

## **Confidentiality and Statement of Compliance**

### **1.0 Purpose**

The Foundation for the Accreditation of Cellular Therapy (“FACT”) is a not-for-profit professional association established to 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, release for administration, and administration of cellular therapy products and cord blood units.

In the regular conduct of its business of accreditation, FACT, its volunteers, and staff are in receipt of considerable confidential information from various sources. It is understood that damage could be incurred by FACT, its accredited or applicant organizations or their personnel, or to the Officers and Board Members of FACT should such information become generally known.

### **2.0 Scope**

- 2.1 Confidential information includes, but is not limited to, the following:
  - 2.1.1 Names and accreditation status of any applicant or accredited organization
  - 2.1.2 Results of an on-site inspection
  - 2.1.3 Individual policies, procedures, or patient outcomes of organizations
  - 2.1.4 Written documents or summaries prepared by FACT staff or volunteer committees
  - 2.1.5 Business intelligence and strategic initiatives collected and performed by FACT Board members, committees, or staff
  - 2.1.6 Protected personal information related to patients or donors in organizations
  - 2.1.7 Results of other accreditation, approval, or regulatory assessments at an organization
  - 2.1.8 Professional information related to faculty or staff of an organization

### **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, personnel, inspectors, and committee and task force members have access to this SOP.
  - 3.1.2 The guidelines described herein are followed.
  - 3.1.3 FACT’s *Copyright Assignment, Confidentiality, and Duality of Interest Form (2.1.004 Form 1)* is made available to all persons covered by the policy upon initial association with FACT and annually thereafter.

#### **Document Approvals**

**Linda Miller**  
Chief Executive Officer, FACT  
Date: March 30, 2017

**Heather J. Conway**  
Quality Manager  
Date: March 30, 2017

## 4.0 References

4.1 2.1.005 Form 1, *Copyright assignment, Confidentiality, and Duality of Interest Form*

## 5.0 Definitions

- 5.1 ASBMT: American Society for Blood and Marrow Transplantation
- 5.2 ISCT: International Society for Cellular Therapy
- 5.3 Organization: Refers to clinical programs, cell collection, and/or processing facilities, as well as cord blood banks and affiliated sites.

## 6.0 Policy

- 6.1 All information obtained during the accreditation process, including reports of prior inspection visits or results of other external assessments, is confidential material not to be discussed or distributed outside of the relevant FACT work group unless expressly approved by the FACT Board of Directors.
- 6.2 All communications and documents relating to business intelligence and strategic initiatives shall be held and maintained for the sole and exclusive benefit of FACT. All Board Members, Officers, personnel, inspectors, committee members, and task force members shall carefully restrict access to confidential information as is reasonably required and shall not, without prior written approval of FACT, use for his/her own benefit, publish, copy, or otherwise disclose to others, or permit the use by others for their benefit or to the detriment of FACT, any confidential information. Such responsibility does not extend to information that is:
  - 6.2.1 publicly known at the time of disclosure or subsequently becomes publicly known through no fault of the individual;
  - 6.2.2 discovered or created by FACT before disclosure by the individual;
  - 6.2.3 learned by the individual through legitimate means other than from FACT;
  - 6.2.4 is disclosed by the individual with FACT's prior written approval.
- 6.3 All documents, summaries, or data generated or compiled for the purpose of performing any FACT function are to be maintained by individual staff and volunteers only as long as needed to complete the work. Thereafter, these documents shall be discarded in a manner appropriate to confidential information.
- 6.4 Any third party information received by a FACT staff member or volunteer is confidential, but will be investigated according to FACT policies and procedures.
- 6.5 All parties with access to any confidential information on behalf of FACT must agree to abide by FACT's *Confidentiality and Statement of Compliance Policy (2.1.001)* upon association with FACT and annually thereafter.

## 7.0 Revision History

Date	Rev. #	Author / Requestor	Changes	Justification
17Sep2007	0	FACT Board	New Document	New Document
22Sep2008	1	Manager, Standards Development and Education	<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> </ol>	<ol style="list-style-type: none"> <li>1. 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	Quality Assurance Manager	<ol style="list-style-type: none"> <li>1. Adjust formatting of form to reduce pages.</li> <li>2. Include "Program" definition.</li> <li>3. Revise confidentiality statement to encompass committee volunteers.</li> <li>4. Include confidentiality statement regarding use of Programs' materials.</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> <li>3. Confidentiality is required for all volunteers of FACT, including committee members that may not be inspectors.</li> <li>4. Requires FACT volunteers to receive express written consent from the Program(s) prior to personal or professional use of information received from the Program(s).</li> </ol>
29Dec2011	3	Quality Assurance Manager	<ol style="list-style-type: none"> <li>1. Change "Program" to "Organization"</li> </ol>	<ol style="list-style-type: none"> <li>2. There has been confusion regarding the definition of Program outside of FACT Policies. FACT has implemented "Organization" into its documents and materials to help clarify the definition.</li> </ol>
07Sep2012	4	Quality Assurance Manager	<ol style="list-style-type: none"> <li>1. Update policy to include regenerative medicine.</li> <li>2. Include business intelligence and strategic initiatives as confidential information that may be obtained.</li> </ol>	<ol style="list-style-type: none"> <li>1. Language in current policy was outdated and did not include regenerative medicine.</li> <li>2. FACT's recent endeavors include gathering intelligence and developing strategic initiatives that may be subject to confidentiality rules.</li> </ol>
04Feb2013	5	Director of Operations	Add additional information regarding disclosure of business intelligence or strategic initiatives.	FACT volunteers and staff are in possession of critical business intelligence and perform strategic initiatives that, if discovered by competing organizations, could be detrimental to the organization.
30Mar2017	6	Quality Manager	Separate form from policy and reference unique identifier.	Separating the form from the policy allows documentation separate from the policy.