

PHARMABIOTIC RESEARCH INSTITUTE
BYLAWS (VERSION 5.0 – validated 16 Dec 2020)

PREAMBLE

Recent developments of knowledge have shown that understanding of the interactions between the microbiome and its human or animal host could have applications beyond their roles in food and agriculture and that new products emerging from the research relating to the microbiome could be considered as pharmacological agents in their own right, exhibiting a preventive and curative potential of diseases.

These new pharmaceutical products, emerging from the better understanding of the interaction between the microbiome and their host, can include any medicinal product containing living, dead or fragments (or a combination thereof), of components of the microbiome (i.e. bacteria, yeasts, phages etc...) with the purpose to prevent or treat human or animal diseases through a pharmacological, microbiological, endocrinological, neurological, immunological or metabolic mode of action, or make a medical diagnosis, all of which could be at the basis of **new therapeutic or diagnostic products emerging from current and future microbiome science**. In the following document, these products may also be referred to as “Microbiotic Medicinal Products”, or “MMP’s”.

The PRI considers that the microbiome is important for the future of human medicine and wishes to be at the center of this evolution in Europe. The PRI believes in the strong therapeutic potential of Live Biotherapeutic Products (LBPs) and, to a larger extent, all new therapeutic and diagnostic modalities emerging from microbiome science.

New therapeutic and diagnostic modalities emerging from microbiome science should be studied and validated, from research and design all the way to the conditions of production and use, according to suitable pharmaceutical criteria which have yet to be more clearly defined. It is in this light that the Association was founded in 2010, after beginning its existence as cluster of excellence.

Article 1 – Constitution – Name

A non-for-profit association governed by the law of July 1st, 1901 and the decree of August 16th, 1901 is created between the adherents to the present By-laws (hereafter referred to as the Association).

The Association is named “Institut de recherche pharmabiotique”. Its abbreviation is IRP.

The words “Pharmabiotic Research Institute” or “PRI” might be used in common speech to refer to the Association.

Article 2 – Head Office

The Head Office is located at 1 Quai Vallière, Résidence île verte, 11100 Narbonne, Occitanie FRANCE. It can be moved to any location within the Occitanie Region by a simple decision of the Board.

Article 3 – Duration

The Association is formed for an unlimited duration of time.

Article 4 – General Purpose

The PRI, aims at being an ecosystem that creates the appropriate conditions for the emergence of new therapeutic and diagnostic modalities emerging from microbiome science. The PRI is a European multidisciplinary non-for-profit Association aiming at educating and federating the industry, academic institutions and EU regulatory representatives.

The PRI is an independent association.

The PRI is a neutral association. Its neutrality is key for a collaborative approach between actors who may have conflicting interests. In addition, this neutrality is the pre-requisite for a healthy relationship with the competent authorities and the future negotiation relating to regulatory frameworks evolution for new therapeutic and diagnostic modalities emerging from microbiome science.

The PRI is a collaborative association. At the heart of the PRI is its collaborative approach which allows the PRI to more credibly pave the way for regulatory evolutions in Europe. The very essence of this collaborative approach is that stakeholders, as well as competent authorities, may learn from each other and together be able to make a real difference.

In addition, it sheds new light on the decisions which should be made by the actors of the industry, therefore allowing them to better identify the optimal route for their developments.

The PRI therefore wishes to be the main representative organization interrogated by competent authorities regarding the future regulatory framework for new therapeutic and diagnostic modalities emerging from microbiome science (including LBPs) and to become the number one network for the European microbiome pharmaceutical supply chain, federating fundamental actors from the industry, such as stakeholders involved in the development, investment, production and commercialization of new therapeutic and diagnostic modalities emerging from microbiome science.

Article 5 – Action Principles

The PRI can accomplish its purpose by means of research, conferences, networking, task group activities or direct contacts with competent legal and governmental authorities.

