**[insert name of ERN]**

**Rules for Associate Partners representatives (ePAG advocates) Template**

**22/11/2021**

Text and sections highlighted in yellow are optional or can be tailored to your needs, please read the comments to adjust the template

1. Introduction

According to the European Commission Expert Group (EUCERD) patients and patient representatives should play an active role in the decision and opinion making process of the European Reference Networks (ERNs) and be involved in structural and clinical network activities. The Expert Group recommended that ERNs demonstrate meaningful patient involvement, patient-centeredness and empowerment through recognition of the role of patients, as experts by experience and co-producers of knowledge, in the ERNs structural and clinical activities and therefore demonstrate meeting the legal requirements in the Delegated Acts.

These rules for patient engagement aim at facilitating the effective involvement of patient representatives in the activities of [insert name of ERN]. They are based on the [governance framework](about:blank) develop by EURORDIS for patient engagement in the ERNs and contain specific provisions to adapt them to the governance structure of [insert name of ERN].

The [insert name of ERN] ePAG has appointed [add number, the recommendation is having 2 ePAG advocates per work stream] ePAG advocates to be involved in each of the ERN work streams. This policy does not preclude other patient organisations registered in Europe, patient organisations registered outside Europe, individual patients and family members as well as social media-based support groups from collaborating on specific projects as Supporting Partners.

The position of ePAG advocate is a voluntary position and does not involve any financial compensation. Travel and accommodation expenses will be reimbursed according to the [insert name of ERN] policy on reimbursement for travel expenses.

2. Role of [insert name of ERN] European Patient Advocacy Group (ePAG)

The [insert name of ERN] European Patient Advocacy Group (ePAG) is comprised of patient advocates that represent and are endorsed by a patient organisation following the process described in Sections 11 and 12.

The overarching objective of the ePAG is to ensure that the needs of people living with rare and complex conditions covered by the ERN are included in its strategic and operational delivery. To achieve this goal, the ePAG role is to:

* Represent the voice and interests of patients and families within [insert name of ERN].
* Ensure a patient-centric approach in the collaborative activities of [insert name of ERN]in the areas of care, education and training, knowledge sharing and research.
* Support the identification of [insert name of ERN] strategic priorities.
* Provide input on ethical issues.
* Support the Network in the dissemination of its activities and information to the wider patient community to ensure transparency.

The structure and composition of the ePAG is described in Annex I.

3. Role of [insert name of ERN] ePAG advocates

ePAG advocates are patient representatives that are active in the ERN governance structure including the Network Board, in the case of ePAG leads, work streams and working groups. The ePAG advocates role is to:

* Work in partnership with other patient advocates, clinicians and researchers involved in [insert name of ERN];
* Champion the diversity of views of the ERN patient community, and not just to represent their own disease area nor their own experience;
* Support the ERN to disseminate information, primarily to the patient community, but as appropriate to other communities (e.g. healthcare providers, health authorities, clinicians and medical professionals and their professional bodies)
* Contribute, where needed, to the development of patient information, clinical practice guidelines, other clinical decision support tools and referral pathways;
* Contribute to the development of research priorities and ensure the needs of patients and families area taken into consideration;
* Contribute to other [insert name of ERN] collaborative activities where patient involvement is required, as appropriate.
* Provide input on ethical issues, and balance patient and clinical needs appropriately;
* Scout for or make recommendations for new patient organizations to cover under-represented disease groups or patients from other EU countries.

4. Responsibilities of [insert name of ERN] ePAG advocates

All ePAG advocates will be required to:

* Participate in [insert name of ERN] working groups (depending on interests, expertise and availability).
* Participate regularly in the majority of the ePAG calls, and send apologies in advance if unable to attend.
* Report regularly in the ePAG calls and meetings on the progress of the work and projects in which they are directly involved in [insert name of ERN]. If unable to attend, the update should be sent by email ahead of the meeting or call.
* Participate in [insert name of ERN] annual meetings, where possible. Travel and accommodation expenses will be reimbursed subject to the ERN budgetary rules.
* Contribute to identify and develop the ePAG annual objectives and work programme.
* Contribute to the assessment of new applications for membership of the ePAG.
* Respect the confidential nature of the discussions when it is made clear that this is a requirement by the person who is chairing a call or meeting.
* Comply with the [insert name of ERN] conflict of interest policy.
* Adhere to the terms of the mediation agreement in the case of a mediation process described in the [EURORDIS ePAG Constitution and Rules of Procedure](about:blank).

