



European Reference Networks

ERN disclosure form personal interests

Authors: members of the ERNs Working Group (WG) on Legal & Ethical issues & relations with stakeholders, the ERNs LES WG (see full list of WG (past and current) members at the end of this document)

Table of Contents

| | |
|--|----|
| | 1 |
| Definitions | 2 |
| Introduction: ERNs Disclosure Personal Interests and Conflict of interest | 3 |
| Instructions | 4 |
| Part A: personal interests..... | 4 |
| 1. Personal information | 4 |
| 2. Financial interests..... | 4 |
| 2.a. Personal financial gain..... | 5 |
| 2.b. Research | 5 |
| 2.c. Investment interests | 6 |
| 3. Other relations with commercial third parties, including indirect funding | 7 |
| 4. Intellectual Property Rights - Patents & Copyrights | 7 |
| 5. Non-financial personal interests | 8 |
| 6. Interests not covered above | 8 |
| Consent to disclosure: | 10 |
| PART B | 11 |
| Full list of past and current members of the ERNs LES WG (ERN Working Group on Legal & Ethical issues & relations with Stakeholders) who contributed to this document: | 12 |

Definitions

ERNs – *European Reference Networks*

HCPs – *Healthcare Providers*

COI – *Conflict of interest*

GDPR – *General Data Protection Regulation*

CPMS – *Clinical Patient Management System*

ERNs activity – *ERNs activities include the exchange of knowledge among health professionals to facilitate the diagnosis and treatment of patients with low and rare disease, the production of good practice guidelines, the implementation of outcome measures and quality control, as well as among others, the contribution to research activities¹*

Affiliated partners - *Associated National Centres, Collaborative National Centres and National Coordination Hubs²*

Industry- *definition includes among others the pharmaceutical industry but also industry involved, for example, in the developing tools, software and methods for diagnostics, care and well-being of rare disease patients.*

ERNs Individuals – *those are individuals involved within ERNs activities, including:*

- i. Members of the ERNs Boards, committees or any other governing body in the ERNs,*
- ii. Professionals employed by the HCPs that are individual members of the ERN and are engaged with the activities of that ERN.*
- iii. All patient representatives who are active in the governance structure and activities of the ERNs.*
- iv. ERNs coordination officers (project management and ERNs support staff, such as IT staff to be hired for CPMS activities)*
- v. In certain cases, such as in the CPMS, individual external expert invited to contribute in panels members can be included within this definition.*
- vi. Affiliated Partners.*

Immediate family member - *refers to a person's parents, or spouse of a person's parent if that parent has remarried, and siblings, as well as his own family.*

¹ Based on Article 12 of Directive 2011/24/EU.

² The Commission Implementing Decision (EU) 2019/1269 of 26 July 2019 amending Implementing Decision 2014/287/EU and the Board Statement of 10 October 2017 defines Affiliated Partner. The legal act can be found in here https://ec.europa.eu/health/sites/health/files/ern/docs/boms_affiliated_partners_en.pdf.

Immediate family also refers to a person's spouse and children. Immediate family can include individuals not related by blood, such as stepchildren or adopted children. Further, a person's immediate family for legal purposes also includes the spouse of his child, brother, or sister, as well as the father, mother, brother, and sister of his spouse.

Introduction: ERNs Disclosure Personal Interests and Conflict of interest

The European Reference Networks (ERNs) community at EU level (ERNs Coordinators & members, ERN Board of Member States, ERNs team in DG SANTE of the European Commission) is aware that a high level of scientific expertise often goes hand in hand with various interests. Some of these interests could, internally or externally, be regarded as potentially affecting the impartiality of the decisions of a group of experts. The ERNs Working Group on Legal & Ethical issues and relations with Stakeholders (ERNs LES WG), where several ERNs and ERNs Member States' representatives are present, thus prepared the present "disclosure form" to provide all 24 ERNs with a common form to enable the disclosure of interests.

The Board of ERN <name (to be filled in)> strives for transparency in this area and wants to take responsibility for this. Therefore, the Board of ERN <name (to be filled in)> asks you to indicate any financial or other interest in companies, institutions and groups, so that the Board of your Network, as governance body of your Network, is able to apply the procedures concerning conflicts of interest.

In this disclosure form, two types of personal interest are distinguished: financial and non-financial. Both types are relevant to report and can lead to conflicts with the interest of the ERNs.