- The PRI operates mainly in Europe
- The PRI is a Regulatory expert
- The PRI works on all products relating to diagnosis, prevention and cure.
- The PRI operates within the EU pharmaceutical regulatory and legal framework
- The PRI supports its members for their regulatory questions in order to accelerate developments
- The PRI extracts and provides collaborative regulatory knowledge / standards/ good practices/foresight to all Regulatory and Incubator Members
- The PRI uses scientific standards and approaches to reach consensus
- The PRI organizes public demonstrations, symposia and seminars by bringing together professionals in the field of microbiome and health as well as any other entity, person or corporate, which could be advantageous by their own acts or contributions to the realization of the general purpose defined above
- The PRI edits, publishes, and distributes documents, media, articles within the scope defined in the General Purpose article of these Bylaws
- The PRI can serve the Microbiome and Human health industry in discussions with competent authorities based on the staff's strong regulatory expertise

The PRI will not...

1. The PRI will not engage in paid-for consulting services, marketing activities, market analysis services, nor perform lobbying or other political influencing activities. The PRI will not act as an observatory of the microbiome and its industry.
2. The PRI will not actively address the regulatory challenges surrounding the development and commercialization of food or food supplements, or cosmetic products, but merely track and study these developments for comparative and explanatory purposes. The PRI will also not actively address the regulatory challenges surrounding the development of other microbiome-based consumer care products and services, in as much as they are not intended to treat, prevent, or cure disease or make a medical diagnosis.
3. The PRI will not directly address the regulatory challenges surrounding the development and registration of new therapeutic and diagnostic products emerging from microbiome science outside of the European Union. *While the PRI realises it is important to monitor and understand foreign regulatory frameworks, they will not actively engage with non-EU authorities but build strategic partnerships and collaboration with other relevant industry or academic organizations.*
4. The PRI will not own any of the intellectual property gathered through the collaborative approach as this information is available to all Regulatory and Incubator Members.
5. The PRI shall not engage in price-fixing, anticompetitive agreements, or any other unfair methods of competition that restrain trade and are prohibited.

Article 6 – Membership

a) Categories of Members

The Association proposes different levels of membership.

1. Active Members

'Active Members' are private-, public- or government-owned corporate entities, that play a part in the development, commercially exploiting or planning to commercially exploit new therapeutic and diagnostic modalities emerging from microbiome science under whatever form (strain, bulk, or finished product), by any method of distribution, towards all sorts of clients (BtoB or BtoC) in any arena worldwide. Any private corporate entities proposing services to the corporate entities described above may as well be an Active Member of the association. **Active Members** are also private-, public- or government-owned corporate entities that wish to perform and finance R&D initiatives or create consortium projects in which they employ the expertise and know-how of the PRI.

'Active members' are divided into three sub-categories:

- 'Active **Regulatory Members**' are those which are interested in the 'regulatory' activities of the Association.
- 'Active **Incubator Members**' those which are involved in technology transfer, incubation or acceleration of translational research and interested in the 'regulatory' activities of the association.
- 'Active **Partnering Platform Members**' are those which are interested in R&D activities as well as being put into contact with other actors in the microbiome and health area.

2. Associate Members

'Associate Members' are any academic or public research entities that have developed expertise in the field of research or development of new therapeutic and diagnostic modalities emerging from microbiome science and wishing to participate in the realization of the overall goal of the Association.

b) Further specifications

1. General statements

Legal entities are represented by their practicing legal representative, or by any other person whose capacity to this effect has been submitted to the Association.

A **private corporate entity** is understood in these Bylaws as an independent legal entity which operates under its own business registration number and commercial identity (e.g. 'branding' or 'trademark'), irrespective of ownership. Corporate entities which have partial or total ownership of a current or future PRI Active Member which operate under their own business registration number and commercial identity may not benefit from or participate in Association activities, unless they too become a PRI Active Member.

In case of doubt regarding the membership eligibility or particular membership status of an entity, the Board of Directors acts as the final arbiter on such questions.

2. Statements regarding the Membership category

Active Incubator Members shall not engage in for-profit regulatory consulting activities with their incubated projects/companies based on knowledge acquired through the PRI collaborative approach. Each and every project/company requiring such information must apply for Regulatory Membership in order to benefit from the PRI collaborative regulatory knowledge.

Private entities having capital venture, investment or for-profit regulatory affairs consulting activities, are not eligible for **Regulatory or Incubator Membership** as by Article 8 they cannot act as intermediate organizations to disseminate regulatory collaborative knowledge built by the Association's regulatory members to third parties which are not PRI members.