All ePAG advocates also commit to adhering to the following set of **core values**:

* Respecting the mission of the [insert name of ERN] and its governance structure;
* Listening to the opinions and requests of others;
* Showing solidarity, mutual respect and support;
* Adhering to the principles of equity and social justice;
* Conducting themselves with professionalism in engaging with the clinical, research leads and fellow patient advocates;

5. ePAG advocates substitutes

ePAG advocates may nominate a substitute from his/ her own patient organisation to attend specific ERN or ePAG meetings if adequately briefed beforehand on the topic area. The ERN Coordinator or the ePAG lead shall validate the participation of such substitutes in the ERN or ePAG meetings, respectively. Substitutes must comply with the [insert name of ERN] conflict of interest policy and with the core principles lay down in Section 4 when attending ERN or ePAG meetings.

6. ePAG Leads role and responsibilities

[Please provide a brief description of the ePAG leadership team and tasks. As an example, please see below the description of the EpiCare ePAG leadership team. You may also add here a reference to the function of the ePAG leads as liaisons with the ERN Coordinating team]

The ERN EpiCARE ePAG has one ePAG Coordinator and one ePAG Deputy Coordinator who are responsible for coordinating the ePAG group, they represent the ERN EpiCARE ePAG and the ePAG Community on the ERN EpiCARE Board.

In addition to the role and responsibilities of the ePAG advocates mentioned in Section 5, the ERN EpiCARE ePAG Coordinator and ePAG Deputy Coordinator have the following responsibilities:

* Represent the voice of ERN EpiCARE ePAG advocates and the ePAG Community to the ERN EpiCARE Board and network meetings.
* Share important news and update the other ERN EpiCARE ePAG advocates and the ePAG Community on ERN EpiCARE activities as appropriate.
* Consult with the other ERN EpiCARE ePAG advocates and the ePAG Community on relevant issues and feedback information to the ERN EpiCARE Network Coordinator.
* Ensure the sustainability of the ePAG advocates group.
* Assign ePAG advocates to Working Groups.
* Monitor ePAG advocates activities in the Working Groups
* Coordinate the activities of the whole group, and report shared vision with ERN Coordinator/steering Committee
* Coordinate the activities of the whole group, and report shared vision with EURORDIS Steering Committee/ Transversal Group etc.

Decisions in the ePAG are taken by consensus, but vote is possible if necessary. In the event of non-consensus, the voice of the ePAG Coordinator is predominant.

Furthermore, the ERN EpiCARE ePAG has appointed an ePAG Secretary who is responsible for supporting the administrative tasks of the ePAG group, including welcoming the new ePAG advocates or the new members of the ePAG Community; setting up the regular ePAG meetings (agenda, minutes, follow-up actions) and disseminating any relevant information to the ePAG group.

7. Skills and experience for ePAG advocates

Required skills and experience:

* Have knowledge of, or experience of living with, one of the rare and complex conditions included in the scope of the ERN;
* Willingness and motivation to get involved, contribute actively to the discussions and work of the ePAG and the ERN working groups;
* Ability to work effectively, constructively with other patient representatives and clinicians from different EU countries;
* Ability to represent the interests of all represented diseases that are under the scope of the ERN, beyond their own disease.
* Ability to bring independent judgement from a patient representative perspective;
* Have an awareness of, and commitment to, equality, diversity and inclusiveness;
* High level of organisation and self-motivation;
* Understand the need for confidentiality;
* Able to communicate in English to be able to follow and contribute to meetings.
* Have computer skills and equipment to communicate through email, webinars, and videoconferences.
* Have knowledge, or is willing to acquire knowledge, on the rare disease policy environment.

It is desirable to have experience working in a committee setting with clinicians and patient representatives.

8. Time Commitment

ePAG advocates will be required to attend ePAG calls approximately every two months that will generally take place during working hours.

They will also need to attend the calls of the ERN working groups in which they decide to be involved, as well as the ERN annual meeting, that is usually at least a full day meeting. Attendance to the annual meeting will be subject to the ERN budget availability.

In addition, they will need to dedicate time to review and read documents if necessary, ahead of the meetings and calls. This implies a commitment of typically 2 days per month, depending on ERN projects and activities, and can increase to approximately 5 days per month in the case of the ePAG leads.

9. Benefits of becoming an ePAG advocate

ePAG advocates role and position in the ERNs give these representatives the possibility to:

* Work closely with clinicians, researchers, and other patient representatives to transform healthcare services and accelerate research to improve the health outcomes of people living with a rare disease in Europe.
* Participate firsthand in the development of the ERN objectives and infrastructure to ensure that it remains driven by patients’ needs.
* Increase their international exposure and expand their international network, specifically across Europe.
* Improve their understanding of healthcare models across Europe and European Reference Networks.
* Further develop soft skills such as communication, public speaking, conflict resolution, etc. acquired through trainings such as the ones provided by EURORDIS through its Open Academy, EUPATI and others, and through active participation in the ePAG.
* Share and learn from other ePAG advocates and build their own capacities as patient representatives, broadening knowledge both within their own field of rare diseases and beyond.

