

Bone Marrow Donors Worldwide House Rules

1. Definition

Bone Marrow Donors Worldwide (BMDW) is a service provided and managed by Eurodonor Foundation located in Leiden, The Netherlands, and the BMDW Office is located at Eurodonor Foundation's facility. Eurodonor Foundation has the legal responsibility for BMDW.

2. Statement of Purpose

BMDW is a voluntary collaborative effort of stem cell donor registries and cord blood banks with the goal to provide centralised information on the HLA phenotypes and other relevant data of unrelated stem cell donors and cord blood units and make this information easily accessible (after obligatory authorizations) to the physicians or search coordinators of patients in need of a hematopoietic stem cell transplant.

3. Participation

BMDW participation is open for a fee, to any unrelated donor registry or public cord blood bank that provides HLA and other information on its donors or cord blood units in an anonymized fashion to the central database in Leiden for the purpose of enabling that information to be searched, and which is able and willing to provide stem cell products to domestic and international patients. Application for participation is via the BMDW Office in Leiden.

4. Editorial Board (EB)

- 4.1. The Editorial Board monitors the development of the service provided by BMDW, suggests any necessary changes and improvements, reviews and approves budgets, and has voting rights on major policy changes, substantial budget and fee changes and other significant issues that may affect the role or functioning of BMDW.
- 4.2. The Editorial Board is composed of one representative (the Registry Representative to the Editorial Board) from each donor registry and cord blood bank that lists its donors/cord blood units in BMDW and whose fees are current.
- 4.3. Registry Representative
 - 4.3.1. Each organisation will designate one individual to serve as its representative on the BMDW Editorial Board.
 - 4.3.2. The Registry Representative will receive all BMDW mailings and other communications including nomination materials for BMDW Advisory Committee elections and background information and ballots for the purpose of voting on significant issues.
 - 4.3.3. Only the designated Registry Representative (or in his absence, his deputy) is eligible to speak and cast votes on behalf of the organisation
 - 4.3.4. An organisation may change its designated representative at any time by notifying, in writing, the BMDW Office.

5. Advisory Committee (AC)

- 5.1. The Advisory Committee not only represents the interests of the Editorial Board but also functions as a sounding board for the BMDW office. It functions
 - to provide an initial vetting of proposed policy changes
 - to contribute to the development of new policies
 - to review annual operating budgets
 - to contribute to Editorial Board meeting agendas and
 - to provide or request background information on issues raised.
- 5.2. The Advisory Committee shall be composed of eight elected representatives of registries or cord blood banks, BMDW staff representation, and the chairman of the BMDW Editorial Board. Advisory Committee members should represent both large and small donor registry and cord blood bank interests.
- 5.3. BMDW office will receive all Advisory Committee communications at the same time as the Advisory Committee members.
- 5.4. The World Marrow Donor Association (WMDA) IT working group will advise on technical issues and name a representative to be invited to attend an Advisory Committee meeting if deemed necessary by the Advisory Committee or BMDW office.

