	SOP Complaints and Appeals			
	Document type	Operating procedure	Approved by	ASC
	Document reference	ACC_7130_SOP	Approval date	4/18/2023
	Version	23.0	Approval status	approved
	Pillar / Scope	P4 / Certification body	Status	Public

WORLD MARROW DONOR ASSOCIATION
SOP: COMPLAINTS AND APPEALS

CHANGE RECORDS

Version	Date	Change Type	Change Description
0	2021-07-10	Document creation	Subdivided up Accreditation Policy and Procedure Manual into separate policies and procedures
1	2023-03-20	Addition	Clarified whether audit will be conducted; added process for complaint to be noted by future review team From now on, version control will be managed by SharePoint.


1. INTRODUCTION

1.1 PURPOSE AND SCOPE

The World Marrow Donor Association (WMDA) has developed standards, a certification scheme, and a certification process for registries involved in the international exchange of donors. This document describes how complaints and appeals are received, evaluated and decisions made.

This document covers the following sections:

1. Introduction
2. Documentation
3. Review of a registry following a complaint by a third party
4. Review of an assessment following a failure to comply with requirements for compliance
5. Appeals and complaints regarding assessment

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1.2 PARTY RESPONSIBLE FOR THIS DOCUMENT

The WMDA Accreditation Steering Committee (ASC) develops and reviews this document.

1.3 APPLICABLE AND REFERENCE DOCUMENTS

Here below are listed the documents needed to understand the information provided by this policy and intended to be an extent of the policy itself.

Reference No.	Title
FNDN-110-01-F	Impartiality/Conflict of Interest/Confidentiality Statement
ACC-4400-P	Policy: Certification Body Application Requirements and Levels
ACC-7130-01-F	Complaint Form
ACC-7401-04-WI	Evaluation of Compliance with Certification Agreement

The following documents, although not a part of this policy, amplify or clarify its contents.

Reference No.	Title
ACC-SOP-7500	SOP: Accreditation Committee
ACC-7200-SOP	SOP: Application and Application Review
ACC_7400_SOP	SOP: Evaluation Activities
ACC-7200-SOP	SOP: Corrective and Preventative Actions

1.4 ABBREVIATIONS AND DEFINITIONS

Accreditation / accredited, Full compliance with WMDA Standards

Certification / certified, Benchmark L1 status

Qualification / qualified, Benchmark L2 status


Client or Applicant or Registry, Organization responsible for coordination of the search for hematopoietic stem cells from donors (including cord blood) unrelated to the potential recipient, for the collection and transport of the donation, and for the care of the donor. It includes both unrelated donor registries and umbilical cord blood banks.

Share, on-line collaboration platform

WMDA, World Marrow Donor Association


2. DOCUMENTATION

The office component within the Certification Body will record and track complaints, noncompliance with requirements, and appeals and the actions taken to resolve them.

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3. REVIEW OF A REGISTRY FOLLOWING COMPLAINT BY THIRD PARTY


- Complaints by any person, registry, or organization are directed to the WMDA Impartiality Officers or to the WMDA office. The receiving party will acknowledge receipt of the complaint and will log the complaint.
- The impartiality officers will determine whether the complaint is minor (e.g., problem with Share application form) or major. Minor complaints will be dealt with by the relevant party but will be logged. Major complaints will be sent to the Board.
- The receiving party will ask the Board to determine if the major complaint should be referred to the Accreditation Steering Committee or to another component of WMDA. If the complaint appears to be justified and suggests noncompliance with WMDA Standards by an assessed registry, the Accreditation Steering Committee will initiate an immediate investigation of the complaint.
- Based on the severity of the complaint, the Accreditation Steering Committee may alert the Board that it will request the Accreditation Committee to suspend compliance until the investigation is complete. The community will be notified of any change in the registry status. The way in which notification is performed will be determined by the Board on a case-by-case basis.
- The client under investigation will be notified in writing at the beginning of the investigation. Usually, the registry will be notified first by email and, if no response, second by written letter sent by express courier, and third by personal contact and/or letter.
- The client under investigation and the complainant will be asked to submit any documentation necessary to address the standard(s) related to the complaint or problem. The Accreditation Steering Committee may require a timeline for this submission.
- The Accreditation Steering Committee will identify an evaluation team (**SOP: Application and Application Review**). The team will sign an impartiality, conflict of interest, confidentiality form.
- Evaluators will receive copies of pertinent documents related to the complaint and where the registry may be noncompliant with specific WMDA Standards. The assessment will focus only on those WMDA Standards which are in dispute.
- Evaluations may include a short notice audit of the registry.
- The evaluation team members have six weeks to submit a written report to the Accreditation Steering Committee. A conference call may be used to discuss the issues. The Accreditation Steering Committee will summarize the reports on behalf of the evaluation team and no chair will be selected.

