



Operating Committee

IRDiRC Governance Changes

1 March 2017

For vote by the CA

[N.B., in the survey, each of the below for vote will have a click box: (1) Approve; (2) Do Not Approve. Each will also include a comment box.]

Below are the two items that were discussed during the CA meeting in Paris, but now require full CA vote. For each, we have listed the final language that will be edited or added to the Governance document along with a brief description of why the change is necessary.

1. IRDiRC membership – Patient Advocacy Group definition and application for membership

a. Update language:

i. Definition:

1. *To be considered as an IRDiRC Patient Advocacy Group member, the organization must be an umbrella patient organization representing broad patients' interests for ALL rare diseases in AT LEAST one country or larger area. Once approved, the organization can nominate one representative to the CA. Each approved Patient Advocacy Group representative will serve on the Patient Advocates Constituency Committee.*

ii. Process:

1. *For IRDiRC membership consideration, the organization must submit a letter of motivation stating the reasons for desiring to join IRDiRC, and a Letter of Intent signed by the organization's legal representative.*
2. *Generally, IRDiRC will not accept membership applications from local umbrella organizations unless there is no established umbrella organization in the region they are applying from. If this is the case, IRDiRC prefers that the organizations within the region come together and appoint a representative for that region ("Group of Patient Advocacy Groups").*

b. Description:

- i. *This change was deemed necessary since the current criteria for Patient Group membership is not clearly defined and the governance currently states that the CA invites Patient Groups to participate. The update is aimed to create an objective set of criteria and application process that balances inclusiveness within the realm of IRDiRC without getting overwhelmed by too many groups. Additionally, we want to make it clear that the PACC is analogous to the other CCs (in that members are made up of that constituency on the CA) rather than the SCs (in that members are external to IRDiRC).*

2. Conditions of IRDiRC CA membership

a. Add language:

- i. *To remain in good standing, CA members must attend at least two meetings or teleconferences per year. If not, the member will receive an email stating that*



- they are on a 6-month probationary period, during which time s/he must attend a meeting. If not, IRDiRC will consider the member inactive and will remove the member from CA-related communications and the organization from the IRDiRC listing. Note – if a member cannot attend a meeting, sending comments via email beforehand will count as participating in the meeting.*
- ii. The Sci Sec will collect in writing the developments at member organizations relevant to the IRDiRC mission and to CA members on an annual basis. The information collected should be non-proprietary and include only about 2-3 bullets per year as a high-level collection of programmatic activities.*
 - iii. As a condition of IRDiRC membership, the Sci Sec will request updated information regarding their funding commitment toward IRDiRC objectives from Funders and Companies every 2 years to ensure that they continue to reach the minimum commitment of US\$10 million over 5 years.*
- b. Description:
- i. This change was deemed necessary to (1) ensure that we have committed members and put into language how to terminate inactive members; (2) put into official implementation the collection of developments at member organizations related to the IRDiRC mission (collected verbally at CA meetings); and (3) ensure that Funders and Companies are continuing to allocate the minimum funding levels.

Approved

Below are the four items that were discussed and approved during the CA meeting in Paris. For each, we have listed the final language that will be edited or added to the Governance document.

1. Information exchange between OC and CA

- a. Add language:
 - i. After each OC meeting, a synopsis including the topics and action items covered will be sent to the CA. The link to the entire OC meeting report, available on the private website, will also be sent to the CA. Each CA meeting will include an agenda item for the CA Chair to give a brief summary of the topics and action items covered by the OC since the last meeting. At any time, CA members can send the Sci Sec items for the OC to discuss and consider.*

2. SC membership definition

- a. Update language:
 - i. SC Chairs and Vice Chairs are members of the CA and can participate and vote as representatives of the SC, as a whole. SC Chairs and Vice Chairs each get one vote. All other SC members are not CA members, but upon proposal from a CA member, the CA can decide to invite observers to its meetings. Such invitations will be done by the CA Chair in consultation with the OC members.*

3. SC and CA membership distinction

- a. Update language:
 - i. Individual CA members can be nominated to also participate in a SC under the stipulation that they are acting in their capacity as an individual scientist and not representing their organization, as a whole. In cases of conflict of interest, the*



member must recuse him/herself from such discussions and note that to the SC Chair, Vice Chair, and Sci Sec.

4. Updates based on current operation

- a. Update language re: CCs:
 - i. *IRDiRC has three Constituency Committees, one for each of the major areas of representation – Funders, Companies, Patient Advocates. The Constituency Committees (1) identify overlap of priorities and activities and gaps within each constituency space; (2) identify common roadblocks across constituency space worldwide; (3) determine how the constituency will contribute to the goals; (4) implement Task Forces and coordinate solutions to address priorities and gaps; and (5) inform other committees of scientific and programmatic needs. Each Constituency Committee is composed of those on the Consortium Assembly who are identified as part of that constituency.*
- b. Update language re: election of Vice Chairs of Committees:
 - i.

Commentaire [LL1]: To update after the procedure is defined by the OC

For further deliberation

Below are the two items that were discussed at the CA meeting in Paris, but were determined to need further deliberation. The FCC/OC will be tasked with addressing these items and developing recommendations to be presented to the CA. For each, we have given a brief description of the discussions to-date.

- 1. **IRDiRC member definition – funders re: LDCs** → *tasked to the FCC*
- 2. **IRDiRC member definition – ineligible organizations (e.g., ICORD, ERN, IFPMA, GA4GH)** → *tasked to the OC*