Partnership for the Assessment of Risks from Chemicals

Deliverable D10.2

Ethic Assessment report for Year 1

OEI - Requirement No. 2

WP 10

EUROPEAN PARTNERSHIP

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Technical References

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Responsible author	Basile Cazalis de Fondouce, ANSES, basile.cazalisdefondouce@anses.fr
Co-authors	PARC Management Board
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[1] PU = Public
PP = Restricted to other programme participants (including the Commission Services)
RE = Restricted to a group specified by the consortium (including the Commission Services)
CO = Confidential, only for members of the consortium (including the Commission Services)

Document history

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1. Authors and Acknowledgments

Basile Cazalis de Fondouce (ANSES) ;
PARC Coordination Team ;
PARC Management Board.

2. Background

This Ethics Assessment report (D10.2) provides an update to the PARC Ethic Self-Assessment Report submitted alongside the proposal. The D10.2 focuses on the activities that will be implemented during the **first year** of PARC.

3. Results

0 - Foreword:

PARC aims to consolidate and strengthen the EU's R&I capacity for chemical Risk Assessment (RA) to protect human health and the environment. Consequently, Research activities of PARC in RA, including in the first year, require the collection and processing of data (ex: personal, biological and health related), sampling (ex: human and animal cells/tissues, environmental samples) and analysis performed in line with national and EU legislations.
The PARC partners are experienced and aware of the ethical responsibilities that their activities entail. PARC will ensure that the design of the activities and their implementation

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follow the highest ethical standards as well as to limit as much as possible any ethical risks from occurring.
Indeed, PARC will operate with a legal and ethical model that will make data and samples available through lawful means, such as informed consent. Other lawful means for the collection, storing and use of data and the collection, storing, transfer and use of biological samples for research purposes will also be included in PARC.

1 – Human embryonic Stem Cells and Human Embryos

PARC activities are not planning and do not expect to involve Human Embryonic Stem Cells.
Consequently, PARC activities of the first Annual Work Plan do not involve the use of HESC nor human embryos.

2 – Humans

PARC activities during the first year will necessarily involve humans from participating organisations for the realisation of the activities (ex: scientists) and the management of the partnership. PARC activities during the first year will involve human participants from outside of the partnership in WP4.

Careful processes will be followed to ensure that the Partnership activities do not result in any negative outcomes for the participants.
In line with ethics guidelines, the participation of humans will be voluntary and the activities will obtain and document participants' informed consent prior to their involvement, as well as the ethic approval (where necessary).
Already recruited individuals in cohorts will be approached to voluntarily provide biological matrices (blood or urine). The highest ethical standards will be applied, including the procurement of ethics approvals and informed consents. For research involving persons unable to give consent and children, informed consent will be obtained from the legally authorised representatives.

3 – Human cells / tissues

PARC activities during the first year are expected to involve the use of human cells/tissues in WP4, possibly WP5 and WP6.

The activities of the first year will notably follow the ethics provisions set out in the Grant Agreement as well at the applicable international, EU and national law (in particular, EU

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Directive 2004/23 on standards for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells).
The activities concerned will keep track of the origin of the cells and tissues used during the first year, obtain the necessary accreditation/designation/authorisation/licensing for using, producing or collecting the cells or tissues and ensure that donors have given their free and fully informed consent.
Human inducible pluripotent stem cells used by PARC will be EU approved and from commercial sources only. Highest ethical standards will be applied, ethics approvals will be obtained and all legal requirements followed. Permissions to use these cells from respective authorities will be available at partners involved in this exercise.

4 - Personal data

PARC activities during the first year will include the collection and use of personal data for the realisation of the activities of the partnership.
WP4 and WP6 activities will notably involve the processing of special categories of personal data and involve further processing of existing personal data. The only purpose of access and use of data on human subjects will be to meet the objectives of PARC.
PARC WPs may also collect personal information from outside parties. For instance, WP9 is planning to collect information on laboratories that may include contacts information of individuals (ex: email addresses of persons in case the laboratory does not have a company email such as lab@company.com). In addition, personal data required for the proper management of the partnership, as well as for communication activities will be collected, used and stored in accordance with ethical guidelines and relevant legislations (ex: GDPR).

