

 <p>Policies and Procedures</p>	<p>Policy</p>	<p>Document #: ACC.6.1.009 Revision: 1 Approval Date: 07/June/2023 Page 1 of 2 Effective Date: 07/June/2023</p>
<p>Remote Director Policy</p>		

1.0 Purpose

All editions of FACT-JACIE International Standards for Hematopoietic Cellular Therapy, NetCord-FACT Standards for Cord Blood Banking, FACT Common Standards, and FACT Immune Effector Cell Therapies require that there be Directors and Medical Directors of the program, bank, and participating facilities. Standards define specific qualifications and responsibilities.

Responsibilities for remote directors do not differ from the responsibilities of any director; however, there may be more challenges in completion and documentation of these responsibilities. This policy defines the requirements for remote directors.

2.0 Scope

This policy applies to organizations interested in or applying for initial or renewal FACT accreditation.

3.0 Responsibility

- 3.1 It is the responsibility of FACT to ensure that personnel and organizations have access to this policy and adhere to it.
- 3.2 Organizations applying for initial or renewal FACT accreditation are responsible for following the policies described herein.

4.0 References - NA

5.0 Definitions and Abbreviations

- 5.1 Organization: Clinical program, cellular therapy collection facility, cellular therapy processing facility, cord blood bank (including cord blood collection sites and cord blood processing facilities), facility under the Common Standards, or immune effector cellular therapy program that has achieved or is applying for FACT accreditation. An organization consists of the facilities, personnel, policies, procedures, and records.
- 5.2 Remote Director: Remote Directors and Medical Directors are those directors with professional responsibilities in more than one metropolitan geographic area, or those whose residence is outside of the metropolitan geographic area of the accredited facility.

6.0 Policy

- 6.1 A director must be fluent in the language of each site and must meet the minimum credentials, training, experience, competency, and continuing education requirements as defined in the current edition of Standards.
- 6.2 A director is responsible to lead the accredited program, facility, or bank and to provide oversight of the services, personnel, products, and procedures.

- 6.3 A director is expected to be actively engaged in the decision-making process, policy and procedure development, and quality management activities. This involvement must be documented.
- 6.4 When a director is physically not present at the site, there must be a qualified designee named and documented to manage those responsibilities that require immediate or in-person attention. Further, all critical director functions must be covered.
 - 6.4.1 A qualified designee must meet minimum director qualifications for the delegated function, and have a defined scope of authority and activity.
- 6.5 A Clinical Program Director must be licensed to practice medicine in the jurisdiction of each clinical site and credentialed in each institution in which a clinical site is located.
- 6.6 Specific responsibilities of each director and medical director type are defined in the applicable set of Standards. Documentation of director involvement in these responsibilities must be available during the on-site inspection for review by the inspector.
- 6.7 Documentary evidence of the remote director's specific involvement in leadership and oversight of the program, in addition to performance of designated responsibilities, must be available during the on-site inspection for review by the inspector. Examples of documentation include, but are not limited to:
 - 6.7.1 Meeting minutes.
 - 6.7.2 Record review.
 - 6.7.3 Personnel review.
 - 6.7.4 SOP review and approval.
 - 6.7.5 Donor or recipient management.
 - 6.7.6 Investigation report review.
 - 6.7.7 Qualification/validation studies: plan and final report review and approval.
 - 6.7.8 Planned deviation pre-approval.
 - 6.7.9 Product release authorization.

Approved by (date):

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