



## **Models for ethics assessment at research funding organisations**

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### **Annex 8**

**A reasoned proposal for a set of shared ethical values, principles and approaches for ethics assessment in the European context**

#### ***Deliverable 4.1***

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**CONTENTS**

1	Introduction .....	3
2	Ethics Assessment by research funding organisations: goals and criteria .....	4
3	Organisational structures and resources for ethics assessment .....	7
4	Procedures for ethics assessment .....	9
5	Recommendations – summary .....	11

## 1 INTRODUCTION

The aim of this report is to formulate recommendations for ethics assessment in research funding organisations based on the research performed under previous work packages of the SATORI project.

The report focuses on ethics assessment by research funding organisations. Ethics assessment, as defined in the SATORI project, is any kind of assessment, evaluation, review, appraisal or valuation of research or innovation that makes use of ethical principles and criteria.<sup>1</sup> In the context of research funding organisations, ethics assessment relates to the screening and review of project proposals.

The report does not in particular deal with ethical guidance. Ethical guidance, as defined in the SATORI project,<sup>2</sup> does not concern an evaluation of practices and products of research and innovation that have already occurred, but rather presents rules, codes, and recommendations to which future scientific practices, innovation practices, and developments in science and technology are expected or recommended to adhere.

The report first deals with goals and criteria of ethics assessment in research funding organisations. This part takes into account the work of WP1 of the SATORI project and reviews reasons that research funding organisations have for engaging in ethics assessment. It then offers recommendations that ethics assessment should meet if it is to serve the interests and goals of the respective organisation and of society.

As a second step, the report deals with organisational structures and resources for ethics assessment in research funding organisations. It discusses how research funding organisations can effectively and efficiently mobilize their resources for ethics assessment and how ethics assessment can best be organised within a research funding organisation. The section also discusses whether ethics assessment can come into conflict with other goals and tasks of the research funding organisation and what kind of expertise is needed for ethics assessment in research funding organisations.

As a third step, the report deals with procedures for ethics assessment. It recommends procedures for ethics assessment in research funding organisations on the basis of their resources and goals. This section also highlights the impact of research funding organisations on ethical guidance, although these organisations do not as such engage in ethical guidance. Finally, this section deals with issues related to transparency which can be dealt with through dissemination policies.

The report concludes with a summary of recommendations divided into recommendations on criteria for ethics assessment, recommendations on the organisational structure of ethics assessment, and recommendations on procedures of ethics assessment in research funding organisations.

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<sup>1</sup> See e.g., Annex 3.h-Industry of Deliverable 1.1. <http://satoriproject.eu/media/3.h-Industry.pdf>

<sup>2</sup> See e.g., Annex 3.f-Government and Government-Funded Organisations of Deliverable 1.1. <http://satoriproject.eu/media/3.f-Govt-and-govt-funded-orgs.pdf>

## 2 ETHICS ASSESSMENT BY RESEARCH FUNDING ORGANISATIONS: GOALS AND CRITERIA

The aims of ethics assessment in research funding organisations relate to the protection of research subjects (which include humans), to enhancing ethical conduct of research staff, to justifying the research funded by the organisation vis-à-vis the public, and to complying with national legislation.

Ethics assessment therefore contributes to research being “perfectly clean” ethically-speaking, which contributes to achieving excellence in research. The promotion of excellence in research is beneficial to society in so far as it will help to meet the grand societal challenges<sup>3</sup> of the century. In addition, it is beneficial to research funding organisations as it helps them to prove that the funds (which are mostly of public origin) have been spent in an orderly manner, and it helps researchers to produce better results through deliberations in the related ethics procedures.<sup>4</sup>

Criteria which are used by funding organisations relate to ethical principles provided by law in the field of human subject research, animal research, and data protection .Some research funding organisations use criteria for ethics assessment going beyond those criteria provided for by law in order to meet the challenge of ethics assessment. The challenge of ethics assessment relates in particular to new technologies. Ethics assessment in the field of new technologies will always remain a moving target, as legislation will always lag behind scientific developments and leave unregulated areas where ethics assessment is necessary.

