1. The community
ERION is the Ethics and Research Integrity Officer Network within EARMA. It is an open community to discuss the practical and implementation side of Research Ethics and Integrity. The community is for all those that need to ensure compliance, efficiency, functionality, fairness and robustness in the practices and processes in their organisation. Participants may have titles such as Ethics/Integrity Officer, Administrator and many others, but what is important is that they have a role at the practitioner level. In this respect, there is a clear distinction between ERION and other ethics groups and committees targeted at policy, high level, philosophical or strategic advice. Of course, more general ethical issues may naturally arise as part of the work within the community, but the main focus of the community is not development of theory or policy itself, but rather putting theory and policy into practice. In other words, this is a community of practitioners, rules and procedure experts, and its main purpose is to provide a forum for knowledge-sharing and collaboration in order to facilitate implementation of relevant policy etc. and establishment of best practices. The community will also take advantage of its role as an important stakeholder in this field, for instance by providing input to the EC Ethics and Research Integrity Sector of DG RTD (ERIS) regarding rules, procedures and practice, and participating in research projects and other initiatives of relevance to the community’s interests.

2. Launching process
The initiative for ERION was taken by EARMA, but the launching process has been designed to ensure that prospective members be included in the discussions concerning the guiding principles, scope and focus of the group. On the 9th of March 2018, a launch event was organized in Brussels by EARMA in collaboration with ERIS. The morning session included presentations by representatives of EARMA and ERIS, as well as prospective members of the community who shared their experiences as practitioners in the field. The afternoon session was devoted to discussions in small groups on different research ethics/integrity topics, including (but not limited to) research misconduct, screening/review processes, organisational structures, education/information, processing of personal data, compliance checks, human biological material, animals, Nagoya Protocol, and institutional culture. The groups were asked to list top priorities under the following headlines: What are the items you want to talk about with peers? What are the key issues you are facing in your job? What should this thematic group focus on? The breakout session was followed by presentations by representatives of each group, and notes were collected to be used in the further process of determining the objectives and focus of the community.
On the 8th of November 2018, a second meeting was organized in Brussels by EARMA. The structure of the meeting was similar to the launch event. The morning session was mainly devoted to presentations by representatives of EARMA, ERION and ERIS, and a specially
invited speaker, Anja Gilis, from the IMI project EQIPD (European Quality in Preclinical Data). The afternoon breakout sessions were structured in four topic clusters, based on the feedback collected at the previous meeting: Research Ethics, Research Integrity, Data management & GDPR, Animal research & human experiments, access/benefit sharing and Nagoya Protocol. The breakout session was followed by presentations by representatives of each group. The notes collected by the cluster leaders form the basis for the exposition of the topics in the following section.

3. Topics

In this section, the guiding principles, focus, scope and definitions that are supposed to lay the foundation for the work within ERION are presented. They are sorted under four different headings, corresponding to the topic clusters of the meeting in November 2018.

3.1 Research Ethics

3.1.1. Keeping ethics and compliance together apart

In relation to ethics research institutions have two main requirements: to guarantee a 100% watertight legal compliance and to improve the ethical state of mind of its individual researchers. Both are related to ethics but both have a different finality and therefore require a different working process and equal mindset. Research institutions have to decide whether they want to limit their actions to being a risk averse institution, or evolve on the continuum over a pragmatic implementation of research ethics towards becoming a golden plate institution. Taking a position will have implications for the structure and processes within the organization. How does a research institution make a strategic ‘decision’ on its position?

3.1.2. The (formal) ethics structure and the role of the administrative support staff

As mentioned in 3.1.1. legal compliance and ethical reflection need different bodies, structures and processes but both aspects must remain linked. To make researchers see the entire ethics picture, research institutions need an efficient and transparent flow. What are good practices to do this and who needs to be involved? How does this fit in the ‘regular’ project administration? Do we want/need to strive towards European standardization? With whom lies responsibility?

3.1.3. Creating an ethical state of mind

Ethics is a full principle when building tomorrow’s research environment. How do we make sure ethics isn’t perceived an administrative burden but part of researcher’s second nature? How do we avoid ethics becoming a tick boxing? How do we evolve towards better ethics instead of more ethics? How do we improve researcher’s critical reflexive attitude, especially when ethical approval isn’t a legal obligation e.g. animal testing. One particular aspect of importance is the communication on ethics and ethical procedures, within an organization as well as with stakeholders, e.g. funders, general public, ... . Also training is an important aspect.