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- The Accreditation Steering Committee will forward the summary report and all review documents to the WMDA office.
- WMDA office will provide a copy of the evaluation summary to the members of the Accreditation Committee. The Accreditation Committee will review the assessment and will vote. The expected vote may be (1) Complaint is not justified; (2) Complaint is justified with ranking of observation of concern / major / critical. The Accreditation Committee may also suspend / reduce / terminate the registry’s compliance level.
- The WMDA office will send the results of the Accreditation Committee’s decision to the executive director, WMDA President, to the complainant and to the client identified in the complaint. If the complaint is justified, the response required of the client will be based on the ranking.
- The evaluation summary will be provided to reviewers of the next application or mid-cycle surveillance.
- The community will be notified of any change in the registry status. The way in which notification is performed will be determined by the Board on a case-by-case basis.

4. REVIEW OF ASSESSMENT FOLLOWING A FAILURE TO COMPLY WITH REQUIREMENTS FOR COMPLIANCE.


- Requirements of the certification process ([Policy: Certification Body Application Requirements And Levels](#)) include, but are not limited to:
 - Completing a certification agreement at the time of an application
 - Paying fees for certification
 - Providing information on major changes that might impact certification status
 - Submitting the mid-cycle evaluation at the required time
 - Responding to a major or critical concern raised in an evaluation within the time limit set
 - Using the certificate or marks of conformity appropriately
- Accreditation Steering Committee will notify the registry indicating the requirement, requesting an explanation of the failure to respond, and providing a timeline for response. Usually, the registry will be notified first by email and, if no response, second by written letter sent by express courier, and third by personal contact and/or letter.
- The office will acknowledge lack of compliance using a form and log.
- Accreditation Steering Committee will notify the Board that it will request the Accreditation Committee to either suspend or withdraw compliance to WMDA Standards.
- The applicant registry will be notified in writing and their status changed on the WMDA website.

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- Renewal of their compliance will occur upon the registry’s correct response to the deficiency.

5. APPEALS AND COMPLAINTS REGARDING ASSESSMENT

- An applicant registry may request that a decision be appealed by submitting a written request to the WMDA office within three (3) months of receiving notification of the WMDA decision. This request must include a justification for reversing the decision.
 - An applicant registry may also lodge a complaint regarding the assessment by notifying WMDA of the circumstances that raised a concern.
- The WMDA office will acknowledge receipt of the appeal / complaint in writing. The WMDA office will track the appeal process using Share.
- The WMDA office will forward this request to the WMDA President, executive director and the Accreditation Steering Committee.
- The Accreditation Steering Committee will form a new evaluation team.
- Evaluators will receive copies of pertinent documents including the final report, the registry's reply, and all parts of the application for which the registry was rated as noncompliant with WMDA Standards. Evaluations may include a short notice audit of the registry. The appeal process will focus only on those WMDA Standards for which the applicant was judged as noncompliant, and which are in dispute. The purpose of the review will be to ascertain whether compliance with the standards was evaluated correctly in the original assessment.
 - Similar actions will be taken when investigating a complaint regarding the assessment process.
- The evaluators of an appeal may recommend that the initial decision stand, may recommend modification of the initial decision, or may overturn the original decision.
 - Evaluators of a complaint will identify the root cause and address the issue with preventative and corrective actions (**SOP: Corrective and Preventative Actions**).
- The evaluation team members have six weeks to submit a written report to the Accreditation Steering Committee. A conference call may be used to discuss the issues. The Accreditation Steering Committee will summarize the reports on behalf of the evaluation team and no chair will be selected.
- The Accreditation Steering Committee will forward the summary report and all review documents to the WMDA office.

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- WMDA office will provide a copy of the evaluation summary to the members of the Accreditation Committee. From this point, the same process as followed for the initial review is followed, that is, the Accreditation Committee will vote.
- The office will send the results of the Accreditation Committee’s decision to the WMDA President and to the applicant registry.
- The decision regarding the registry's request to appeal the decision is final and may not be appealed again.