The findings of WP1 show that the following ethical principles and ethical issues are considered by research funding organisations:<sup>5</sup>

<b>Ethical principles</b>	<b>Ethical issues</b>
Human embryos / foetuses	<ul style="list-style-type: none"> <li>– Origin of cells</li> <li>– Informed consent for the use of donated embryos for the derivation of cell lines</li> <li>– Protection of personal data and privacy of donors</li> <li>– Prohibition of financial inducement</li> </ul>
Humans	<ul style="list-style-type: none"> <li>– Free and informed consent</li> <li>– Risks/benefits evaluation, particular in case of invasive techniques</li> <li>– Inclusion of vulnerable populations</li> </ul>
Human cells / tissues	<ul style="list-style-type: none"> <li>– Source of human biological samples and personal data and respective informed consent</li> </ul>

<sup>3</sup> See also: European Commission (n.d.). “Horizon 2020: The EU Framework Programme for Research and Innovation - Societal Challenges”. <https://ec.europa.eu/programmes/horizon2020/en/h2020-section/societal-challenges>

<sup>4</sup> See Annex 3.c-Research Funding Organisations of Deliverable 1.1. <http://satoriproject.eu/media/3.c-Research-funding-organisations.pdf>

<sup>5</sup> Ibid.

Protection of personal data	<ul style="list-style-type: none"> <li>- Privacy/confidentiality and the procedures that will be implemented for data collection, storage, protection, retention, and destruction</li> <li>- Right to be forgotten</li> <li>- Security by design</li> </ul>
Animals	<ul style="list-style-type: none"> <li>- Issues on reduction, replacement and refinement (“three Rs principle”)</li> </ul>
Third countries	<ul style="list-style-type: none"> <li>- Potential exploitation of research participants and/or local resources</li> <li>- Non-compliance with Horizon 2020 ethical rules</li> <li>- Health and safety risks for researchers and staff</li> </ul>
Environmental protection and safety	<ul style="list-style-type: none"> <li>- Harm to the environment can occur as part of the experimental design of the research and as the result of undesirable side-effects of the technologies</li> </ul>
Misuse	<ul style="list-style-type: none"> <li>- Potential misuse of materials, technologies and information (research that involves information on, or the use of, biological, chemical, radiological, explosive and nuclear security sensitive materials and the means of their delivery; research and the development of technologies that could have severe negative impacts on human rights standards if misapplied)</li> <li>- Research that has the potential for terrorist or criminal abuse</li> </ul>
Dual use	<ul style="list-style-type: none"> <li>- Impact of research beyond civilian application</li> <li>- Impact on current standards in military ethics (global ban on weapons of mass destruction, issues of proportionality, discrimination of combatants, accountability in drone and robots development, incendiary or laser weapons)</li> </ul>

**Table 1: Ethics criteria by field of research**

In addition, research funding organisations use principles relating to the ethical conduct of scientists, such as conflict of interest, plagiarism, self-plagiarism and misuse of resources. These principles are overarching and apply to all research fields.<sup>6</sup> They can be summarized as follows:

<b>Making of research</b>	<b>Principles</b>
Research Integrity	<ul style="list-style-type: none"> <li>- Quality of research according to scientific standards</li> <li>- Quality of the research team</li> <li>- Scientific impact</li> </ul>
Scientific misconduct	<ul style="list-style-type: none"> <li>- Plagiarism</li> <li>- Conflict of interest</li> <li>- Misuse of resources</li> </ul>
Additional criteria in relation to individuals <sup>7</sup>	<ul style="list-style-type: none"> <li>- Autonomy / integrity</li> <li>- Protection of human beings</li> <li>- Informed consent</li> <li>- Beneficence</li> <li>- Justice</li> </ul>

<sup>6</sup> Ibid.

<sup>7</sup> These criteria may also be covered by procedures carried out in ethics review by the competent national body, but are reported by one organisation as a precondition for research integrity.