3.1.4. Ethical shopping

Taking into account a more interdisciplinary and international research environment, is it possible to increase uniformity in ethical procedures and ethical decision making? This also to avoid ethical shopping or the moving of parts of research projects to less ‘ethical intensive
areas’. Is it an option to develop minimal European ethical standards for research aspects e.g. informed consent, ethics check list, etc.?

### 3.2 Research Integrity

#### 3.2.1 The (formal) RI structure and the role of the administrative support staff

This topic relates to setting an efficient infrastructure to deal with research integrity issues within (all levels of) an institution, situated on a continuum from informal and ad hoc services to a formal and visible procedure for investigating potential fraud cases as well as setting up all sorts of preventive initiatives. It involves adapting codes and regulations, making policy plans, setting an action plan, getting the right people involved and monitoring all results. It is the core element of installing legitimacy of an RI infrastructure.

#### 3.2.2 Creating a culture of RI

More than having a fitting structure, a research institution needs to bring the topic of research integrity alive. Creating and promoting a culture of RI is a difficult, long term issue that assumes a diversity of initiatives aimed at different topics within RI (authorship, plagiarism, data management, …) with focus on different staff categories (junior, senior, technical, …). Central in this approach is raising the awareness on the scope and importance of RI. Also mentoring and training are key issues. Taking into account the variety of research institutions (small vs big, old vs new, part of Europe, …), their singularity (identity, policy, mission statement, …) and the resources available (time, staff, finances, …), this will inflict format (introduction vs intensive, interactive vs hearing, online vs. face to face, university wide vs. faculty, general vs. topic based, mandatory vs. voluntary, …), content (codes at different levels, regulation, QRP included, difference between ethics and integrity, …) and pedagogy (language, quality concept, methodology, …) of training initiatives.

#### 3.2.3 Quality Assurance

General aim of any policy, including on RI is making a difference in practice. It is therefore important to remain critical towards all initiatives on their impact for researchers. We don’t want to make RI an administrative burden for researchers or generate a ‘tick boxing’ attitude. In order to do this we want to ‘simplify’ the story and make an efficient flow for researchers (RDM, ethics, RI, Nagoya, Dual Use, GDPR, …). The group will also focus on ways to evaluate initiatives and see if and what kind of impact there is in the daily lives of researchers.

#### 3.2.4 Transparency

Part of raising awareness on RI is making RI more visible. Opening up and communicating about policy, initiatives but also breaches and how research institutions respond to them, increase transparency and strengthen the legitimacy of the RI culture. The group will consider effective ways of communicating in- and externally (staff, partners, financers, employers, …), through different media (website, …), taking into account the sensitive character of the topic and the focus of the approach (prevention, adjusting to good practice).
3.2.5 Research Integrity concept

Research integrity is one of the guiding principles of a research environment. Despite the great diversity that typifies academic research in terms of research discipline and research methods, there are general principles and rules of conduct which all scientists must abide by. The theoretical framework of RI is laid down in the European Code of Conduct for Research Integrity (ALLEA, 2017) which is also the general framework for this group. Implementing theory into the practice of Responsible Conduct of Research (RCR) involves more than preying on intentional fraud, such as ‘the big three’ fabrication, falsification and plagiarism. We are convinced that most academic research is being conducted with care and dedication and in all loyalty and conscience. At the same time, we are aware of the highly evolving character of the research environment, both in terms of research content as research infrastructure. Therefore policy focus should be on the positive story of constantly trying to improve the quality of the research (environment). This approach on research integrity also assumes a focus on the so called ‘Questionable Research Practices’ (QRP such as the deliberate and selective omission of undesirable outcomes; image manipulation in order to mask negative results; the selective choice of sample or method to achieve a preconceived outcome, etc.).

