Board.	Change "Material Financial Interest" to "Financial Interest" so that the definition is "any equity interest or compensation from any entity that furnishes goods or services to FACT" and remove any reference to financial ownership interest.
04Feb2013	6	Director of Operations	Members of the FACT BOD or task forces shall not be employed by or on the BOD of other organizations that accredited cellular therapy activities or cord blood banking. Employees of other organizations that accredit cellular therapy activities or cord blood banking shall not be a member of the FACT BOD, task forces, committees, or the inspectorate.	FACT volunteers have possession of important business intelligence and participate in many strategic initiatives that, if discovered by competing organizations, could be detrimental to the Foundation.
10Feb2014	7	Chief Executive Officer	<ol style="list-style-type: none"> <li>1. Add additional requirements for Accreditation Committee Member participation.</li> <li>2. Reconcile Duality of Interest Policy with Duality of Interest Compliance Form.</li> </ol>	<p>Eliminate perceived conflict of interest by Accreditation Committee members by recusing themselves from accreditation discussions.</p> <p>Policy now refers to complete listing of compliance issues on Confidentiality Statement rather than individually listing on policy to avoid incongruences.</p>
08Feb2017	8	Quality Manager	<ol style="list-style-type: none"> <li>1. Add form number</li> <li>2. Consolidate forms to be completed during annual compliance</li> <li>3. Add inspector trainees</li> </ol>	<ol style="list-style-type: none"> <li>1. Forms must be assigned unique identifiers for document control purposes.</li> <li>2. Easier process for user</li> <li>3. Inspectors trainees must agree to comply with this policy when applying to become a FACT Inspector.</li> </ol>