	<ul style="list-style-type: none"> <li>- Balance of benefits and harms in doing research</li> </ul>
Additional policy criteria	<ul style="list-style-type: none"> <li>- Usefulness of science</li> <li>- Open-access strategies</li> <li>- Gender issues</li> <li>- Transparent communication on topics which are researched and the Respective consortia</li> <li>- Ensuring benefit sharing of research capacity and results</li> <li>- Promotion of the social good</li> </ul>

**Table 2: Additional criteria related to the “conduct of research”**

On the basis of a review of the practices of research funding organisations as described in SATORI WP1, the following criteria can be recommended for ethics assessment in research funding organisations:

- Research funding organisations should verify whether the research proposal meets the national legislation and ethics requirements of the country in which the research will be performed.
- Research funding organisations should verify whether the research proposal indicates the timeframe in which possible ethics review of the research proposed as provided by law will be conducted.
- Research funding organisations should evaluate ethical issues going beyond the minimum standards provided by law. Evaluation should include the following aspects with an eye on addressing possible vulnerabilities: Human embryos/foetuses, human subjects, human cells/tissues, protection of personal data, animals, third research, environmental protection and safety, misuse of materials, technology and information, and dual use. In addition, evaluation should be based on ethical principles that are specific to particular kinds of research such as research involving human subjects, research involving animals, and research involving possible environmental risks (as identified in SATORI D4.1).
- Research funding organisations should evaluate research conduct in a proactive manner. Evaluation should include the following aspects: research integrity, scientific misconduct, policy criteria such as usefulness of science, open-access strategies, gender issues, transparent communication, benefit sharing, and promotion of the social good. Funding organisations can test for research integrity and scientific misconduct by examining the project proposal; experts in the field who are on the funding organisation’s ethics panel will know whether project ideas are new in the field or whether the ideas rely heavily on another person’s work. In addition, these experts can judge from the methodology of the proposed project whether there is a probability for misconduct. In this context, it is important that both the objectives and the methodology of the proposed research are well described. Finally, funding organizations can actively promote the aforementioned policy criteria by checking whether they are adhered to in the project proposal.
- Research funding organisations should verify whether the research proposal describes possible implications of results in a satisfactory manner, relating in particular to individuals and the society as a whole.

### 3 ORGANISATIONAL STRUCTURES AND RESOURCES FOR ETHICS ASSESSMENT

Differences among research funding organisations in terms of ethics assessment structure mainly relate to the institutional setup. The majority of the funding organisations rely on ethics assessment provided by the competent national body<sup>8</sup> (external ethics assessment). During the selection process, selection committee of the funding organisation verifies whether the relevant ethics approvals from the competent national body or other certifications provided for by law are annexed to the project proposal.<sup>9</sup>

Some organisations provide for ethics assessment by independent experts assisting the services of the funding organisation with the task of ethics assessment (in-house ethics assessment). In the case of the EU Horizon 2020 programme, for instance, ethics review panels consist of two to five experts. During the pre-screening and screening phase, the panels are composed of two independent ethics experts, one of which serving as rapporteur. In the ethics assessment phase, the panels are composed of five independent ethics experts, again with one serving as rapporteur. The experts and the rapporteurs are appointed by the European Commission.<sup>10</sup>

Other organisations doing in-house ethics assessment have a very similar process, although this process is not always divided as clearly into different phases. Many organisations use a mixed approach in that they rely on both an external ethics assessment procedure and an in-house procedure.<sup>11</sup>

As regards the institutional setup of ethics panels in relation to external, in-house, and mixed models of ethics assessment, these panels rely on independent experts coming from different fields of research. The independence, multi-disciplinarity, and pluralism of competent national bodies in ethics assessment in the external-model is usually enshrined in national law. As regards ethics clearance by internal ethics bodies, these usually also follow the respect for independence, multi-disciplinarity, and pluralism.<sup>12</sup>

In SATORI WP1, funding organisations reported on the one hand the need for more certainty; in regard to ethics evaluation, on the other hand, they also reported complaints with regard to becoming overly bureaucratic in case norms have been established. As ethics in regard to new technologies will always remain a moving target, it is to be expected that legislation will always lag behind scientific developments. In WP1, organisations reported a case by case approach for ethical issues which arise during project selection and a structured exchange on these issues between different research funding organisations.<sup>13</sup>

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<sup>8</sup> In many European countries, this would be the national ethics committee, which has a legal mandate to ethically evaluate human subjects research or animal research.