Financial interests can be directly measured in monetary units, such as stocks or patents owned, money received for commissioned work or an honorarium for a speaking engagement.

Non-financial interests, on the other hand, cannot readily be measured in monetary units and are less tangible and thus more difficult to identify, measure and manage. They include any interest that could be reasonably perceived to affect an individual's objectivity and independence while being engaged in ERNs activities or results. Examples include a desire for professional advancement or prestige or a drive to publish, to obtain research funding, or to improve one's personal standing in the scientific community. One type of non-financial interest is referred to as an "*intellectual conflict of interest*", defined as "*academic activities that create the potential for an attachment to a specific point of view that could unduly affect an individual's judgment about a specific recommendation*"³.

The assessment of any potential conflict of interest is done in accordance with the ERNs Code of Conduct (under development within the ERNs LES WG) and ERNs policy on conflict of interest (version x, date x).

³ Guyatt G, Akl EA, Hirsh J, Kearon C, Crowther M, Gutterman D, et al. The Vexing Problem of Guidelines and Conflict of Interest: A Potential Solution. *Ann Intern Med.* 2010;152:738–741. doi: 10.7326/0003-4819-152-11-201006010-00254

Instructions

This form consists of two parts:

Part A records the personal interests of the ERN individual,

Part B is to be completed in case any of the reported personal interests are in actual, potential or perceived conflict with the ERN activity or results.

The timeframe proposed for this declaration is 36 months prior to declaration, as a general rule for all sections below.

Part A: personal interests

1. Personal information⁴

Name:

Affiliation: for electronic form: (pulldown menu with all 24 ERNs mentioned)

ERN: pulldown menu with all 24 ERNs mentioned

ERN activities and results engaged with: this should allow ticking predefined activities plus allow some free field

Period reported: please, consider adding this item and having here 3 options: INITIAL (period of 36 months prior to declaring COI), UPDATE (past 12 months) and NOVEL COI (reported ad hoc)

2. Financial interests

A financial conflict of interest arises when an ERN individual receives income or monetary support that is related to, or could be affected by, the outcome of the ERN activity or results in which they are involved. This includes both personal financial interests and the interests of the individual's immediate family members (defined as per above).

Public funding sources, such as government agencies, charitable foundations or academic institutions, need not be disclosed. For example, if a government agency sponsored a study in

⁴ Please note that there is the need to include a privacy statement.

which you have been involved and drugs were provided by a pharmaceutical company, you need only list the pharmaceutical company.

2.a. Personal financial gain

Report any money received from a commercial third party in the biomedical arena, such as paid work, consulting income, honoraria for presentations including research outcomes, travel stipend, fellowship, grant – other than for research.

Attendance at courses and conferences funded by a commercial third party needs to be declared only if the ERN individual directly (or through their institute) receives payment by the third party of reasonable expenses (i.e. accommodation and travel costs) directly related to a conference/seminar attendance. Payment beyond reasonable expenses also needs to be declared but would likely result in a conflict of interest (COI).

Examples of what can be omitted from the declaration (minor expenses)⁵ are... (to be completed) which have been obtained in the last 36 months.

Did you or an immediate family member receive remuneration over the reported period from a commercial third party in the biomedical arena?

If yes, is this personal gain in conflict (actual, possible or perceived) with the interest of the ERN activities and results you are engaged with?

| Name of commercial third party | Description | Period | Relates to whom? | Monetary value (appr) | COI? (none / actual / perceived) |
|--------------------------------|-------------|--------|------------------|-----------------------|----------------------------------|
| | | | | | |
| | | | | | |
| | | | | | |

2.b. Research

For the reporting and evaluation of any COI, a distinction is made in basic, preclinical and clinical research. Sponsoring of basic and preclinical research has a low risk to pose a conflict of interest for ERNs activities, yet needs to be reported. For clinical research, a distinction is made in investigator-initiated studies (with study design, protocol, study population etc. entirely written by the investigator) and sponsor-initiated studies (with study design, protocol, study population etc. defined by the sponsor). Sponsor initiated studies have the highest risk to pose a conflict of interest in ERNs activities.

For both types of clinical research studies, any involvement of the sponsor in the data collection, interpretation, analysis or publication that results in a conflict of interest needs to be reported.

⁵ Minor expense is commonly understood as ‘an expense not budgeted or not specified’. This could therefore include light lunch or dinner, gifts or donations of a value lower than 50 euro etc.

