RARE DISEASES INTERNATIONAL

INTERNAL REGULATIONS

The Internal Regulations speak to the operation of the Rare Diseases International (RDI), in conjunction with the Statutes adopted at the RDI Annual General Meeting on 10 May 2018, Vienna, Austria. These Internal Regulations fulfil the role of By-laws as set out in Article 19.

The updated Internal Regulations were adopted by the Council of RDI on 21 October 2024 and will be presented at the RDI Annual General Meeting on 17 June 2025.

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RARE
DISEASES
INTERNATIONAL

1 - REGISTRATION AND OFFICE

Rare Diseases International (hereinafter referred to as “RDI”, is a legal entity registered in the Republic of France on December 7, 2018.

The registered office, from 24 Novembre 2018 is Plateforme Maladies Rares, 96, rue Didot, 75014 Paris 14e.

2 - INTERPRETATION

In these Sections, save as the context otherwise requires:

“A Person Living with a Rare Disease (PLWRD)” means any person who lives with a rare condition, disease, illness, syndrome, organ impairment or disability, or such condition, including family or carers.

"Full Member" means any organization admitted as a Full Member of RDI, whose name appears on the Register of Members. A Full Member has voting right at all General Meetings.

“Associate Member” means any organization admitted as an Associate Member of RDI, whose name appears on the Register of Members. An Associate Member does not have voting rights at all General Meetings.

"Council" means the governing body of RDI.

“CEO” is the Chief Executive Officer of the Organization.

"Council Director” or “Director" means representative who is nominated by a Full Member and duly elected to the Council.

"Chair" means the person elected to hold the office of the chair by the RDI Council Directors.

"Vice-Chair” means the person for elected to hold the office of the Vice-Chair by the RDI Council Directors.

"Secretary" means the person elected to hold the office of the secretary by the RDI Council Directors.

“Treasurer" means the person elected to hold the office of the treasurer by the RDI Council Directors.

"Member" means any Full Member and Associate Member of RDI, and "Membership" shall be construed accordingly.

“Network affiliates” means a group representing PLWRD who does not meet membership criteria but wishes to support the aims and objectives of RDI. They have no voting rights but will be kept informed of RDI’s activities.

“Strategic Partner” means any inter-governmental, professional, academic, industrial or civil society organization designated by RDI with whom we have a formal partnership or collaboration.

"Articles" means the Articles of the RDI statutes.

“Sections” means the sections of these Internal Regulations.

"Ordinary resolution" means a resolution passed by a majority of not less than 50% casting on that resolution.

"Special resolution" means a resolution passed by a majority of not less than two-thirds (2/3) of the votes cast on that resolution.

3 - MEMBERSHIP

3.1. Membership Categories

RDI shall consist of two categories of member organizations: Full Member and Associate Member.

3.2. Full Member

To become Full Members, organizations shall meet all of the following five criteria. The Council has discretion to determine whether each criterion has been met or to waive the criterion.

a. +Be a non-profit and non-governmental organization

b. Have a legal status appropriate to its country of origin, with a written constitution and/or by-laws. If no appropriate legal status exists in the country of origin, the Council shall determine how this criterion is fulfilled.

c. Be an international, regional or national organization, or an umbrella group representing one or more rare conditions.

d. Demonstrate commitment to PLWRDs with reference to rare conditions in their guiding statements, such as their vision, mission or organizational objectives, and their activities.

e. The organization must demonstrate that they are PLWRD-driven. This means that the needs and views of PLWRDs drive the organization’s strategy, policies and activities in a significant way and that the organization is capable of representing the needs and views of these PLWRDs. Organizations must demonstrate that they use at least one of the following methods:

(1) Demonstrate that the majority of the organization’s voting members are PLWRDs, PLWRD representatives or PLWRDs’ organizations with the power to nominate and elect their own governing body.

(2) Demonstrate that the majority of the organization’s governing body are PLWRDs, PLWRD representatives, or representatives of PLWRDs’ organizations.

(3) Demonstrate that the organization has a governance structure which ensures that it is PLWRD-driven: i.e. the needs and views of PLWRDs drive the organization’s strategy, policies and activities in a significant way and that the organization is capable of representing the needs and views of these PLWRDs. A description and/or illustration of the governance structure shall be included in the organization’s application.

An organization may request a waiver or unique / alternate fulfilment of one or more criteria for full membership. The Council shall consider the request along with any submitted rationale or justification. The Council has sole discretion to grant any waiver or exception, including

delayed fulfilment of one or more criteria. The Council shall document in the minutes the deliberations and resolution, along with rationale for its decision.