<sup>9</sup> Annex 3.c-Research Funding Organisations of Deliverable 1.1. <http://satoriproject.eu/media/3.c-Research-funding-organisations.pdf>

<sup>10</sup> Ibid.

<sup>11</sup> Ibid.

<sup>12</sup> Ibid.

<sup>13</sup> Ibid.

Based on the aforementioned recommendation that research funding organisations follow a set of criteria for ethics assessment going beyond criteria provided by law, research funding organisations will need to establish in-house ethics assessment. As opposed to in-house ethics assessment, external ethics assessment by the competent national body is generally limited to criteria that are provided by law. In-house ethics assessment can best be provided through organising independent, multidisciplinary and pluralist ethics panels for ethical review of projects.<sup>14</sup>

In order to guarantee efficiency and efficacy of ethics review, practice has shown that only projects which have been identified as ethically problematic in a pre-screening phase (see section below) usually undergo full ethics review. As regards the selection procedure, project proposals usually only undergo ethics review after they have proven scientific eligibility under the given research programme.<sup>15</sup>

The pre-screening work and the organisation of ethics panels can best be organised by regular staff involved in scientific evaluation after having received training in the field of ethics in order to keep costs low and to install ethics as an over-arching principle within the regular selection process of research funding organisations. In integrating comprehensive ethics review in daily practices of the research funding organisations, it is not expected that conflicts will arise in relation to other goals and tasks of the organisation.

As regards the expertise needed for in-house ethics assessment, there are two components which have to be considered. On the one hand, expertise has to be build up within the organisation among the staff members involved in project selection to organise the pre-screening phase. On the other hand the ethics panels have to be appointed guaranteeing the appropriate expertise. In order to guarantee the appropriate expertise, experts in the field of the particular research project which is proposed, have to sit on the panel. In addition, panels usually include expertise that is not directly connected to the research field of the proposed project in order to include additional policy criteria in the review, such as usefulness of science, open-access strategies, gender issues, transparent communication, benefit sharing, and promotion of the social good (see above). For this, panels usually include experts in the fields of philosophy, law, sociology, and also in ethics, if ethics exists as a separate discipline in the country's national higher education system.

Based on these considerations, the following can be recommended regarding structures and resources for ethics assessment in research funding organisations:

- Research funding organisations should establish procedures for in-house ethics assessment going beyond ethics assessment provided by law.
- Research funding organisations should include ethics assessment in regular project selection procedures in order to install ethics assessment as an overarching principle within their policies.

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<sup>14</sup> See Universal Declaration on Bioethics and Human Rights, Article 19: [http://portal.unesco.org/en/ev.php-URL\\_ID=31058&URL\\_DO=DO\\_TOPIC&URL\\_SECTION=201.html](http://portal.unesco.org/en/ev.php-URL_ID=31058&URL_DO=DO_TOPIC&URL_SECTION=201.html)

<sup>15</sup> Annex 3.c-Research Funding Organisations of Deliverable 1.1. <http://satoriproject.eu/media/3.c-Research-funding-organisations.pdf>

- Research funding organisations should provide regular training activities in the field of ethics for their staff members who are engaged in project selection procedures.
- Research funding organisations should organise ethics panels for full ethics review for all projects that have been identified as ethically problematic in a pre-screening phase by staff members involved in project selection of the respective research funding organisation who have received prior training in the field of ethics.
- Ethics panels should be independent, multidisciplinary and pluralist. They should include expertise in the field of research of the project that is proposed, and should also include expertise in the field of philosophy, law, sociology, and ethics (if ethics exists as a separate discipline in the national higher education system).
- Research funding organisations should organise a permanent structured exchange with their national counterparts in order to discuss ethics in relation to new technologies.