In order to safeguard this principle at all times, every **Regulatory and Incubator Member** will have to sign a non-disclosure agreement about the dissemination of the Association's regulatory collaborative knowledge generated by the Regulatory Members. This non-disclosure document will have to be signed by all new and existing Regulatory and Incubator Members at the time of acceptance of the current Bylaws (Version 5.0).

A separate non-disclosure agreement will have to be signed between the PRI and the representative of an active **Regulatory or Incubator Member** when she/he is also personally involved in remunerated activities, managing activities, or is a share owner of one or more corporate entities which are not listed as **Regulatory or Incubator Member** of the PRI. When the representative of a **Regulatory or Incubator Member** assigns a replacement member in case of illness or for any other reason, the temporary representative will be prone by the same conditions of confidentiality as the official representative. It is the responsibility of the **Active Member** to inform its temporary representative on the conditions subscribed by the representative of a **Regulatory or Incubator Member** concerned.

Associate Members are represented by the researcher having requested membership to the Association or by a person that is officially nominated by the Associate Member.

c) Membership Eligibility

To apply to become a member, the candidate must comply with the process defined in the Internal Policies and Procedures document.

The conditions for applying as an eligible Active or Associate Member, as well as all associated rights and obligations, are defined in the Association's 'Internal Policies and Procedures' document.

Every member is bound to respect and uphold the By-laws, along with the Charter of Ethics, annex to these Bylaws, as well as any other annex to which they become signatory when becoming an Association member.

Payment of the annual membership dues, following signature of the membership contract, confirm the membership of the organization. The table of Membership fees can be found in the Association Internal Policies and Procedures document.

The Board retains the power to affirm, suspend or dismiss any Member.

d) Loss of Membership

Membership of the Association can be lost by Situations that change the company conditions to the extent that they are no longer in agreement with the initial conditions of membership acceptance by the Board. Such situations can be, but are in no way limited to:

- 1) The dissolution of the corporate entity (notably by mergers, acquisitions...), or the declaration of a bankruptcy recovery plan or court-mandated liquidation for such corporate entity.
- 2) Non-payment of membership dues, despite two notifications of late-payment.

Membership can be lost by dismissal on serious grounds, such as, for example, the violation of the Bylaws, of the internal policies and procedures, of the Charter of Ethics, or, for Regulatory or Incubator Members, the violation of the non-disclosure agreement.

Dismissal is pronounced by the Board, following the summons of the member to a hearing session in which he or she can present his or her explanations regarding the alleged facts and/or propose acceptable remediation. The procedure of dismissal of a Member is described in the annex "Charter of Ethics", article "Disciplinary Actions".

Dismissal is notified by the President of the Association by registered mail.

e) Rights and duties of the Members

Members shall not leverage their current or past Membership in the Association as, for example, a measure or assessment of quality for their products or services.

Article 7 – Finances

The resources of the Association are composed of:

- 1) Membership dues calculated as lined out in the Internal Policies and Procedures document;
- 2) European, State (France), regional, departmental, and local grants
- 3) Research funding obtained for traveling, coordination-, management- or dissemination activities;
- 4) Private donations and donations from state-approved organizations;
- 5) Income resulting from property sold, or from services rendered by the Association;
- 6) Revenue from property and assets of any nature owned by the Association;
- 7) Donations and bequests that the Association may be authorized to accept on the grounds of the nature of its purpose;
- 8) All resources non prohibited by applicable law, jurisprudence, and any responses received from the ministries currently in force.

Article 8 – The Board of Directors

a) Composition

The Board is composed of minimum 2 and maximum 25 members, elected by the ordinary General Assembly, for a term of 2 years, drawn from both active and associate members, by a show of hands, or by secret ballot if authorized by the President following the request of a Board Member.

Associate Members are limited to a maximum of 5 Board members at any given time.

Corporate entities are represented by their practicing legal representative, or by any other person whose capacity to this effect has been submitted to the Association.

Exiting Board members are eligible for reelection, with no limitation of the number of reelections.

In the case of one or more vacant Board seats, each seat is to be filled by a member of the PRI appointed by the president, confirmed by the Board, and who has accepted this seat. The term of the new Board Member will end at the same time as the term of the replaced Board member would normally have expired.

