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Laboratory facility director & doctoral degree requirement

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Introduction

The FACT-JACIE Standards, 6th edition, describe the academic requirements for the position of Processing Facility Director:

D3.1.1 There shall be a Processing Facility Director with a medical degree, doctoral degree, or equivalent degree in a relevant science, qualified by a minimum of two (2) years training and experience for the scope of activities carried out in the Processing Facility.


A doctoral degree including a medical degree is considered as the 'gold standard' of scientific and medical achievement. However, the term doctoral degree is not applied in a uniform fashion in all countries. The Guidance to Standard D3.1.1, 6th edition FACT-JACIE Standards reads:

... Some regions of the world may have degrees that are equivalent to the doctoral degree. If a Processing Facility Director has such a degree, significant and compelling information regarding the degree requirements must be submitted to demonstrate equivalency (p.325).

Issue

JACIE has encountered a small number of processing facilities where individuals acting in the capacity of Processing Facility Director (PFD), although well qualified and experienced, hold neither a scientific doctoral degree nor a medical degree. JACIE has previously insisted that where the PFD does not meet the requirements, that the centre names a qualified person as the PFD. Centres typically demonstrate this change by altering their organizational chart and job descriptions. Frequently this results in the nomination of medically qualified staff as the Processing Facility Director and delegating day-to-day responsibilities to the scientific individual. Another scenario encountered has been the nomination of an individual with a scientific doctorate but where its relevance to stem cell processing has been questioned, and again delegating day-to-day responsibilities to an appropriately trained and experienced scientific individual.

An additional difficulty is a perception that following a citation during an inspection where qualified individuals are named as Facility Directors solely in order to meet the standards, that frequently it is a paper-only exercise to satisfy the requirement of the Standard and that little or

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nothing changes in day-to-day operations. From the centre's point of view, it may be difficult to understand this requirement where they have a well qualified and experienced person performing to a high level in managing the laboratory and unrealistic to expect a centre to recruit a new PFD with a doctoral degree just to satisfy the standard. Moreover, such measures may create a perception of the accreditation process as bureaucratic and unrelated to real and evolving professional qualifications and experience.

Moreover, as described below, the same individual may have been accepted by their national competent authority as sufficiently well qualified in accordance with the EU Directives on quality and safety of tissues and cells. Article 17 of EU Directive 2004/23/EC on quality and safety of tissues and cells establishes the role of the Responsible Person – equivalent to the PFD - and requires them to have at minimum the following qualifications:

- (a) possession of a diploma, certificate or other evidence of formal qualifications in the field of medical or biological sciences awarded on completion of a university course of study or a course recognised as equivalent by the Member State concerned;
- (b) at least two years' practical experience in the relevant fields.

Response

On 14 March 2014, the JACIE Accreditation Committee agreed to consider such situations as variances from the Standard and to allow for equivalent qualifications to be accepted on a case-by-case basis. On 27 February 2015, the same Committee agreed to continue to allow for exceptions to the Standard where equivalence can be demonstrated and identified the need for an equivalence assessment tool. This document describes how equivalence will be assessed.

Proposal


For the individual identified as the Processing Facility Director on an operational basis (day-to-day), JACIE will take into account that person's qualifications and experience, both scientific/medical and managerial. This will be done via a *points scheme* which will assign scores to different areas of an individual's profile.

Scoring system

The points-based system will assess equivalence of alternative combinations of education and experience to a doctoral degree for the role of PFD.

The scheme is designed to emphasize not just academic achievement but to also stress practical experience and leadership qualities along with evidence of continuous professional development (CPD) or continuous medical education (CME). For instance, a doctoral degree holder after 5 years of education and 1 year of experience would not meet the criteria whereas a non-doctoral degree holder with 4 years' experience plus 1 year of leadership and evidence of CPD would.

A minimum of 10 points is required to comply with the Standard.

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Area	Points awarded
Education	-
- Medical degree / Doctoral degree ¹ in relevant science	3
- Master's degree in relevant science	1
- Basic degree in relevant science (minimum requirement)	1 / year (max 4)
Experience (minimum requirement)	1 / year (min 2 / max 5)
Leadership* (minimum requirement)	1 / year (min 1)
Continuous professional development in preceding 2 years (attendance at relevant meetings/events) (minimum requirement)	1 (1-2 events) min 1 2 (3 -5 events) 3 (>5 events)
Working in identifiable laboratory network	1
Total	Min 10

Leadership and experience counted separately for the same years.

** Leadership covers supervision or management roles. It can also include positions in charge of scientific or technical working groups, committees or similar.*

Expected evidence

The facility director can hold a science degree complemented by at least 2 years' experience in a supervisory or management role within the laboratory facility and show evidence of continuous professional education / development beyond an undergraduate degree including participation in cellular therapy-related meetings and events.

There shall also be clearly established and documented sharing of responsibilities with the Processing Facility Medical Director. Where a laboratory is part of an identifiable network e.g. national blood service, this will also be taken into account.

In all cases, the onus is on the applicant centre to demonstrate equivalence.

Effective date:


Immediate from publication of this document on the JACIE web site.

This mechanism was developed with the invaluable contributions of Maria Vittoria Gazzola, Dominique Latinne and Monique Grommé, processing experts of the JACIE Accreditation Committee, John Snowden, JACIE Medical Director and approved by the members of the JACIE Committee.


References:

1. FACT-JACIE International Standards for Hematopoietic Cellular Therapy Product Collection, Processing, and Administration, 6th edition (March 2015)

¹ The highest point of learning in a given field of study

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2. FACT-JACIE International Standards for Hematopoietic Cellular Therapy Product Collection, Processing, and Administration, Accreditation Manual, 6th edition (March 2015)
3. Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells

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Examples

<u>Example 1</u>	A person with a doctoral degree following more than 5 years of university, 4 years of lab experience, 3 years in a supervisory role and 0 events attended. Works in independent lab.
<u>Example 2</u>	A person lacking a doctoral degree but with 3 years of University, a Master's degree, 10 years of lab experience, 2 years in a supervisory role and 4 events attended. Works in independent lab.
<u>Example 3</u>	A person with a doctoral degree following more than 5 years of university, 1 years of lab experience, 0 year in a supervisory role and 0 events attended. Works in independent lab.
<u>Example 4</u>	A person lacking a doctoral degree but with 4 years of University, 3 years of lab experience, 1 years in a supervisory role and 1 events attended. Works in national blood service lab

Area	Points available	Example 1	Example 2	Example 3	Example 4
Education	-	-	-	-	-
- Doctoral degree in relevant science	3	3	0	3	0
- Master's degree in relevant science	1	1	1	1	0
- Basic degree in relevant science	1 / year (max 4)	4	3	4	4
Experience	1 / year (min 2 / max 5)	4	5	1	3
Leadership	1 / year (min 1)	3	2	0	1
Continuous professional development in preceding 2 years	1 / 1-2 events 2 / 3 -5 events 3 / >5 events	0	2	0	1
Working in laboratory network	1	0	0	0	1
Total	Min 10	15	13	9	10
		COMPLIANT	COMPLIANT	NON-COMPLIANT	COMPLIANT