#### 4 PROCEDURES FOR ETHICS ASSESSMENT

Procedures for ethics assessment in research funding organisations can be divided into the following three categories: before the start of a particular research project, during the implementation of the research project, and after the implementation of the research project.

The research under WP1 showed that ethics assessment in the phase before the start of the research projects is more developed than ethics assessment in the phases during or after project implementation. Most organisations that do not provide in-house ethics assessment have developed a light non-standardised procedure (mixed model) to go beyond ethics assessment provided for by law during this initial phase. Ethics assessment in this initial phase mainly looks at ethical issues related to research-specific questions, including their societal impact.<sup>16</sup>

The phase during project implementation is characterised by ethics assessment with regard to “the conduct of research” and mostly relates to questions of research integrity or scientific misconduct.

The phase after the implementation of the project is the weakest and has been reported by only one organisation in the SATORI WP1 research. It addresses compliance with regard to issues which have come up during previous phases of ethics assessment.

Procedures before the start of a research project are common and therefore of particular interest. Funding organisations doing in-house ethics assessment usually report three different phases of assessment, which are the following:<sup>17</sup>

- During proposal submission the applicant is asked to fill in an ethics self-assessment of their research proposal and an ethical issues table.

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<sup>16</sup> Ibid.

<sup>17</sup> Ibid.

- Ethics pre-screening is done on any application with the help of independent experts. In case no ethical issues have been declared or ethical issues have been adequately addressed, this is confirmed through “ethics clearance”. In case additional ethical issues are identified or ethical issues have been inadequately addressed in the pre-screening phase, the project will undergo ethics review by an ethics panel.
- The ethics review with the help of independent experts confirms and checks all ethical issues which have not been adequately addressed. The independent experts can provide “conditional ethics clearance”, recommend an “ethics assessment”, or “refuse ethics clearance”.

During project implementation, research funding organisations report that they practice monitoring in which they also address issues related to “the conduct of research”, such as research integrity, and scientific misconduct.

Practice has shown that there is little need for procedures of ethics assessment related to the phase after project implementation. Thus, no recommendations will be formulated for this phase.<sup>18</sup>

Research funding organisations usually do not engage in ethical guidance on the national level as such. Ethical guidance, as understood in this report, does not concern an evaluation of practices and products of research and innovation that have already occurred, but rather as presenting rules, codes, and recommendations to which future scientific practices, innovation practices, and developments in science and technology are expected or recommended to adhere. Research funding organisations do, however, publish the ethical principles and issues they use in their selection procedure. Through this, they contribute to ethics guidance in that the research community will need to deal with the standards set by research funding organisations and will have to comply with them.

In addition, research funding organisations reported that they engage in a permanent structured exchange with their national counterparts in order to discuss ethics with regard to new technologies, which also leads to a certain ethical guidance as a common view on ethical challenges is built through this practice.<sup>19</sup>

Furthermore, research funding organisations report that a particular focus of their work lies in transparent communication towards the research community and the public via websites. The procedures (related forms) and standards that are applied are usually published on the official website of the respective research funding organisation.<sup>20</sup>

Based on the above considerations, the following can be recommended regarding procedures for ethics assessment in research funding organisations:

- Research funding organisations should establish transparent procedures for ethics review.

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<sup>18</sup> Ibid.

<sup>19</sup> Ibid.

<sup>20</sup> Ibid.