3.3. Associate Members

RDI Associate Members may be rare condition specific or related organizations that are not eligible to become RDI Full Members but meet the following four criteria:

(a) Be a non-profit and non-governmental organization
(b) Have a legal status appropriate to its country of origin, with a written constitution and/or by-laws. If no appropriate legal status can be obtained in the country of origin, the Council shall determine how this criterion is fulfilled.
(c) Be an international, regional or national organization, or an umbrella group representing one or more rare conditions.
(d) Demonstrate commitment to improving various aspects of living with rare conditions in their guiding statements, such as their vision, mission or organizational objectives and their activities. The organization may be a multi-stakeholder umbrella coalition or alliance.

3.4. Membership Application

In order to become a RDI member, the applying organization must complete a membership application form available from RDI. Approval or rejection of a membership application is determined by the Council according to 3.2. and 3.3. of these Internal Regulations.

3.5. Membership Fees

Membership fees may be set and amended by the Council. Please see *Appendix 1*

3.6 Termination of Membership

An organization's membership may be terminated by the following:
By the member:
(a) A written letter of resignation addressed to the Chair of the Council.
(b) Legal liquidation proceedings or dissolution

By the Council, after due deliberation, may recommend the suspension or termination of any organization's membership of RDI. Sufficient cause for suspension or termination shall be:
(a) Violation of any by-law, rule, policy or practice duly adopted by the Annual General Meeting and/or the Council of RDI.
(b) Any other conduct materially prejudicial to the interests of RDI.
(c) Non-payment of fees for membership of RDI.
(d) A deviation from the elements in the application from which membership was granted.
(e) Dissolution of the organization and/or loss of the organization's legal status.
(f) A significant reputation controversy or actual actions which may affect the reputation of RDI.

Such suspension or termination shall be ratified by a vote of the Council. Suspension can be immediate. Termination, specifying the grounds for such action shall have been given to the member organization in question at least twenty days' notice before final action is taken. At the meeting at which such action is proposed to be taken, the Member or Associate in question shall be given the right to appear to present any defence or mitigation to such charges before the aforementioned vote of the Council is taken.

3.7 Network Affiliate Status

The Council may decide to award 'Network Affiliate' status to such non-profit organizations which do not fulfil the membership criteria in certain aspects but otherwise would well represent the rare disease community, for example groups run by clinicians or researchers. Network Affiliates are affiliated to RDI by supporting RDI's aims and objectives, but do not have voting rights. Network Affiliates may sit on committees and working groups if selected.

4 - GENERAL MEETING

4.1. General Assembly

Each RDI full member may send one person to vote on behalf of their organization to RDI's General Assembly. This representative shall be known as a delegate of their organization to the General Assembly.
The General Assembly can be in person or virtual online.

4.2. Annual Meetings

An Annual Meeting of the General Assembly shall be held once in every calendar year and not more than 18 months shall pass between one Annual Meeting and the next.
Matters subject to the approval by voting of the Annual General Meeting shall include:

(a) Annual Activity Report for the previous year.
(b) Annual Financial Reports for the previous financial year.
(c) Annual Action Plan and Budget for the current financial year.
(d) Any other such business as may be appropriate.

4.3. Extraordinary Meetings of the General Assembly

Extraordinary Meetings of the General Assembly may be called by the Chair of the Council who shall fix the time and place for the meeting. Extraordinary Meetings and votes can be organized online. The Chair may call an Extraordinary Meeting at the request in writing of not less than twenty percent of the Full Members. Written notice of the date, time and place of each extraordinary meeting shall be given to each Member within 14 days.

4.4. Voting at General Assembly

Each Full Member of RDI shall have the right to cast one vote at Annual and Extraordinary Meetings of the General Assembly. Such vote may be cast in person by the Member's RDI Representative, or by written proxy duly executed by or on behalf of such Member. Proxy Holder must be a Full Member of RDI. No Proxy Holder may hold more than five proxy votes to be cast at the Meeting.

4.5. Casting Vote

In the case of an even number of votes, the Chair of the Meeting shall be entitled to a second or casting vote.

4.6. Quorum of General Meetings

There is no quorum for the Annual General Assembly. RDI will seek to engage as many members as possible and will keep a record of members who have participated. The members' opinions recorded are the opinions or votes expressed in the meeting or by electronic means; results are anonymized.
Voting, by secret ballot, is by simple majority of votes cast. Please See Appendix 2

5. THE COUNCIL

5.1. Role of Council

The Council elected by the General Assembly shall be the executive body of RDI, responsible to the General Assembly of its members. Please See *Appendix 3: Council Charter*.

The Council has governance and fiduciary responsibility with strategic oversight. Please see *Appendix 4: Decision-Making Delegations*.

The Council approves the documentation for the General Assembly, including the validation of the activity report and financial report of the previous year, the action plan and budget of the current year, the resolution and other relevant documents submitted to the votes of the General Assembly.

The Council approves the annual work plan and supports the CEO in implementation.