Research integrity is a primary concern that has day-to-day relevance. It is central to all processes (integrated approach). Moreover, the concern for integrity and quality in academic practice is a permanent responsibility at all levels (professors, ATP staff, postdocs, doctoral students, students) and across all disciplines (inclusive approach). This group strives for a streamlined approach to research integrity, however with respect for differentiated approaches to further optimize ‘good research practices’, in accordance with the underlying universal values.

Research Integrity is a theoretical and general concept. By putting it into practice, researchers commit themselves to responsible conduct of research. However, daily practice challenges researchers on different subtopics in relation to RI. In order to foster a widespread culture of Research Integrity the group will look at ways to tackle challenges on authorship and publishing, anti- (self) plagiarism, dealing with data, … .

3.3 Data management and GDPR

3.3.1 Guidelines, procedures, structures

There is a need for guidelines, procedures and structures that can help us implement the GDPR, as some of the provisions are difficult to understand and sometimes vague and/or undefined. For instance, guidance is needed on pseudonymisation, research derogations, conditions for data transferring across countries and institutions, collection of data in third countries with lacking protection, open science vs. integrity, national data retention terms, national and institutional policies, genetic data (which can rarely be anonymized), obstacles to international collaboration (both present, e.g. with the U.S., and future, e.g. with the U.K. after Brexit), secondary use, geolocalisation, data from the internet (especially social media), etc.

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1 This concept is based on the Research Integrity policy plan of Ghent University, Belgium.
3.3.2 Organizational issues
Many functions in the organization may need to collaborate on data protections issues, e.g. DPO, Research–IT, ethics officer, archive, legal counsel, and not least the researchers. Who in the organization is responsible for what and what is the best model for integration and division of labour? How can these different competences be integrated in order to optimize efficiency and quality of services?

3.3.3 Information and education
How do we communicate rules and guidelines to researchers and other staff, and how do we incentivise them to follow them? For instance, what can we do to make them avoid non-compliant services, like survey platforms and cloud services with servers outside of the EU?

3.3.4 Legal vs Ethical aspects
Not all ethical issues that arise in this area are covered by law. How do we broaden the perspective of researchers, staff and leadership to include the whole spectrum? How do we prevent a “compliance mentality” from becoming dominant?

3.3.5 Platform for knowledge/experience sharing
There is a need for a platform within the community for sharing ideas, knowledge and experiences on these issues. Such a platform could also be used to collect questions to be forwarded to European and national data protection authorities.

3.4 Animal research & human experiments, access/benefit sharing and Nagoya Protocol
This topic was seen as of importance during and after the first meeting but received much smaller interest during the second meeting and most participants chose other topics. This topic remains on the ERION radar and can be picked up if there is enough interest for this in the online exchanges of the community and during event.

4. ERION online community platform
An online community has been set up for ERION within the SINAPSE platform: https://europa.eu/sinapse/directaccess/earma_erion/

5. Organisation
ERION can be joined by applying here: http://earma.wildapricot.org/event-3246242

The community is organised in 2 groups of which:
1. Members of the ERION (online) community: open to all with the right profile
2. Core group members: a group of 6-12 ERION members led by the ERION chair duo (2 leaders of the community)

Members of category 2 and 3 must be EARMA members.
1. Are expected to be active participants
2. The core group will:
ERION

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Nik Claesen

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Level of confidentiality Public

a. help to organize the
erion events by moderating, finding speakers, assembling the agenda and promoting
the event
b. Help guide and moderate the online discussion and share relevant information on the
community platform

3. The ERION chairs will have the main responsibility and final say on the event agendas, take
the content lead and moderate the events (or engage others to moderate). The chairs will be
the link between the EARMA board and the EARMA office. The chairs will be the main link
between ERION and the stakeholder in consultation with the EARMA MD. The EARMA MD will
advise the chairs on when board approval is needed.

No ERION member of any group may represent or commit EARMA without the proper written consent
by the EARMA board or the EARMA MD depending on the issue. The EARMA board may at any time
choose to remove people from any group.

ERION members will be registered on the online platform and will need to agree for their contact
details to be shared within the closed group which is open to newcomers.

The ERION chairs will be appointed initially by the EARMA Managing Director but this will be changed
to an election process by the ERION core group to be confirmed by the EARMA board.

Being an ERION members doesn’t grant the right to attend ERION events. Events will have
their own registration.