- Procedures should consist of different phases. Before the start of the project, they should include a self-assessment phase, pre-screening phase, and a full ethics review, if applicable.
- During the implementation of the project, monitoring should also include aspects relating to research integrity, and scientific misconduct. Monitoring of ethics issues during project implementation, if necessary, should be organised through the inclusion of an ethics work package which involves monitoring/evaluation of ethics issues in the project at hand.
- Research funding organisations should make available guides on their ethics assessment procedure, including forms for the self-assessment phase clarifying which ethical principles and issues will be regarded as being of particular importance.
- Research funding organisations should hold a permanent structured exchange with their national counterparts in order to discuss ethics in regard to new technologies.
- Research funding organisations should write regular reports on their deliberations regarding the permanent structured exchange with their national counterparts.
- Research funding organisations should publish their procedures, related guides, and the regular reports of their exchanges with their national counterparts on their official website.

## 5 RECOMMENDATIONS – SUMMARY

The summary of recommendations is structured in the same manner as the report and is divided into recommendations on criteria for ethics assessment, recommendations on the organisational structure of ethics assessment, and recommendations on procedures of ethics assessment in research funding organisations.

### **Recommendations on criteria for ethics assessment:**

- Research funding organisations should verify whether the research proposal meets the national legislation and ethics requirements of the country in which the research will be performed.
- Research funding organisations should verify whether the research proposals indicates the timeframe in which possible ethics review of the research proposed as provided by law will be conducted.
- Research funding organisations should evaluate ethical issues going beyond the minimum standards provided by law. Evaluation should include the following aspects with an eye on addressing possible vulnerabilities: human embryos/foetuses, human subjects, human cells/tissues, protection of personal data, animals, third country research, environmental protection and safety, misuse of materials, technology and information, and dual use. In addition, evaluation should be based on ethical principles that are specific to particular kinds of research such as research involving human subjects, research involving animals, and research involving possible environmental risks.

- Research funding organisations should evaluate research conduct in a proactive manner. Evaluation should include the following aspects: research integrity, scientific misconduct, policy criteria such as usefulness of science, open-access strategies, gender issues, transparent communication, benefit sharing, and promotion of the social good.
- Research funding organisations should verify whether the research proposal describes possible implications of results in a satisfactory manner relating in particular to individuals and the society as a whole.

**Recommendations on organisational structure of ethics assessment:**

- Research funding organisations should establish procedures for in-house ethics assessment going beyond ethics assessment provided by law.
- Research funding organisations should include ethics assessment in regular project selection procedures in order to install ethics assessment as an overarching principle within their policies.
- Research funding organisations should provide regular training activities in the field of ethics for staff members engaged in project selection procedures.
- Research funding organisations should organise ethics panels for full ethics review for all projects that have been identified as ethically problematic in a pre-screening phase by staff members involved in project selection of the respective research funding organisation who have received prior training in the field of ethics.
- Ethics panels should be independent, multidisciplinary and pluralist. They should include expertise in the field of research of the project that is proposed, and should also include expertise in the field of philosophy, law, sociology, and ethics (if ethics exists as a separate discipline in the national higher education system).
- Research funding organisations should organise a permanent structured exchange with their national counterparts in order to discuss ethics in relation to new technologies.

**Recommendations on procedures for ethics assessment:**

- Research funding organisations should establish transparent procedures for ethics review.
- Procedures should consist of different phases. Before the start of the project they should include a self-assessment phase, pre-screening phase, and a full ethics review, if applicable.
- During the implementation of the project, monitoring should also include aspects relating to research integrity, and scientific misconduct. Monitoring of ethics issues during project implementation, if necessary, should be organised through the inclusion of an ethics work package which involves monitoring/evaluation of ethics issues in the project at hand.

- Research funding organisations should make available guides on their ethics assessment procedure, including forms for the self-assessment phase clarifying which ethical principles and issues will be regarded as being of particular importance.
- Research funding organisations should hold a permanent structured exchange with their national counterparts in order to discuss ethics in regard to new technologies.
- Research funding organisations should write regular reports on their deliberations regarding the permanent structured exchange with their national counterparts.
- Research funding organisations should publish their procedures, related guides, and the regular reports of their exchanges with their national counterparts on their official website.