The services of a Board Member cease by resignation, loss of membership, or three consecutive unexcused absences from the Board meetings. A Board Member can be dismissed *ad nutum* by the General Assembly.

The terms of the Board members are served without financial compensation.

b) Powers of the Board of Directors

Board activities include, but are not limited to:

The Board of Directors defines the associative project, the policy and the general orientations of the association.

The Board of Directors is provided the power for managing, directing, and administrating the Association, except for those activities explicitly reserved to the General Assemblies, or to the Executive Committee.

The board of Directors makes the final strategic and shaping decisions for the Association led by proposals from the Executive Committee.

The Board of Directors may also direct the Executive Committee to investigate and report on any subject it deems appropriate.

The Board of Directors makes the final decision following information and reports provided by the Executive Committee.

The Board of Directors elects the Executive Committee according to article 9 a).

c) Operating Rules for the Board of Directors

The Board is presided by the President of the Association, or in his/her absence, by the First Vice-President, or in his absence by the Second Vice-President.

The Board meets at least twice a year, on the initiative of and by the summoning of the President, or in the case that he/she is unavailable by one of the two Vice-Presidents.

The Board can also meet on the initiative of one third of the Board membership or on the request of the Executive Committee, in both cases followed by the summoning by the President.

Summons are carried out by mail or email, and, except for emergency meetings, must reach the Board Members at least 8 days before the date chosen for the meeting.

Emergency meetings are those qualified as such by the president and mentioned at 8. d).

Summons contain the agenda of the Board of Directors meetings.

The agenda is established by the Executive Committee. When the Board meets on the request of one third of its members or at the request of the Executive Committee, the agenda should explicitly specify the reason for such meetings.

The Board of Directors may also however discuss and debate any other topic it deems appropriate (which may or may not be on the meeting agenda).

The Board of Directors may only legitimately deliberate if at least half of the membership is present or represented. If this quorum is not reached, the session is adjourned, and the president shall summon a new Board meeting with the same agenda at least 8 days later. At said date, the Board may then deliberate, no matter the number of Members present or represented.

Any Board member unable to attend may decide to be represented by any other Board member of his/her choice; to this effect a specific voting proxy power document should be signed by both parties. The number of such powers held by a single member shall not exceed two. Any Board member not present may also remit their voting powers to the Head Office. In the latter case, voting powers are considered to be in favor of every deliberation, except on matters of election and dismissal for which they are not taken into account.

The Board of Directors decisions are reached by way of discussion, debate, consensus. In the absence of consensus, and on the request of any member of the Board, the President can decide to put the discussion to a vote.

A simple majority is required for the adoption of deliberations. The President holds the tie-breaking vote.

The Executive Director is invited to participate in all Board meetings in an advisory role. He/she does not participate in the vote of any decisions. When absent for substantiated reasons, his/her role is taken over by the President or by a PRI staff member nominated for that role by the President. He/she can be asked by the President to leave the Board meeting.

The president may invite any expert to assist in its deliberations, on his own initiative or at the request of a Board member.

The Board of Directors members may meet by videoconference, conference call, fax or e-mail, as well as by any other means of telecommunication that allows their identification and effective participation in the meeting and voting.

Members who participate by videoconference, conference call, fax or e-mail and by any other means of telecommunication shall be deemed to be present for the calculation of the quorum and majority.

Minutes are taken of every Board meeting by the Secretary or one of the PRI staff members. The minutes are made without omission or erasure and signed by both the President and a Board member; they are re-transcribed in chronological order, within the records of deliberations of the Association, given a classification entry and initialed by the President. The minutes of the meeting shall record the remote participation of some members. In the event of such occurrences, the minutes shall record the possible occurrence of any technical incident relating to videoconferencing or electronic telecommunications that disrupted the course of the meeting.

d) Emergency Board meeting

When deemed necessary by the President, an extra emergency Board meeting can be called. Summons in this case are carried out by telephone during which a common meeting time is agreed. The date and hour are confirmed by mail or email and will contain the details of the agenda for this emergency meeting. The quorum of half of the Board members, present or represented, must be reached for such emergency board meetings to take place.