5.5. Advisory Committee Elections

- 5.5.1. Each year, approximately one-third of the Advisory Committee positions will be open for election.
- 5.5.2. BMDW Advisory Committee elections will be held annually to fill open positions.
- 5.5.3. Elections will be held prior to the BMDW annual meeting.
- 5.5.4. Any Registry Representative of a BMDW participant in good standing is eligible for nomination and election to serve on the Advisory Committee.
- 5.5.5. The BMDW Office will assume responsibility for handling all election correspondence and distributing nomination forms and ballots.
- 5.5.6. Call for Nominations
 - 5.5.6.1. A written call for nominations for all open Advisory Committee positions will be issued to all Registry Representatives on 1 September or the nearest working day
 - 5.5.6.2. All Registry Representatives of BMDW participants in good standing will receive nomination forms. The nomination form will require an abbreviated curriculum vitae and a signature attesting the willingness to serve.
 - 5.5.6.3. A separate nomination form will be prepared for each open position.
 - 5.5.6.4. The nomination form will list the responsibilities of the position and include spaces for three Registry Representatives to sign the nomination form indicating their endorsement of the candidate.
 - 5.5.6.5. The nomination deadline is 15 October.
- 5.5.7. Balloting
 - 5.5.7.1. Ballots will be distributed on 1 November or nearest working day to all BMDW Registry Representatives.
 - 5.5.7.2. Registry Representatives may cast only one vote.
 - 5.5.7.3. Ballots must be completed and returned to the BMDW Office, which is responsible for tabulating election results.
 - 5.5.7.4. Ballots may be returned by facsimile or mail and must be received by 1 December.
 - 5.5.7.5. The BMDW staff will review votes cast and tally results for each candidate.
 - 5.5.7.6. Where one candidate only is nominated there will be no balloting.
- 5.5.8. Election Results
 - 5.5.8.1. The nominee with the highest number of votes will be elected to fill the open position for which he/she was nominated.
 - 5.5.8.2. Tie votes will be broken by the toss of a coin at the first BMDW Advisory Committee meeting following balloting.
 - 5.5.8.3. Results will be ratified by the Advisory Committee.
 - 5.5.8.4. Election results will be distributed, in writing, within 30 days of ratification.
 - 5.5.8.5. The ballots must be retained by the BMDW Office until 1 month after distribution of election results and be available for review if requested by a participant of the Editorial Board.

SUMMARY of ADVISORY COMMITTEE ELECTION PROCESS

Date	
1 st September or nearest working day	Written call for nominations
15 th October	Deadline for nominations
1 st November	Ballots to be distributed to all Registry Representatives
1 th December	Deadline for receipt of ballots
	Results ratified by the Advisory Committee
Within 30 days of Advisory Committee ratification	Election results to be distributed
1 st January	Ballots to be retained and available for review until this date

5.6. Terms of Office

- 5.6.1. Each elected Advisory Committee member will serve a three-year term with the opportunity to serve a second consecutive three-year term.

- 5.6.2. The Advisory Committee shall elect a Chair from amongst the elected Advisory Committee member.
- 5.6.3. The Advisory Committee Chair will serve one term of three years, with no option of a second three-year term.
- 5.6.4. If the chair's term as an Advisory Committee member terminates before his term as chair, the person will stay on the Advisory Committee, for his term as a chair, as an additional Advisory Committee member.