The Council Directors are required to declare any potential competing interests, both monetary and non-monetary. Please see *Appendix 5: Competing Interests*.

5.2. Quorum of Council

The Council shall consist of not less than FIVE (5) and no more than NINE (9) Directors. The actual number of Directors to be voted in for any given election term will be set by a majority vote of the Council prior to the election.

The Council may identify representational needs or expertise in the Council when advertising vacancies, aiming that the majority of the Council has lived experience of a rare condition. These can be, for example, regional representation where there is none; more global disease-specific representation; or expertise in a particular area (e.g. finance or governance).

The Council shall aim to be as diverse as possible including as many aspects as possible of diversity, including gender, geographic representation, disease representation, persons affected by a rare disease.

5.3. Election of Council

Each Full Member may nominate one (1) representative to stand for election of Council. Election shall be conducted every year online the month prior to the General Assembly Meeting. Only Full Members shall have ballot to vote in the election. No Member Organization can have more than one elected Director on the Council at any given time.

5.4. Term of Council Directorship

Each Council Director shall be elected for a term of three (3) years, corresponding to three (3) Annual General Meeting (AGM) cycles. For the purpose of these Regulations, a term runs from the AGM at which the Director is elected until the third subsequent AGM.
A Director elected to complete the remaining term of another Director shall serve an interim mandate. Such interim mandate shall not count toward the calculation of maximum tenure.
Outgoing Council Directors are eligible to stand for re-election for up to two (2) additional consecutive terms (maximum of three (3) terms in total). After completing the maximum tenure, a Director shall not be eligible for re-election until at least two (2) AGMs have passed following the end of their last term. Eligibility is restored from the third AGM thereafter. This is to enable opportunity for more Full Members

to have representation on Council, and to allow RDI's governance to be nourished by fresh ideas and perspectives.

A Full Member cannot nominate another representative to replace its elected representative's Council Directorship prior to the end of his / her / their term.

5.5. Termination of Council Directorship

Directorship of Council shall be terminated by:

(a) A Council Director tendering their resignation.
(b) the Council Director is no longer a representative of the RDI Member Organization which nominated them.
(c) the Full Membership of the Member Organization who nominated them is discontinued.
(d) Contravention of the Competing Interests Policy
(e) Fraudulent activity
(f) Bringing RDI into disrepute
(g) Death.

A Council Director shall be dismissed by a two-thirds vote of the other Council Directors after all reasonable attempts to resolve issues are unsuccessful.

5.6. Vacancies

In the event of a vacancy on the Council prior to the end of a Director's term, the vacant position may be filled by the candidate who obtained the next highest number of votes at the most recent election. In the event of a tie, the Chair of Council shall decide.

The appointed Director shall serve for the remainder of the term of the departing Director. Any such appointment shall constitute an interim mandate as defined in Section 5.4.

5.7. Council Meetings

The Council will meet 4 to 12 times a year (normally via teleconference or web conference), with at least one (1) physical meeting each year.

The Chair decides on the date and time of the meeting and sets a provisional agenda with consultation from the other directors, which is reviewed and approved at the beginning of the Council's Meeting. Two (2) or more directors can also initiate a Council Meeting, which the chair cannot reject.

A quorum shall consist of at least half of the Council plus one and shall not include a proxy of an absent Director.

5.8. Voting

When votes are necessary, the rule is a simple majority. In case of split vote, the Chair has the pre-eminence.

5.9 Decisions between Council meetings

The Council may take decisions by email between meetings provided that the majority agree. These decisions will be recorded by staff and recognised in the minutes of the next meeting.

5.10. Remuneration

The Council Directors shall not receive any salary or other remuneration for their work as such; expenses in line with RDI Travel and Expenses policy shall be reimbursed.

6. Council of Officers

6.1. Officers

RDI office bearers shall consist of Chair, Secretary and Treasurer. The Council may elect additional officers such as Vice Chair. Please see Appendix 6 RDI Council of Officers Roles and Responsibilities; Appendix 4 Decision-Making Delegations.
No Council Director may hold more than one office concurrently.

6.2. Election and Term of Office Bearers

The office bearers shall be elected by and from the Council for a term of one year. Office bearers may be re-elected to the same position.

a) It is noted that, if possible, it is best practice for those intending to stand for Office to have been on Council for at least one year.
b) An invitation should be sent to existing Council Directors the month before the AGM inviting expressions of interest in standing or re-standing for office.
c) In line with Section 5.4, no person should hold an office for more than 9 years.
d) Elections of officers will take place as soon as possible but no later than one-week after the AGM.
e) The elections will be on the day of the Council meeting, by secret ballot, with an external person or single person of the Organization overseeing the process, maintaining confidentiality of votes cast. The first part of the meeting will present the nominations of who is standing for office, then there will be a vote, then there will be the announcement immediately following.
f) The election of officers will be by simple majority.
g) In the event of a tie between candidates for an Officer position, an additional ballot shall be conducted between the tied candidates. If the additional ballot also results in a tie, further ballots shall be held as necessary until a simple majority is achieved and a candidate is elected.
h) New officers will take up their roles immediately.