Article 9 – Executive Committee

a) Composition

The Executive Committee of the Association is composed of the President, two Vice-Presidents (First Vice-President and Second Vice-President), a Secretary and Treasurer.

The Executive Committee meetings of the Association are presided over by the President or in his/her absence, by the First Vice-President, or in his absence by the Second Vice-President.

During the first meeting following its election, the Board calls for candidates to the Executive Committee membership within the Board members.

Within one month following this meeting:

- Board members who wish to do so establish one or more lists of candidacies composed of a President, a First Vice-President, a Second Vice-President, a Secretary and a Treasurer;
- The Executive Committee are elected by the Board of Directors by slate vote.

If only one list was put to the vote, and it was not adopted, within one week following the latter Board meeting:

- The Board members who wish to do so establish one or more lists of candidacies composed of a President, a First Vice-President, a Second Vice-President, a Secretary and a Treasurer, that must be different from the one previously established;
- the Board meets again to proceed to a slate vote, this meeting being considered as urgent;
- If no list is presented and adopted, the list initially established is considered to be adopted and its candidates elected as Executive Committee.

The previous Executive Committee Members shall remain in office after the expiry of their term of office and the election of a new Board of Directors until the election of the new Executive Committee by the Board; during this period of time, they may only perform acts of day-to-day management necessary for the continuity of the association's activity. However, in cases of emergency, they can act beyond this scope with a specific authorization of the Board of Directors.

The members of the Executive Committee are elected for a term of two years. Exiting members can be reelected.

The services of a member of the Executive Committee cease by the occurrence of the end of the term of office, resignation, loss of membership in the Association, dismissal by the Board of Directors, which can take place *ad nutum* and by a simple incident meeting, and by the dissolution of the Association.

In the event that a member of the Executive Committee other than the President resigns, is no longer eligible to serve, or no longer has the capacity to serve, the President may proceed to nominate an eligible replacement member from within the Board of Directors.

This replacement must be then approved by a simple majority vote by the Board of Directors, either during a normal or emergency meeting, or by way of email or web conference communication.

In the event the President resigns, is no longer eligible to serve, or no longer has the capacity to serve, the First Vice President assumes the role of President-Interim until the next Board of Directors meeting (scheduled or emergency).

The terms of the Executive Committee members are served without financial compensation.

The Executive Director is invited to participate in all Executive committee meetings in an advisory role. He/she doesn't participate to the vote of any decisions. When absent for substantiated reasons, her/his role is taken over by the President or by a PRI staff member nominated for that role by the President. He can be asked by the president to leave the Executive committee meeting.

The president may invite any expert to assist in its deliberations, on his own initiative or at the request of an Executive Committee Members.

b) Powers

The Executive Committee recommends strategic and shaping decision proposals for the Association.

The Executive Committee prepares and sets the Agenda for the Board Meetings.

The Executive Committee makes the final decision on the topics to be brought to the attention of the Board of Directors following information and reports provided by the Executive Director and at the occasion of the Board of Directors' agenda preparation.

The Executive Committee plays an active role in the investigations carried out by the association on any subject the Board of Directors deems appropriate

The Executive Committee plays a primary role in the pursuit of the Association's objectives and strategic decisions.

The Executive Committee works closely with the Executive Director and the Association paid-staff.

The Executive Committee appoints and dismisses all the Association's paid-staff.

c) Operating Rules for the Executive Committee

The Executive Committee convenes as often as necessary, on the initiative of and by the summoning of the President, or in the case that he/she is unavailable by the First Vice-President, or in the case that he/she is unavailable by the Second Vice-President.

Summons are carried out by any means at least 5 days before the date chosen for the meeting. This period is reduced to two days in case of emergency.

The agenda is established by the President.

The Executive Committee may also however discuss and debate any other topic it deems appropriate even if it does not lead to any deliberation.

The Executive Committee decisions are reached by way of discussion, debate, consensus. In the absence of consensus, and on the request of any member of the Executive Committee, the President can decide to put the discussion to a vote.

A simple majority is required for the adoption of deliberations. The President holds the tie-breaking vote.

The Executive Committee members may meet by videoconference, conference call, fax or e-mail, as well as by any other means of telecommunication that allows their identification and effective participation in the meeting and voting.