6. Policy Changes and Voting

- 6.1. The Advisory Committee will consider all recommendations and proposals submitted in writing to the BMDW Office by a Registry Representative, the chairman of the Editorial Board or the BMDW office, in particular those affecting the BMDW budget.
 - 6.1.1. The following matters shall always require a formal vote by the Editorial Board. The Advisory Committee may formulate information and a recommendation to be presented to the Editorial Board with the voting request.
 - 6.1.1.1. Budget increases over 10%.
 - 6.1.1.2. Significant policy changes.
 - 6.1.1.3. Critical changes in the BMDW software.
 - 6.1.2. In all other matters the Advisory Committee may recommend to accept or reject them without a formal vote by the Editorial Board. This decision will become valid unless any Registry Representative present at the next Editorial Board meeting objects.
- 6.2. Editorial Board Vote Allocation
 - 6.2.1. The number of votes of each Registry Representative is dependent upon the number of donors and cord blood units registered in BMDW. Cord Blood Units are counted as 8 donors:
 - 6.2.1.1. Registries with > 1,000,000 "donors" will be assigned 20 votes
 - 6.2.1.2. Registries with >100,000 - <1,000,000 "donors" will be assigned 10 votes
 - 6.2.1.3. Registries with >20,000 - <100,000 "donors" will be assigned 5 votes
 - 6.2.1.4. Registries with <20,000 "donors" will be assigned 2 votes
- 6.3. Decision Process
 - 6.3.1. Alterations to BMDW operations or these house rules may be proposed by any Registry Representative or authorized transplant centre.
 - 6.3.2. The proposer will prepare a document that provides background information on the issue (i.e., rationale, benefit summary, cost estimate, etc.).
 - 6.3.3. The Advisory Committee may add information on their opinion(s) and/or a recommendation of the Advisory Committee and also if a formal vote of the Editorial Board is requested or required. Lack of unanimous agreement in this respect amongst the Advisory Committee members would indicate the necessity for a formal Editorial Board vote.
 - 6.3.4. BMDW staff will distribute the background document and a ballot by e-mail or fax to each Registry Representative in good standing with instructions on completing and returning the ballot and a specified deadline of at least three weeks for returning completed ballots to the BMDW office. If a quorum of >50% of the votes is not met at the deadline, Registry Representatives will be informed and given at least another three weeks to vote. Then, the decision will be valid in any case.
 - 6.3.5. Any ballots received after the specified deadline will not be counted.
 - 6.3.6. Votes will be tallied by the BMDW office and the count verified by the chairman of the Advisory Committee.
 - 6.3.7. Decisions need a majority of 2/3 of the votes cast according to the counting defined under 6.2 to be accepted.
 - 6.3.8. Major decisions need to be approved by the Board of the Europdonor Foundation to become final.
 - 6.3.9. Alterations, which are minor or urgent and essential for the continuous functioning of the BMDW operation can be started by the BMDW office immediately, but will be reported to the Advisory Committee and Editorial Board as soon as possible.

7. Finance

- 7.1. The Editorial Board will determine any changes to participation fees
- 7.2. The BMDW Office will collect the fees.
- 7.3. The BMDW Office must prepare an annual budget and have it reviewed by the Advisory Committee. The budget will be presented to the Editorial Board at the annual meeting.

- 7.4. The budget should include:
- BMDW Personnel and facilities expenses
 - Development costs of Editorial Board approved projects
 - Meeting expenses
 - BMDW Office expenses
 - Any other expenses which can be foreseen

8. Fees

- 8.1. Participation fees will be levied in accordance with the number of unrelated donors/cord blood units registered in BMDW, as follows (in the assignment below cord blood units count as 1 donor):
- 20 shares for Registries/Cord Blood Banks with >1,000,000 donors/cord blood units
 - 10 shares for Registries/Cord Blood Banks with >100,000 - <1,000,000 donors/cord blood units
 - 5 shares for Registries/Cord Blood Banks with >20,000 - <100,000 donors/cord blood units
 - 2 share for Registries/Cord Blood Banks with <20,000 donors/cord blood units
- The actual annual budget decided will be split among the participants in proportion to the number of shares.
- 8.2. Fees will be levied annually, lasting for one calendar year.
- 8.3. Fees will be due on or before 1 June. A list will be maintained by the BMDW Office of all participants in good standing current with their annual participation dues. The list of BMDW participants and financial contributors will be available upon request to the BMDW Office.
- 8.4. International accredited transplant centres in countries without a hub or a non-functioning hub can request authorisation directly from BMDW and must pay an annual fee. In 2008 the fee is € 670.00. Authorized transplant centres have no voting rights.

9. The BMDW Office

- 9.1. The BMDW Office is the central administrative office of the BMDW.
- 9.2. This office will collect dues, maintain and distribute essential documents including the BMDW annual report, maintain the BMDW website, and maintain lists of participants in good standing.
- 9.3. The list of participants will include the name, address, fax number and e-mail address for each participant, its Registry Representative as well as coding for representation in the Advisory Committee, and terms of services, where applicable.
- 9.4. The BMDW Office is responsible for the daily maintenance of the BMDW software and hardware as well as for developing and/or implementing new software changes.