6.3. Vacancy

A vacancy in any office occurring for any reason, including a dismissal, shall be filled by another Council Director for the remainder of the term.

6.4. Chair

The Chair shall preside at all General Assemblies of RDI and all the Council meetings; and shall be an ex-officio member (with the right to vote) of all committees.

6.5. Vice Chair

The Council may appoint a Vice Chair. The Vice Chair shall chair the General Assembly of RDI, the Council and all Committees in the absence of the Chair. They shall also perform such other duties as may be assigned from time to time by the Chair or Council.

6.6. Secretary

The Secretary shall keep or cause to be kept an accurate record of the proceedings of the General Assembly and shall give or cause to be given notice of all General Assemblies and of the Council. The Secretary shall review all membership applications, with the support of the Organization. They shall also perform such other duties as may be assigned from time to time by the Chair or Council.

6.7. Treasurer

The Treasurer shall supervise the preparation of the annual budget and its regular follow up by the Organization the annual financial accounts and statements, the audit reports for presentation to the Council and General Assembly. The Treasurer shall provide oversight to the administration and good use of funds, working closely with the CEO and FO, including policies on investment, reimbursement of funds, and signatures on accounts, to be adopted by the Council.

7. Chief Executive Officer (CEO)

The CEO is responsible for driving the organization's goals as stated in the strategic plan and annual budget; developing the annual work plan; and providing organizational leadership to deliver RDI's vision and mission.

The CEO manages the staffing team and volunteers, builds relationships with partners, and secures resources.

Working closely with the Council, the CEO is responsible for delivering RDI's strategy as set by the Council; leading the efforts in policy, research and advocacy; and ensuring that PLWRDs' voices are heard.

The CEO manages the organization's day-to-day operations, observing the policy and procedures set out by the Council. The CEO represents RDI externally and manages its affairs, in regular liaison with the Council and its Officers. The CEO reports directly to the Council of RDI.

The CEO has an annual appraisal led by the Chair with one other Council Director. Performance against workplans and expected outcomes will be evaluated. External input might be sought as part of this process.

See *Appendix 4: Decision-Making Delegations* for further delineation of duties.

8. COMMITTEES, WORKING GROUPS AND TASK FORCES

The Council, working with the CEO, may constitute and delegate specific authorities and duties to committees and working groups, which from time to time may be required, to pursue the policies, programs, projects, commitments and membership guidelines it has established.

Each Committee or Working Group is established with a clear purpose and specific objectives, accountabilities, reporting requirements and a timeframe. These terms are approved by the Council.

The Committees and Working Groups are managed by the Organization who reports back to the Council about their activities and decisions.

Short-term Task Forces (up to 6 months) may be set up by the CEO to promote agility, with Terms of Reference. If these groups become more established, the Council can approve them becoming Committees or Working Groups with defined Terms of Reference.

9. STRATEGIC PARTNERS

To ensure and enhance the well-being of PLWRDs living with rare condition world-wide, RDI may, from time to time, designate and collaborate with any global or regional inter-governmental, professional, academic, industrial or civil society organization or formal network as its Strategic Partner.

Such strategic partnerships can be proposed by the CEO or council directors and are decided by vote at a Council meeting, The Alliance of Companies is a formal collaborative network of industry partners who support RDI's capacity to reach its aims. Please see *Appendix 7 Alliance of Companies Code of Conduct* and *Appendix 8 Policy on the Relationship and Financial Support by Commercial Companies*.

10. AMENDMENT OF STATUTES OR INTERNAL REGULATIONS

The Statutes may be modified by the General Assembly acting at an extraordinary meeting, upon proposal by the Council, or upon proposal of at least one quarter of the full members of the association. In both cases, the proposal of amendment is mentioned in the agenda of the next General Assembly, which must be notified to all members of the Assembly at least thirty (30) days in advance. At least half plus one of the full members must vote (physically or electronically).
If this proportion in not reached, the assembly is convened again, after at least a fifteen-day interval and this time it may carry out its deliberations validly whatever the number of members present or represented. In all cases, the statutes may only be modified with a majority of two-thirds of the votes cast.
The Internal Regulations are the set of rules under which RDI operates. The Council is responsible for drafting, adopting, monitoring and updating the Internal Regulations which will determine the application details of these Statutes.

These Internal Regulations will be presented to the General Assembly and available on RDI's website, as will any modifications.

11. FINAL PROVISIONS

All the powers not assigned by law or the Statutes or the By-Laws to other bodies are vested in the Council.