- Basic and preclinical research sponsored by a non-commercial third party, like a funding agency or charity foundation does not need to be reported.
- Basic and preclinical research sponsored by a commercial third party needs to be reported when carried out during the previous 36 months.
- Clinical research needs to be reported when sponsored by any third party and carried out during the previous 36 months. Investigator-initiated clinical studies sponsored by a third party and sponsor-initiated clinical studies need to be carefully evaluated for a conflict of interest, especially when a treatment or procedure under investigation is relevant for the ERNs. In both types of studies, the sponsor cannot have any influence on the analysis and reporting of the study.

Within the past 3 years, have you or has your research unit received support from a commercial third party in the biomedical arena for research, (financial or non-financial, such as donations of drugs, equipment, laboratory space, etc.)? Include all research that you have performed during the past 3 years and include an expected end date if the research is still ongoing.

If yes, is this support for research in conflict (actual, possible or perceived) with the interest of the ERN activities and results you are engaged with?

| Name of commercial third party | Type ⁶ | Research topic ⁷ | Period | Monetary value (appr) (please specify if money or other costs) | COI? (none / actual / possible / perceived) |
|--------------------------------|-------------------|-----------------------------|--------|--|---|
| | | | | | |
| | | | | | |
| | | | | | |

2.c. Investment interests

Do you or an immediate family member have current investments in a commercial third party in the biomedical arena? These include stocks, bonds, stock options, or commercial business interests (e.g. proprietorship, partnerships, joint ventures, board memberships, controlling interest in a company)?

If yes, is this investment in conflict (actual, possible or perceived) with the interest of the ERN activities and results you are engaged with?

⁶ Basis, preclinical or clinical research.

⁷ Describe topic in relevance to ERNs.

| Name of commercial third party | Type of interest | Belongs to you or a family member? | Monetary value (appr) | COI? (none / actual / perceived) |
|--------------------------------|------------------|------------------------------------|-----------------------|----------------------------------|
| | | | | |
| | | | | |
| | | | | |

3. Other relations with commercial third parties, including indirect funding

Do you or an immediate family member have relations with commercial third parties that are not yet mentioned that might be relevant for the ERN activities and results?

If yes, is this relation in conflict (actual, possible or perceived) with the interest of the ERN activities and results you are engaged with?

| Name of commercial third party | Type of interest | Belongs to you or a family member? | Monetary value (appr) | COI? (none / actual / perceived) |
|--------------------------------|------------------|------------------------------------|-----------------------|----------------------------------|
| | | | | |
| | | | | |
| | | | | |

4. Intellectual Property Rights - Patents & Copyrights

Do you have any Intellectual Property Rights, whether planned, pending or issued, broadly relevant to the work?

If yes, are these Intellectual Property Rights in conflict (actual, possible or perceived) with the interest of the ERN activities and results you are engaged with?

| Intellectual Property Rights | Type | Licensee | Stage ⁸ | Royalties | Comments | COI? (none / actual / perceived) |
|------------------------------|------|----------|--------------------|-----------|----------|----------------------------------|
| | | | | | | |
| | | | | | | |
| | | | | | | |

⁸ Pending, issued or licensed.

5. Non-financial personal interests

Non-financial interests include academic, professional, and personal interests. Financial and non-financial interests can overlap. For example, intellectual interests related to career advancement obviously have a monetary component. Like for previous personal interests considered in the previous sections, the time frame considered for the declaration are the 36 months prior to declaration.

Examples of roles or positions that might interfere with the objective assessment of a body of evidence include:

- prior publications of a study, research, systematic review or any other type of publication for example involvement with other relevant clinical guidelines with European or international scientific societies, that is part of the evidence base under consideration in the guideline;
- prior public declaration of a firm opinion or position, as in public testimony during a regulatory or judicial process, or in an editorial in a journal; or
- professional or personal affiliation with an organisation advocating for products or services related to the subject of the ERN activity or results.

Non-financial conflicts of interest are ubiquitous and would not inherently constitute a COI. However, they must be identified and appropriately managed if an unbiased, credible guideline is to be produced.

Do you have a non-financial personal interest that relates to the ERNs activities that might result in a COI?