10. Meetings

- 10.1. The BMDW Office will convene an Editorial Board meeting and an Advisory Committee meeting once a year or more often if deemed appropriate.
- 10.1.1. The Advisory Committee meeting will usually take place prior to the Editorial Board Meeting.
- 10.1.2. Meetings will usually take place in conjunction with another appropriate national or international meeting.
- 10.2. The BMDW Office and Advisory Committee Chair will co-ordinate the production and distribution of meeting agendas.
- 10.3. The BMDW Office will invite items for the Editorial Board meeting agenda from the Registry Representatives eight weeks before the date of the meeting and allow a two-week period to respond.
- 10.4. The Office will compile the Editorial Board meeting agenda and send the draft to the Advisory Committee at six weeks before the meeting.
- 10.5. The Editorial Board meeting agenda will be completed and sent to the Registry Representatives by the Office at four weeks before the meeting.
- 10.6. Registry Representative of participants in good standing will receive notices of all meetings as well as copies of all minutes.
- 10.7. Registry Representatives will be welcome to attend, speak and vote at Editorial Board meetings.
- 10.8. Other donor registries, cord blood banks and transplant centres are welcome to attend and speak at Editorial Board meetings, but cannot vote.

11. Communication

- 11.1 Editorial Board mailings
- 11.1.1. Participant organisations in good standing will receive all relevant mailings.

- 11.1.2. Distribution of this material is the responsibility of the BMDW Office.
- 11.2. Advisory Committee Communication
 - 11.2.1. Members of the Advisory Committee will receive copies of relevant documents.
 - 11.2.2. Preparation of Advisory Committee material will be the responsibility of the Chair and distribution of materials will be the responsibility of the BMDW Office.
 - 11.2.3. The BMDW Office will be copied with any material produced by, or in use by, the Advisory Committee, which has not originated from the Office.
 - 11.2.4. Participants will communicate by the most expedient method, including e-mail, telephone conferencing, and in-person meetings. The BMDW Office will be notified or copied in any such communication.
- 11.3. BMDW Website
 - 11.3.1. The BMDW website will contain the following communication related information:
 - Names and contact details of Editorial Board participants.
 - BMDW Office structure and contact details of the staff.
 - Names and contact details of Advisory Committee members.
 - Announcements concerning BMDW.
 - Notification of Editorial Board meetings.
 - Minutes of the Editorial Board meetings approved by the BMDW Office.
 - The annual reports.
 - 11.3.2. The website will be maintained by the BMDW Office.

12. Utilization of data from BMDW

- 12.1. The participants provide their data to BMDW in order to facilitate the search for suitable donors or cord blood products for HSCTs. This purpose is primarily fulfilled by sharing the data among the participants (re-distribution of the compiled data) and by providing authorized users with a search facility on the data pool (online or otherwise).
- 12.2. All participants and BMDW itself are encouraged to use the BMDW data for research to improve the speed and quality of donor searches and the understanding of the underlying mechanisms.
 - 12.2.1. Any utilization of the data to improve their own use for identifying an unrelated donor is allowed without special extra permission of the contributors. However such improvements should be communicated to the participants and the BMDW office.
 - 12.2.2. Publication of methods where data from individual contributors are needed and shown as specific examples may be published "anonymizing" the contributing registries. Otherwise the registries shown or easily identified have to be asked and given the opportunity to review and object their names and/or data to be shown.
 - 12.2.3. Systematical analysis and publication of the data of the individual contributors requires permission of each contributor even if these analyses were done in connection with efforts allowed under 12.2.1. This applies to all form of publication (printed, electronic, or other). It also applies to analyses where data are systematically pooled for analysis (e.g. by country or region) or by overviews showing or comparing several or all registries.
 - 12.2.4. Any analysis not covered by the endorsement in 12.2. generally requires the permission of each participant whose data is used.
 - 12.2.5. Any study using (part of the) BMDW file must be reviewed by the BMDW office before the study is started and before the results of the study are submitted for publication. In mutual understanding it will be decided whether a representative from the office will be included as a co-author of the submitted paper.