

	<b>Policy</b>	Document #: CON.2.1.001 Revision: 9 Approval Date: 05/04/2020 Page 1 of 3 Effective Date: 05/04/2020
<b>Conflict of Interest Policy</b>		

**1.0 Purpose**

The Foundation for the Accreditation of Cellular Therapy (“FACT”) is a not-for-profit professional association founded to establish and promote high quality standards in cellular therapy and regenerative medicine 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 FACT personnel carry out the mission of FACT through service on the Board of Directors, as members of committees and task forces, as inspectors, inspector trainees, 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 personnel have diverse interests and participate in activities outside of FACT. These outside interests and participations enhance the experience and expertise that volunteers and personnel bring to their various roles in serving, governing, or representing FACT.

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

**2.0 Scope**

2.1 This policy applies to FACT personnel and volunteers.

**3.0 Responsibility**

3.1 The FACT Quality Manager or designee ensures that this policy is made available to FACT personnel and volunteers upon initial association with FACT, at a minimum.

3.2 It is the responsibility of all personnel and volunteers to understand and comply with this policy.

3.3 The Executive Committee or its designee is responsible for:

3.3.1 The reporting and disclosure process to ensure that it is consistent with the purpose of this policy.

3.3.2 Regular reports to the Board of Directors to affirm that all appropriate FACT personnel and volunteers have submitted compliance statements.

- 3.3.3 When necessary, consulting legal counsel.
- 3.3.4 Review of this policy and recommendations for revisions whenever appropriate.

#### **4.0 References**

- 4.1 *FACT Annual Compliance, CON.FRM.2.003*

#### **5.0 Definitions**

- 5.1 Volunteers
  - 5.1.1 Officers
  - 5.1.2 Members of the Board of Directors
  - 5.1.3 Committee and task force members
  - 5.1.4 Inspectors and inspector trainees
  - 5.1.5 Other persons assigned to an activity of FACT (e.g., society representative, inspection observer, regulatory or industry representative)

#### **6.0 Policy**

- 6.1 A conflict of interest exists when FACT volunteers 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.
  - 6.1.1 Most often, a conflict 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.
  - 6.1.2 Types of conflicts of interests subject to disclosure to FACT are detailed on the *FACT Annual Compliance form, CON.FRM.2.003*.
- 6.2 Reporting Process
  - 6.2.1 Volunteers and FACT personnel who are subject to this policy must complete and submit the *FACT Annual Compliance form, CON.FRM.2.003*, at the time they are nominated, appointed, employed, or become officially associate with an activity of FACT, at a minimum.
  - 6.2.2 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.
    - 6.2.2.1 The conflict of interest information submitted is considered current unless FACT is notified in writing of material changes.

- 6.3 In addition to reporting potential conflicts of interest, FACT volunteers and personnel who are subject to this policy are required to abide by the following:
- 6.3.1 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.
  - 6.3.2 A Program Director may request that any proposed inspector, or inspector trainee, be replaced if the Director perceives such a conflict of interest. In this event, a different inspector or inspector trainee will be selected.
  - 6.3.3 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.
  - 6.3.4 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.
  - 6.3.5 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.
  - 6.3.6 An active member of the FACT Board of Directors, task forces, 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.
  - 6.3.7 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.

Approved: Heather Conway (Quality Manager) (05/04/2020), Linda Miller (CEO) (05/04/2020)