

	<b>Policy</b>	Document #: CMP.15.1.009 Revision: 8 Approval Date: 07/05/2022 Page 1 of 3 Effective Date: 07/05/2022
<b>Confidentiality 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, release for administration, and administration of cellular therapy products and cord blood collection, banking, and release for administration.

In the regular conduct of its business of accreditation, FACT, its volunteers, and personnel 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 This policy applies to FACT personnel and volunteers.
- 2.2 Confidential information includes, but is not limited to the following:
  - 2.2.1 Names and accreditation status of any applicant or accredited organization.
  - 2.2.2 Results of an on-site inspection.
  - 2.2.3 Individual policies, procedures, or patient outcomes of organizations.
  - 2.2.4 Written documents or summaries prepared by FACT personnel or volunteer committees.
  - 2.2.5 Business intelligence and strategic initiatives collected and performed by FACT Board members, committees, or personnel.
  - 2.2.6 Protected personally identifiable information (Protected PII)
  - 2.2.7 Protected health information (PHI)
  - 2.2.8 Results of other accreditation, approval, or regulatory assessments at an organization.
  - 2.2.9 Professional information related to faculty or personnel of an organization.

## 3.0 Responsibility

- 3.1 The FACT Quality Manager or designee ensures 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 FACT Executive Committee or its designee is responsible for:
  - 3.3.1 Regular reports to the Board of Directors to affirm that all appropriate personnel and volunteers have submitted *FACT Conflict of Interest & Acknowledgements*.
  - 3.3.2 Review of this policy and recommendations for revision whenever appropriate.

#### **4.0 References**

- 4.1 FACT Conflict of Interest & Acknowledgements, CMP.FRM.15.001

#### **5.0 Definitions and Abbreviations**

- 5.1 Code of Federal Regulations: CFR
- 5.2 FACT work group: a group of individuals comprised of FACT volunteers and personnel (e.g., Cellular Therapy Accreditation Committee).
- 5.3 Protected personally identifiable information (Protected PII): an individual's first name or first initial and last name in combination with any one or more of types of information, including but not limited to, social security number, passport number, credit card numbers, clearances, bank numbers, biometrics, date and place of birth, mother's maiden name, criminal, medical and financial records, educational transcripts. This does not include PII that is required by law to be disclosed. Refer to CFR § 200.82.
- 5.4 Protected health information (PHI): individually identifiable health information.
  - 5.4.1 Health information means any information, whether oral or recorded in any medium that:
    - 5.4.1.1 is created or received by FACT; and
    - 5.4.1.2 relates to the past, present, or future physical or mental health or condition of an individual, or the provision of health care to an individual.
  - 5.4.2 Records containing PHI, in any form, are the property of FACT. The PHI contained in the record is the property of the individual who is the subject of the record.
- 5.5 Volunteers
  - 5.5.1 Officers
  - 5.5.2 Members of the Board of Directors
  - 5.5.3 Committee and task force members
  - 5.5.4 Inspectors and inspector trainees
  - 5.5.5 Other persons assigned to an activity of FACT

#### **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 communication and documents relating to business intelligence and strategic initiatives shall be held and maintained for the sole and exclusive benefit of FACT. FACT volunteers and personnel who are subject to this policy shall 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 Disclosed by the individual with FACT's prior written approval.
- 6.3 All documents, summaries, or data generated or compiled for performing FACT functions are to be maintained by individual personnel and volunteers only as long as needed to complete the work. Thereafter, these documents must be discarded in a manner appropriate for confidential information.
  - 6.3.1 Upon separation of employment and at the end of a board member's term, she or he must return, all documents, papers, and other materials, that may contain confidential information.
  - 6.3.2 If individuals have a question relating to appropriate use or disclosure of Confidential Information, consult with appropriate FACT personnel
- 6.4 Unauthorized release or carelessness in the handling of confidential information is considered a breach of the duty to maintain confidentiality and may be grounds for immediate termination and/or possible liability in any legal action arising from such violation.
- 6.5 The duty to maintain confidentiality continues after FACT personnel and volunteers resign or are terminated.
- 6.6 At a minimum FACT volunteers and personnel who are subject to this policy must complete and submit *FACT Conflict of Interest & Acknowledgements* at the time they are nominated, appointed, employed, or become officially associated with an activity of FACT.

**Approved by (date):**

Heather Conway (Quality Manager) (07/05/2022), Linda Miller (Chief Operating Officer) (07/05/2022)