Members who participate by videoconference, conference call, fax or e-mail and by any other means of telecommunication shall be deemed to be present for the calculation of the majority.

The minutes of the meeting shall record the remote participation of some members.

In the event of such occurrences, the minutes shall record the possible occurrence of any technical incident relating to videoconferencing or electronic telecommunications that disrupted the course of the meeting.

Article 10 – President

a) Position

The President concurrently holds the positions of President of the Executive Committee, Board of Directors, and of the Association. Board Members who represent any Active or Associate Member may be a candidate for the Presidency of the Association. The Board of Directors is responsible for ensuring that candidates meet all eligibility criteria and present no conflict of interest to hold this position.

b) Powers

The President governs the daily management of the Association. He/she acts in the name of and on the behalf of the Association, under the supervision of the Executive Committee and the Board.

In particular, the President:

- 1) represents the Association in all the matters of civilian life, and possesses all powers to such an effect;
- 2) is representing the Association in court, as a plaintiff or defendant; he/she may only be replaced by a mandated proxy acting by virtue of a special power of attorney;
- 3) may, under his/her own initiative, file any and all legal actions in court, for the defense of the interests of the Association, consent to any settlements, and mount any appeal;
- 4) summons the Executive Committee, the Board and the General Assemblies, and presides their meetings;
- 5) is empowered to open and operate, in any bank or financial institution, any monetary accounts or savings;
- 6) carries out the decisions ratified by the Board;
- 7) signs any contract of purchase or sale and, more generally, all documents and contracts necessary for the execution of the decisions of the Board and the General Assemblies;
- 8) has control over all expenditures;
- 9) presents an annual progress report to the General Assembly;
- 10) may delegate, in writing, his powers and signature to a member of the Executive Committee, to a member of the Board or to the Executive Director; he/she may at any moment put an end to such delegated powers; the President must keep the Board up to date concerning the powers that have been delegated in this manner, to whom and for what purpose;
- 11) The President manages and evaluates the Executive Director.

Any documents and engagements beyond the scope of the powers defined above will have to be authorized beforehand by the Board, or the General Assembly or the Executive Committee if they are competent for that matter.

Article 11 – Vice-President(s)

In the event that the President cannot fulfill his duties, he/she is replaced by the First Vice-President, or by the Second Vice-President in the event that the First Vice-President cannot fulfill his duties.

The Vice-Presidents assist the President in the course of his/her duties. The Vice-Presidents may act in the President's stead, but always under the President's direction. The Vice-Presidents may receive specific empowerments, temporary or permanent, defined by the President.

The Vice-Presidents may delegate, in writing, his/her powers and signature to a member of the Board or the Executive Director with the consent of the President. The Vice-Presidents must keep the Board up to date concerning the powers that have been delegated in this manner, to whom and for what purpose.

Article 12 – Secretary

The Secretary watches over the material, administrative, financial, and legal operations of the Association.

The Secretary takes the minutes of the meetings of the Executive Committee, Board of Directors, and General Assemblies, as specified in Article 10d. The Secretary compiles the records of the Association.

The Secretary conducts all legal notifications to the local representatives of government (*préfecture*), and to the official government register (*Journal Officiel*), with respect to the regulatory or legal provisions.

The Secretary may delegate, in writing, a member of the PRI staff to execute the above tasks on his/her behalf with consent of the President. The Secretary must keep the Executive Director up to date concerning the powers that have been delegated in this manner, to whom and for what purpose.

Article 13 – Treasurer

The Treasurer records the annual accounting of the Association.

The Treasurer is responsible for the annual collection of membership dues.

The Treasurer compiles a financial report, which he/she presents along with the annual accounting of the Association to the annual General Assembly. On delegation of the President, the Treasurer is empowered to open and operate, in any bank or financial institution, any monetary accounts or savings.

The Treasurer presents the annual budgets and sees to their implementation.

On delegation of the President, the Treasurer may sign any contract of purchase or sale and, more generally, all documents and contracts necessary for the execution of the decisions of the Executive Committee, the Board of Directors and the General Assembly.

In partnership with the Executive Director the Treasurer keeps track of all records of requests for grants and subsidies.

The Treasurer may complete or initiate the payment of expenses and the depositing of moneys paid.