10. How to apply

Patient organisations may contact the ERN project management team to express their interest in engaging as Associate Partners and designating an ePAG advocate. EURORDIS should be made aware of all expressions of interest to kick-start the application process. EURORDIS ePAG managers will send the prospective applicant an application package composed by: application form, ERN bylaws, ERN Rules for patient engagement, endorsement letter template and ERN Conflict of Interest policy.

## Prospective applicants should complete and sign the application form in Annex II and send it to PEM-ePAGs@eurordis.org.together with the following documents:

1. Endorsement letter signed by the legal representative of the patient organisation
2. Statutes of the patient organisation;
3. List of Board of Directors, indicating for each person if they are a patient or family member of a patient
4. Most recent Annual Report, including financial statement.

11. Assessment of Applications

Once received, the applications are processed as follows:

1. EURORDIS ePAG manager shares the application and accompanying documents with the [insert name of ERN] ePAG lead and project management team.
2. The ERN project management team will review the information pertaining to the patient organisation to ensure that the requirements for patient organisations described in the ERN bylaws are met.
3. The application is reviewed and discussed by the ePAG. Applicants will be assessed against the required skills and experience outlined in Section 7. Selection will be made on the basis of the content of the application form and accompanying documents.
4. The ERN project management team and ePAG lead may request further information or arrange an informal call with the prospective applicant to get additional information on his or her skills, experience and motivation.
5. Priority will be given to prospective applicants that represent a country or a disease not currently represented in the [insert name of ERN] ePAG.
6. Approval of new ePAG advocates is through agreement in the ePAG and in consultation with the ERN Coordinator.
7. All applications will receive a successful or unsuccessful notification.
8. In case of a successful application, the ERN Coordination team will send the patient organisation an Associate Partnership Bilateral Agreement. Once the agreement is received and signed by the ERN Coordinator and the Patient Organisation, the ePAG advocate will be able to join the ERN and ePAG meetings.

This process is further detailed in Annex III.

The appointment of a new ePAG advocate is initially forasix-month period. During this period, the new ePAG advocate will have the opportunity to get familiar with the activities and with his/her role and responsibilities. After this period, the [insert name of ERN] ePAG, in consultation with the Network Coordinator, will validate the appointment of the new ePAG advocate.

12. Induction for new ePAG advocates

[insert name of ERN] ePAG will request that all new ePAG advocates complete an interactive online induction session delivered by EURORDIS on a quarterly basis. This webinar lasts an hour and a half and will provide some background information to the European Reference Networks and European Patient Advocacy Groups and the work that they do.

In addition, new ePAG advocates will also receive an induction on the work of [insert name of ERN] delivered by one of the seasoned ePAG advocates.

13. Duration and renewal of ePAG advocates mandate

The mandate of ePAG advocates expires at end of each five-year funding period of the ERNs. The mandate of ePAG advocates appointed for a given 5-year period may be renewed by another 5-years by reconfirming their willingness and presenting a new letter of endorsement signed by their patient organisation. ePAG advocates who joined the last year of any 5-year ERN period, will not be required to renew their mandate.

Appointment of the ePAG Leads is for a period of 2 years, their mandate may be renewed with the agreement of [insert name of ERN] ePAG and in consultation with the ERN Coordinator.

14. Termination of role of ePAG advocates and voluntary suspension

The mandate of an ePAG advocate shall terminate in any of the following cases:

1. The ePAG advocate sends a notice of resignation to the [insert name of ERN] ePAG, the ERN Coordinator and to EURORDIS.
2. The Patient Organisation withdraws the endorsement given to the ePAG advocate.
3. The ePAG advocate does not respond to emails, attend meetings or does not contact the ePAG group in a period of 3 months.
4. An Evaluation Committee composed by a clinical lead, an ePAG advocate, a EURORDIS representative and the [insert name of ERN] project manager decides that he or she is unable to fulfil the responsibilities or respect the core values listed in Section 4. The Evaluation Committee may seek advice from clinicians, ePAG advocates and project managers involved in other ERNs

In the circumstances referred to in points 3 and 4 above, before any decision is made to remove someone from being an ePAG advocate:

* the ePAG advocate as well as his/her endorsing Patient Organisation must be informed of the reasons why it is proposed to remove them (this includes an opportunity for open discussion), and
* at least one month should be allowed for mediation and any concerns raised to be addressed.

At any time, ePAG advocates can send a notice of temporary suspension to the [insert name of ERN] ePAG, the ERN Coordinator and to EURORDIS, in case he or she would like to voluntarily step down for a period of time.

15. Amendment of the Terms of Reference

The ePAG on annual basis will make the necessary amendments to ensure they remain fit for purpose.

16. Authority of the [insert name of ERN] Board

Nothing in this document removes the rights of the [insert name of ERN] Network Board to interpret and/or amend its content in the best interest of the Network or to comply with relevant directives or guidance from the European Commission.