The partnership acknowledge the obligations of the Grant Agreement, as well as the relevant national and European legislations (ex: GDPR) and is committed to adhere to them.
During the first year, PARC will further details procedures and define how these concerns are addressed in the Ethics and Data Protection Policy (D1.5), the Communication and Dissemination Strategy (D3.2) and Data Management Plan (D7.1)
PARC is committed ensure that personal data on human subjects are processed (collected, handled, transferred and analysed) in a secure setting.
Personal data will be used for defined purposes and not further processed for incompatible purposes, and will not be kept for a longer period than is necessary. The data produced will nevertheless be a sustainable resource for broader policy and research access beyond PARC (under conditions respecting GDPR). The partnership partners will furthermore ensure that processing of the data is compliant with the GDPR.

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Samples and data previously collected in other studies such as exposure, age, gender, genetic, molecular, biometric, health, lifestyle and geospatial data may be re-used and shared in PARC in alignment with ethical standards and legislations.

5 - Animals

The use of animals in PARC activities during the first year will be limited to WP5 within in vivo studies following GLP and OECD guidelines (ex: Repeated Dose 90-Day Oral Toxicity Study in Rodents – OECD G 408).

Through its activities, the Partnership will strive to contribute to and support the uptake of non-animal testing methods in RA in regulatory processes. Indeed, PARC aims to promote the regulatory acceptance of non-animal toxicological methods to decrease animal uses for RA (3Rs rule). However, to confirm the appropriateness of some in vitro assays, animal studies (involving vertebrates) may be needed. In the latter case, the highest ethical standards as well as relevant international, EU and national legislation will be followed such as the EU Directive 2010/63 on the use of animals for scientific purposes. Processes in place will be adhered to limit animal suffering.

6 – Non-EU Countries

Non-EU countries will be involved in the activities of PARC from the first year of PARC (ex: Iceland, Norway, Switzerland, Israel, UK) across several WPs.
Activities carried out in non-EU member states will be closely monitored to ensure that they remain aligned with EU's legislations and do not leave opportunities of ethical mismatch resulting from lesser standards in the non-EU member states where the activity is implemented. PARC will notably ensure that the first year activities performed in non EU-countries will remain in line with at least one EU member state's legislations.

Transfer of material and data outside the EU is possible with participating Horizon Europe associated countries and Switzerland.

Collaboration and networking may not be limited by the EU boundaries over the duration of the PARC. Potential involvement in expert networks is also valid for countries in the wider European region and OECD countries. For instance, the development of the International Board (IB) (with potentially non-EU countries representatives) (Milestone #5) will be achieved during the first year.

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7 – Environment, Health and Safety

WP5 activities during the first year will involve the use of substances or processes that may cause harm to humans or the environment. Nevertheless, PARC's first year activities are not expected to occasion damage to the environment.

On the contrary, the Partnership will go beyond the 'Do No Significant Harm' principle embedded in the activities as it will actively strive to improve and support environmental health assessment and control.
Scientists working with hazardous materials during the first year will follow due safety procedures and existing legislation to prevent and / or minimise risks for the environment and for human health (including their own health).

8 – Artificial Intelligence

WP8 will develop and/or use artificial intelligence during the first year of PARC.

In line with the ethics guidance, The AI tools developed during PARC, including the first year will follow key prerequisites for ethically sound AI systems (Human agency and oversight, Privacy and data governance, Transparency, Fairness, diversity and non-discrimination, Societal and environmental well-being and Accountability).

9 – Other ethics issues

No specific ethics issues not covered above have been identified for the first year of PARC.

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