The Treasurer may delegate, in writing, to a member of the PRI staff to execute the above tasks on his/her behalf. The Treasurer must keep the President and the Executive Director up to date concerning the powers that have been delegated in this manner, to whom and for what purpose.

Article 14 – General Assemblies

a) Common Provisions

All members of the Association that have paid their membership dues on the date of the summons, have access to the General Assemblies and may participate in voting.

Each member holds one vote. The President holds the tie-breaking vote.

- 1) Corporate entities are represented by their practicing legal representative, or by any other person whose capacity to this effect has been submitted beforehand to the Association.
- 2) The General Assemblies are summoned by the President by mail or email at least one month in advance. The summons contains the agenda set by the President. General Assemblies may also be summoned by the President following the request of one third of the members. This one third may request the listing of desired questions or points of discussion on the agenda.
- 3) The members sign a presence sheet when entering the General Assembly Meeting. This may be a physical paper or an electronic registration in case of a web-based conference meeting.
- 4) At the beginning of each General Assembly Meeting, a chairing committee is composed of at least the President, the Secretary and the Executive Director.
- 5) The President presides over the General Assemblies, outlines the points on the agenda, and guides the debates (Article 12b-4). The First Vice-President stands in for the President in the event that he/she cannot fulfill their duties, or the Second Vice-President in the event that the First Vice-President cannot fulfill his duties.
- 6) The General Assembly may only rule on the points of the agenda, with the exception of the dismissal of members of the Board (Article 10a).
- 7) The General Assembly Meetings are either 'Ordinary', or 'Extraordinary': their decisions, which have been passed according to the law, are mandatory for all concerned.
- 8) Any Association Member unable to attend a General Assembly Meeting may be represented by another Association Member holding a special power to this effect. The number of such powers held by a single member shall not exceed two. Any Member not present may remit their voting power to the Executive Committee. Such powers are then to be distributed by the President amongst the Board Members by preference and the members of the General Assembly in second rank, respecting the aforementioned limitations (Article 10d).
- 9) Absentee voting is forbidden, except for remote meetings prescribed under the current bylaws and if authorized by the President.
- 10) The Executive Director as well as any other relevant PRI staff member may be invited to participate in the General Assembly Meeting in an advisory role. In addition, when deemed necessary, any Member of any Task Group can be invited to participate in the General Assembly Meeting in an advisory role.
- 11) The President may invite any expert to assist in its deliberations, on his own initiative or at the request of a member.
- 12) The general assembly may hear any person who may shine light on its deliberations.
- 13) Votes are counted by a show of hands or are recorded by a certified electronic or web-based system.
- 14) Minutes are taken by the Secretary (Article 14), registering the proceedings and resolutions passed by the General Assembly during the General Assembly Meetings. The minutes are made without omission or erasure and signed by both the President and the Secretary of the session; they are re-transcribed in chronological order, within the records

of deliberations of the Association, and given a classification entry and initialed by the President.

15) The General Assemblies members may meet by videoconference, conference call, fax or e-mail, as well as by any other means of telecommunication that allows their identification and effective participation in the meeting and voting.

Members who participate by videoconference, conference call, fax or e-mail and by any other means of telecommunication shall be deemed to be present for the calculation of the quorum and majority.

The minutes of the meeting shall record the remote participation of some members.

In the event of such occurrences, the minutes shall record the possible occurrence of any technical incident relating to videoconferencing or electronic telecommunications that disrupted the course of the meeting.

b) Ordinary General Assemblies

1) Powers

The Ordinary General Assembly convenes at least once a year, within the six months following the end of the fiscal year. When necessary additional Meetings can be organized on the initiative of the President, or on the initiative of at least one third of the Association Members.

The Ordinary General Assembly hears the progress report, the financial report, and if it should occur, the report of a financial auditor.

The Ordinary General Assembly signs off on the balance sheet of the closing fiscal year, votes on the provisional budget and acknowledges that the Board has properly managed the Association's finances.

The Ordinary General Assembly decides on agreements referred to in article L.612-5* in the French code of commerce, which are to be submitted to the General Assembly by the President, or, if these exists within the Association, by the financial auditor(s).

The Ordinary General Assembly elects and dismisses the members of the Board.