Annex I – Composition of the [insert name of ERN] ePAG

*[****This annex is optional****, in case you want to provide additional details. Please provide a brief description of the structure of the ePAG. See as an example the composition of EpiCare ePAG]*

|  |  |  |  |
| --- | --- | --- | --- |
| **ERN Board** | **ePAG advocates** | **Patient Organisation** | **Role** |
| ERN EpiCARE Steering Committee | Isabella Brambilla | Dravet Italia Onlus | ePAG Coordinator |
| ERN EpiCARE Steering Committee | Allison Watson | Ring20 Research & Support UK | ePAG Deputy Coordinator |
| N/A | Emma Nott | Hope for Hypothalamic Hamartomas UK | Secretary |

The nominated ERN EpiCARE ePAG advocates, also named ePAG workpackage leads, (as listed below) represent the voice of the patients within the ERN EpiCARE and they contribute actively to the regular activities and meetings.

| **ERN Workpackages** | **ePAG WP Leads** | **Patient Organisation** |
| --- | --- | --- |
| **WP 1 Network Coordination** | Isabella Brambilla (lead) | Dravet Italia Onlus |
| Allison Watson (deputy) | Ring20 Research & Support UK |
| **WP 2 Diagnostics** | Carol-Anne Partridge (lead) | CDKL5 – UK |
| Allison Watson (deputy) | Ring20 Research & Support UK |
| **WP 3 Neuroimaging** | Emma Nott (lead) | Hope for Hypothalamic Hamartomas UK |
| Alva Fontell | Finnish Epilepsy Association |
| **WP 4 Neurophysiology** | Barbara Nicol (lead) | Lennox-Gastaut, Purple Day Spain, |
| Torie Robinson (deputy) | Epilepsy sparks |
| **WP 5 Neuropsychology** | Rosaria Vavassori (lead) | AHC18+ e.V. Association |
| Torie Robinson (deputy) | Epilepsy sparks |
| **WP 6 E-neuropathology** | José Ángel Aibar (lead) | Fundación Síndrome de Dravet |
| Monica Lucente (deputy) | Associazione Italiana Glut1 Onlus |
| **WP 7 Targeted Medical Therapies** | Barbara Nicol (lead) | Lennox-Gastaut, Purple Day Spain, |
| Isabella Brambilla/Rosaria Vavassori (deputy) | Dravet Italia Onlus/ AHC18+ e.V. Association |
| **WP 8 E-pilepsy (surgery)** | Emma Nott (lead) | Hope for Hypothalamic Hamartomas UK |
| Torie Robinson (deputy) | Epilepsy sparks |
| **WP 9 Neonatal seizures** | Rosaria Vavassori (lead) | AHC18+ e.V. Association |
| Barbara Nicol (deputy) | Lennox-Gastaut, Purple Day Spain, |
| **WP 10 Diet** | Monica Lucente (lead) | Associazione Italiana Glut1 Onlus |
| Carol-Anne Partridge (deputy) | CDKL5 – UK |
| **WP 11 Dissemination** | Torie Robinson (deputy) | Epilepsy sparks |
| Alva Fontell (deputy) | Finnish Epilepsy Association |
| **WP I E-database** | Allison Watson (lead) | Ring20 Research & Support UK |
| Rosaria Vavassori (deputy) | AHC18+ e.V. Association |
| **WG II E-guidelines** | Isabella Brambilla (lead) | Dravet Italia Onlus |
| N/A |  |
| **WG III Education & Training** | Allison Watson (lead) | Ring20 Research & Support UK |
| José Ángel Aibar (deputy) | Fundación Síndrome de Dravet |
| **WG IV Genetic Research** | Barbara Nicol (lead) | Lennox-Gastaut, Purple Day Spain, |
| Isabella Brambilla/Rosaria Vavassori (deputy) | Dravet Italia Onlus/ AHC18+ e.V. Association |
| **WG V Clinical Trials** | Barbara Nicol (lead) | Lennox-Gastaut, Purple Day Spain, |
| Isabella Brambilla/Rosaria Vavassori (deputy) | Dravet Italia Onlus/ AHC18+ e.V. Association |

Annex II - ePAG advocate Application Form

**Full Requirements Online application form Template**

https://form.jotform.com/eurordisforms/epag-application

For the ERNs that have included the following requirements for the patient organisation in their ERN Bylaws:

* Has a governing board made up of a majority patients or of family members of patients.
* Is financially independent, particularly from the pharmaceutical industry (max. 50% of funding from several companies).
* Holds non-profit status.
* Has proven activities such as patient support and/or advocacy activities and/or research

**Limited Requirements Online application form Template**

<https://form.jotform.com/211962393900355>

For the ERN that have NOT included the above requirements for the patient organisations in their ERN Bylaws:

Annex III: ePAG advocate application assessment process supported by EURORDIS