If yes, is this non-financial personal interest in conflict (actual, possible or perceived) with the interest of the ERNs activities and results you are engaged with?

| Type of non-financial conflict | Belongs to you or a family member? | Monetary value (appr) | COI? (none / actual / perceived) |
|--------------------------------|------------------------------------|-----------------------|----------------------------------|
| | | | |
| | | | |
| | | | |

6. Interests not covered above

Use this section to report other interests that readers could perceive to have influenced, or that give the appearance of potentially influencing, your contribution to the ERNs activities or results.

For example: directorships and executive or non-executive board memberships of relevant entries – these could be companies, third sector bodies, professional organisations, learned societies etc. The ERNs LES WG advises that ERNs individuals provide here a list, keeping in mind that only some could be problematic, for example, someone sitting on the Board of a company or acting as a clinical advisor (paid or unpaid).

Are there other relationships or activities that readers could perceive to have influenced, or that give the appearance of potentially influencing, your contribution to the ERNs activities or results?

| Type of interests not covered above | Belongs to you or a family member? | Monetary value (appr) | COI? (none / actual / perceived) |
|-------------------------------------|------------------------------------|-----------------------|----------------------------------|
| | | | |
| | | | |
| | | | |

Consent to disclosure:

By completing and signing this form, you consent to the disclosure of any relevant conflicts to ERNs activities and results to the Board of your ERN and if necessary (in particular for ERNs Coordinators) to the ERNs Coordinators' Group or even ERN Board of Member States and DG SANTE. The COI forms will be collected and stored (possibly through a common workable PDF document or IT tool) at the level of each ERN in line with the Data Protection Regulation 2016/679 (GDPR)

DECLARATION

I hereby declare on my honour that the disclosed information is true and complete to the best of my knowledge.

Should there be any change to the above information, I will promptly notify the ERN Coordinator and update the *ERN disclosure form of personal interests* to describe the changes.

First and last names:

ERN:

Email address:

Date:

Signature:

PART B

This part would record the type of COI, and any information that the ERN (its Board) needs to record, including mitigation measure (to be developed). This part will not be open.

Full list of past and current members of the ERNs LES WG (ERN Working Group on Legal & Ethical issues & relations with Stakeholders) who contributed to this document:

| | |
|---|---|
| 1) On the side of European Reference Networks (ERNs): | |
| ERN GENTURIS | ERN for Genetic Tumour Risk Syndromes |
| Nicoline Hoogerbrugge | ERN Coordinator, chair of the WG until Sept. 2018, before merge with ERN BoMS industry WG |
| Lisette Giepmans | |
| Joan Brunet Vidal | |
| ERN RITA | ERN for Rare Immunodeficiency, Auto-inflammatory and Auto-Immune Diseases |
| Nico Wulffraat | ERN Coordinator, co-chair of the WG since Sept. 2019 |
| MetabERN | ERN on Rare Metabolic Disorders |
| Maurizio Scarpa | ERN Coordinator, co-chair of the WG, Oct. 2018-Sept. 2019 |
| Viktor Kozich | |
| Christina Lampe | |
| ERN-EYE | ERN for Rare Eye Diseases |
| Hélène Dollfus | ERN Coordinator |
| ERN ITHACA | ERN for Rare Congenital Malformations and Rare Intellectual Disability |
| Jill Clayton-Smith | First ERN Coordinator |
| VASCERN | ERN for Rare Multisystemic Vascular Diseases |
| Romain Alderweireldt | |
| Bruno Fonteyn | |
| 2) On the side of the ERN Board of Member States (ERN BoMS): | |
| Finland | |
| Helena Kääriäinen | co-chair of the merged WG, chair of the past BoMS WG on industry |
| France | |
| Anne-Sophie Lapointe | |
| Jérôme Weinbach | |
| Ireland | |
| Eileen Treacy | |
| Italy | |
| Lucia Guidotti | |
| Spain | |
| Laura Chamorro Gonzalez | |
| Inés Palanca | |
| Carmen Perez | |
| Laura Marin | |
| United Kingdom | |
| Monika Preuss | |
| 3) On the side of the European Commission, DG SANTE, Unit B3, ERNs team: | |
| Hélène Le Borgne | Supporting this WG from May 2018 to Dec. 2019 |
| Anna Mirandola | |

| | |
|----------|--|
| | Supporting this WG from Jan 2020 – until now (May 2020) |
| Adam Day | Blue-Book Trainee (Oct. 2019 – Feb. 2020) |