The Ordinary General Assembly authorizes the Board to sign all official documents, to bring to a close any commitment, and to incur duties which go beyond the scope of their statutory powers. The Ordinary General Assembly decides the specific themes and subject of each task group

The Ordinary General Assembly deliberates on all points of the agenda, especially those which do not explicitly come under the sphere of another body of the Association.

2) Quorum and Majority

The Ordinary General Assembly may only legitimately deliberate if one third of its Members are present or represented. If the quorum is not reached by the first summons, the Ordinary General Assembly is to be re-summoned, but no less than 8 days after and with the same agenda. At this time, the Assembly may legitimately deliberate, whatever the number of Members present or represented may be.

Decisions are made by a simple majority of votes.

c) Extraordinary General Assemblies

1) Powers

It is within the authority of the Extraordinary General Assembly to go forward with changes in Bylaws, the dissolution of the Association and the dispersal of its assets, and the merging or transformation of the Association. In a general manner, it is within the authority of the Extraordinary General Assembly to make any decisions which may change the nature of its existence or its main purpose.

The Extraordinary General Assembly is summoned each time as is necessary, by the initiative of the President or by the initiative of at least a third of its members.

2) Quorum and Majority

The Extraordinary General Assembly may only legitimately deliberate if one third of its members are present or represented. If the quorum is not reached by the first summons, the Extraordinary General Assembly is to be re-summoned, but no less than 15 days after and with the same agenda; at this time, the Assembly may legitimately deliberate, whatever the number of members present or represented may be.

The decisions are made by a majority of two third of the members present or represented.

Article 15 – Fiscal Year

The fiscal year begins October 1st and ends September 30th.

Article 16 – Accountancy – Accounts and Annual Balance Sheets

The Association records the annual accounting, according to current standards of accounting and bookkeeping.

The annual balance sheets are made available for every member, along with the annual progress report, the financial report, and, whenever available, the financial auditor's report, during the 15 days preceding the date of the Ordinary General Assembly summons.

Article 17 – Financial Auditors

If the legal conditions are met, the Board appoints a head financial auditor, as well as a deputy financial auditor, registered on the list of auditors of the *Compagnie Régionale*.

The financial auditor carries out his/her duties according to the norms and rules of his/her profession. The financial auditor composes and presents, each year, a report rendering an account of his/her work and certifying the regularity and sincerity of the accounts in the presence of the ordinary General Assembly that is to rule on the balance sheet of the closing fiscal year. When applicable, he also composes and presents a report on agreements referred to in article L.612-5* in the French code of commerce.

Article 18 – Dissolution

In case of dissolution, the extraordinary General Assembly designates one or many liquidators who are in charge of the liquidation operations. At the closure of the liquidation operations, the Extraordinary General Assembly pronounces the dispersal of the net assets conforming to the French law of July 1st, 1901 and of the French decree of August 16th, 1901.

Article 19 – Transitory stipulation

As of the next Board election following the approval of these amendments to the By-Laws, all Board of Directors members will be elected at the same time and for two years.

During this first election governed by the modified by-laws, all the seats on the Board of Directors will be up for election, regardless of the fact that some terms of office may not have expired under the former clauses of the by-laws.

Article 20 – Internal Policies and Procedures

The Internal Policies and Procedures is updated by the Board and specifies and compliments, such as needed, the statutory measures related to the operations of the Association. Accession to the Bylaws is an implied accession to the Internal Policies and Procedures. Any changes must be communicated to all Members of the Association.

Article 21 –Charter of Ethics (ANNEX)

The Charter of Ethics, in Annex of this document, is updated by the Board and specifies the ethical do's and don'ts of the Association. Accession to the Bylaws is an implied accession to the Charter of Ethics. Any changes must be communicated to all Members of the Association.

Article 22 – Non-Disclosure document (ANNEX)

The non-disclosure formulations, in Annex of this document, are updated by the Board and specify the secrecy conditions to be respected by the Regulatory and Incubator Members when they join the Association. Accession to the Bylaws is an implied accession to the conditions specified in this non-disclosure document. Any changes must be communicated to all Regulatory and Incubator Members of the Association.

Signatory's Full Name:

Company/ Corporate entity:

Please write the phrase “ read and approved”, the Date, and your Signature: