	S(P)EAR Committee Operating Document			
	Document type	SOP	WG/Committee	SEAR
	Document reference	20170517-SEAR-S(P)EAR Operating	Approved by	SEAR
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WMDA S(P)EAR Committee Operating Document


OBJECTIVE

The S(P)EAR committee (hereinafter, “committee”) is responsible for review of all events/reactions reported to WMDA as potential SEARs or SPEARs (together, “S(P)EARs”) and evaluation of the events/reactions’ Imputability and Impact. The Committee will regularly report its findings to the WMDA board, designated individuals responsible for S(P)EAR reporting and WMDA membership. In addition, at the discretion of the committee and the WMDA board, these findings may periodically be made available to the public in a form and manner prescribed by the committee and the WMDA board.

The work undertaken, materials created, and findings issued by the committee are solely for educational and informational purposes of the WMDA community and its stakeholders. The committee does not (and must not be deemed by any WMDA member or other third party to) assume any responsibilities of any entity or individual arising out of regulation, law, or otherwise, including but not limited to reporting responsibilities to regulatory agencies or responsible authorities.


DEFINITIONS

1. **Committee:** S(P)EAR committee acting as a committee of the pillar Donor Care
2. **Definite:** As defined in WMDA 20170517-SEAR-S(P)EAR SOP, “Reporting Serious Adverse Events and Reactions to the WMDA.”
3. **Excluded:** As defined in WMDA 20170517-SEAR-S(P)EAR SOP, “Reporting Serious Adverse Events and Reactions to the WMDA.”
4. **Impact:** As defined in WMDA 20170517-SEAR-S(P)EAR SOP, “Reporting Serious Adverse Events and Reactions to the WMDA.”
5. **Imputability:** As defined in WMDA 20170517-SEAR-S(P)EAR SOP, “Reporting Serious Adverse Events and Reactions to the WMDA.”
6. **Not Assessable:** As defined in WMDA 20170517-SEAR-S(P)EAR SOP, “Reporting Serious Adverse Events and Reactions to the WMDA.”
7. **Possible:** As defined in WMDA 20170517-SEAR-S(P)EAR SOP, “Reporting Serious Adverse Events and Reactions to the WMDA.”
8. **Probable:** As defined in WMDA 20170517-SEAR-S(P)EAR SOP, “Reporting Serious Adverse Events and Reactions to the WMDA.”
9. **SEAR:** Serious Events and Adverse Reactions.
10. **SPEAR:** Serious Product Events and Adverse Reactions.
11. **Unlikely:** As defined in WMDA 20170517-SEAR-S(P)EAR SOP, “Reporting Serious Adverse Events and Reactions to the WMDA.”
12. **WMDA:** World Marrow Donor Association.

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GENERAL

1. Responsibilities
 - 1.1 It is the responsibility of the committee to review each S(P)EAR report and make a determination regarding Imputability and Impact. The committee has defined a predefined classification which is used by the initial reviewer and medical consultant to determine the Imputability and Impact.
 - 1.2 The committee will provide regular feedback to the WMDA board and the WMDA membership.
 - 1.3 The committee will facilitate expedited review and reporting when a rapid alert is required.
2. Membership
 - 2.1 The committee shall consist of no less than five (5) and no more than ten (10) WMDA members, each having equal voting rights of one vote per committee member (“voting members”). The voting members should be predominately members with clinical experience, including but not limited to: Chair and Chair-elect of the Working Group Medical and a member of the NetCord-WMDA Cord Blood Working Group and a member with expertise in transport incidents. In addition to the voting members, the committee shall also include one non-voting liaison member with legal background, and one non-voting liaison member of the WMDA office. Non-voting members with other areas of expertise may also be appointed at the discretion of the committee chair.
 - 2.2 The committee chair shall be nominated and approved by a majority vote of the current-voting members of the committee.
 - 2.3 Members of the committee shall be nominated by the committee chair based upon recommendations made by the current voting members of the committee. Once nominated, proposed committee members shall be approved by the WMDA board. All committee members must sign a confidentiality statement prior to transacting any activity with the committee.
 - 2.4 Term and vacancies.
 - 2.4.1 Each voting member shall serve a three (3) year term. No voting member shall serve more than two (2) consecutive terms (for a total of six (6) consecutive years). Each such term shall begin on January 1st of the calendar year.
 - 2.4.2 In the event of a vacancy due to resignation, removal, end of term, or any other reason, such vacancy shall be filled, if necessary and/or desired, by the process set forth in Section 2.2, above.
3. Attendance
 - 3.1 It shall be the duty of committee members to attend the meetings so as to take part in its discussions and decision-making.
 - 3.2 The position of any committee member may be vacated, at the discretion of the committee chair, if such member neglects to attend more than half of the meetings in a given year.
 - 3.3 Any member may participate in a committee meeting by means of a conference telephone or similar telecommunications or electronic device, which allows all persons participating in the meeting to hear each other.

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Participation by telephone shall be equivalent to presence in person at the meeting for purposes of determining if a quorum is present.

COMMITTEE MEETINGS

1. Regular Meetings
 - 1.1 The committee shall endeavour to meet approximately twice a year, to review predefined classification, to discuss trends and debate difficult cases and to identify trends or quality issues.
 - 1.1.1 Meetings may be scheduled more frequently, if deemed necessary by the committee chair.
2. Special Meetings
 - 2.1 Special meetings may be called in case a rapid alert needs to be prepared.
3. Notice
 - 3.1 Notice of the time, day, and place of any regular meeting should be given at least one (1) month in advance of the meeting. Notice may be given in writing by electronic mail and will be deemed given when received.
 - 3.1.1 Notice for special meetings may be given at any time and in any of the manners described above. Notice for special meetings shall state the purpose for which the special meeting is called.
4. Quorum
 - 4.1 A quorum of voting members must be present to make a decision regarding Imputability and Impact of a S(P)EAR report. A quorum for the purposes of this operating document is defined as a majority of the voting members.
 - 4.2 If a committee member anticipates that he or she will not attend a meeting, that member may provide to the committee an opinion regarding Imputability and Impact for any S(P)EAR report on the agenda for that particular meeting. Such an opinion must be provided to the committee chair, in writing, by the close of business the day prior to the meeting in order to be considered. Opinions received in this manner will be treated only as recommendations and shall not be counted as a vote for decision-making purposes. The committee chair shall provide copies of each opinion to the committee members in attendance during discussion on a S(P)EAR report.
5. Minutes
 - 5.1 Minutes of all committee meetings shall be prepared by the chair, or his/her designee, and filed with the WMDA office and maintained as confidential.
6. Meeting Materials
 - 6.1 Materials for the committee meeting should be made available to members at least five (5) business days in advance of the meeting.
 - 6.2 Materials will include: an agenda, each S(P)EAR report to be discussed, and any supporting documentation requested from the reporter by the committee chair.

DECISION-MAKING

1. At the meeting, the medical consultant gives an overview of the reported incidents.

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- 1.1 The committee will discuss each reported event/reaction that does not fit in the predefined classification.
 - 1.1.1 The committee must assign the event/reaction an Imputability classification—Definite, Probable, Possible, Unlikely, Excluded, or Not Assessable.
 - 1.1.1.1 After discussion, the committee will endeavour to reach an imputability classification. If a majority decision is made, the imputability classification will become final and be added to the predefined classifications.
 - 1.1.1.2 If the committee is unable to reach a majority decision regarding an imputability classification, the committee may request further information from the reporting party. The additional information, if available, will be presented at to the committee at which time the committee will assess what imputability classification should be assigned.
 - 1.1.2 If there is a discrepancy between the committee’s Imputability classification and the reporting party’s relatedness assessment, such discrepancy may be reported by the committee chair to the reporting party, at the committee chair’s discretion, to inform the reporting party of the discrepancy.
 - 1.1.3 Reports relating to quality issues in cord blood units will periodically be forwarded to the chair of the NetCord-WMDA Cord Blood Working Group in an anonymised manner. The responsibility to monitor trends will lie with the NetCord-WMDA Cord Blood Working Group.
- 1.2 Upon a decision of the committee on Imputability, the committee will assess and document the Impact of the reported event/reaction.
 - 1.2.1 After discussion, the committee will come up with a recommended Impact statement. The voting members in attendance will then take a formal vote on the recommendation. If a majority of the voting members in attendance approve of the recommendation, the Impact Statement for that S(P)EAR report will become final.
- 1.3 A S(P)EAR report will be deemed a final report once the committee has reviewed the Imputability classification and Impact statement.

REPORTING

1. Feedback on individual reports will be communicated to the reporting registry. Each year an annual report will be prepared and shared with outside organisations (e.g. on the World Health Organization Vigilance and Surveillance website at <http://www.notifylibrary.org>) if appropriate).
2. Expedited reporting to WMDA members will take place, if required.