



Relevance and Challenges of Ethics Committees

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Abstract. This article explores the role of ethics committees in ensuring ethical research and innovation, which is essential for maintaining trust in science and innovation. The paper argues that the ethics infrastructure must function at the levels of research and innovation institutions, as well as regional and national levels, and should follow agreed-upon rules and requirements. The changing role of ethics committees is discussed, emphasizing their involvement in investigating potential research misconduct and coordinating the activities of all ethics committees within an institution. The article concludes that for a research and innovation institution, it is of crucial importance to consider the entire ethics infrastructure, including the functions of different ethics committees and ways of implementation through transparency, involvement, policies, procedures, and communication to safeguard that both researchers and the public have trust in ethics infrastructure and ethics committees.

Keywords: ethics committees · research ethics · research integrity · responsible research and innovation · governance · oversight · trust in science

1 Introduction

Science is a social arrangement in which different stakeholders (e.g. research-performing organizations, research funding organizations, publishers, and ethics committees) should fulfill their distinctive roles.

Since science is a collective enterprise, it is necessary to build mutual trust. Trust should be built between researchers and innovators, and with society. Researchers and innovators must be able to trust the results of previously conducted research. Society must be able to trust researchers and innovators by giving them the means to carry out research and contribute to it, e.g. participating as research subjects or participating in co-creation. Researchers and innovators can be trusted if they are trustworthy, meaning that they behave honestly, are objective, respect the autonomy and privacy of research subjects, treat animals and the environment with care, and are responsible. To ensure trust in science, it is necessary not only that researchers and innovators fulfill their responsibilities, but also that they have the willingness to do so. Researchers and innovators and research and innovation organizations (both research performing and funding organizations) bear the responsibility for fostering trust in science and ethical research.

Research and innovation organizations should create and sustain environments that encourage ethical research and innovation through education and clear policies e.g. the

Singapore Statement [1]. In The Bonn PRINTEGER Statement [2] the role of the leaders of institutions is specified and institutional responsibilities are described, e.g. increasing transparency in misconduct cases, having effective and safe whistle-blowing channels, establishing a research integrity committee, and appointing an ombudsperson. Moreover, in its report the European Science Foundation has stressed the need to set structures at the national level as well. They have outlined that successful approaches to promoting good research practices include establishing an adequate institutional framework, which includes research ethics committees and research integrity offices, both at the institutional and national levels [3]. Additionally, it should be pointed out that the governance system of ethical research and innovation should fit each country, taking into account its size, research infrastructure, and available resources [3]. Furthermore, if unintended consequences emerge, the system should be revised or policies should be changed accordingly [4]. Also, it should be analyzed whether the members of the research and innovation institutions are motivated to act according to operating principles.

According to Sarah R. Davies, issues related to research integrity can also be regarded more broadly, as a form of soft governance implemented through codes, norms and ELSI (ethical, legal, and social implications) activities [5]. Therefore, ethics committees should be seen and should function as a part of the governance system of ethical research and innovation. Such a system includes stakeholders (e.g. researchers, administration, case investigators), and procedures and requires an ethics-promoting climate [6]; it also consists of oversight, instruction, and policies [7].

One example of an ethical system of governance for research and innovation in organizations has been developed within the Horizon 2020 project ETHNA. Having a clear implementation and governance system that fits the research-performing or funding organizations including responsible research and innovation (RRI) office(r), ethics codes, policies, and tools shows commitment to ethical research and to carrying out research and innovation activities in a responsible way.

2 Ethical Research: From Fragments to the Whole Research Process

It is expected that research and innovation are done ethically and with high quality. Ethical norms should be followed through all stages of research, from planning and applying for research grants to the publication of research results.

While research ethics has been focusing on the protection of research subjects, research integrity has emerged as a response to misconduct cases, mainly about fabrication, falsification, and plagiarism (FFP). Research misconduct is understood more broadly than FFP, especially in Europe. For example, Foeger and Zimmermann state that “[research misconduct] also covers, for example, destruction of primary data, unjustified authorship, and the sabotage of research activities or dishonest attempts to lower the scientific reputation of another researcher” [8]. A more specific list of possible acts of misconduct is presented by Faintuch and Faintuch [9] comprising the following issues: lack of protection of data, violation of confidentiality, clandestine data access; animal abuse; inadequate human consent regarding aims and benefits, risks and harms,

coercion or exploitation of subjects; ghost authorship¹, questionable personal credits, failure of registration and ethical approval, breach of good (clinical) practices, lack of transparency regarding the relationship with funders, undisclosed commercial or personal interests, noncompliance with publisher ethics, nonprofessional language, salami slicing², lack of sharing data with co-investigators, study participants, other authorized parties, harassment, bullying, disrespectful behaviour, dishonest mentoring of students, fellows, junior staff, misuse of research funds, false or exaggerated academic titles, qualifications, professional experience, retaliation against whistle-blowers, deceit, scams, pseudoscience, malicious misconduct allegations. Often, these practices emerge due to the reward criteria in research that value quantity over quality. This issue needs to be dealt with at the level of science as a system. The aforementioned list includes not only acts from the realm of research integrity but also covers the domain of research ethics. It has increasingly been argued (e.g. Ron Iphofen [13]) that the two of them be viewed together, as both are required for ethical research and innovation. Another definition of research ethics and research integrity is provided by Ana Marušić in this book in her chapter “Evidence-based Research Integrity.” Braun, Ravn, and Frankus [14] showed that while research ethics committees do their task before researchers begin the actual research, research integrity offices handle possible misconduct cases after the research has been done and a concrete action or behavior has taken place. Whereas the first of them focuses on planning and design, and the other on conduct and implementation, both are needed to safeguard ethical research. At the practical level, the platform “The Embassy of Good Science” is the outcome of the European Commission’s initiated and funded research projects EnTIRE and VIRT2UE within the H2020 program, focusing both on issues of research integrity and research ethics.

3 What Do We Mean When We Talk About Ethics Committees?

When encountering the term ‘ethics committee’, one must pay attention to its meaning, as any committee or commission that deals with ethical issues can be called an ethics committee. Thus, there are committees that deal with ethical issues in different contexts, with different tasks, and at different levels.

Historically, research ethics committees have the longest tradition in ethical research. Their main task has been to ensure the rights and well-being of human research subjects and/or animals participating in research. As such, they constitute an additional safeguard mechanism, both for subjects and researchers. Based on the written documents submitted to the committee, the task of such committees is to weigh the risks and benefits

¹ Ghost authorship means that someone who has contributed substantially to the manuscript is not named as an author or given acknowledgment. It is problematic as it compromises academic integrity and may mask conflicts of interest [10]. Ghost authorship has also been addressed concerning ethics committees. David Shaw has claimed that when ethics committees improve the quality of a research proposal by suggesting major revisions, they should be acknowledged for their contribution. Ethics committees are ghost authors if they are not credited as authors or their contribution is not mentioned in the acknowledgment section [11].

² The term, ‘salami slicing’ (also salami publication or salami publishing) refers to activities where the smallest publishable unit of data is included in the publication [12].

of the study. Only studies with a proportional relationship between scientific validity, social value, fair participant protection, favorable risk-benefit ratio, independent review, informed consent, respect for participants, and collaborative partnership [15] should be conducted. The role of ethics committees originated in medical research. For example, in the Helsinki Declaration of the World Medical Association [16], it has been a requirement since 1975 to obtain the ethics committee's approval before starting a study. Later, this requirement of prior approval was extended from biomedicine to other fields of research. Social scientists have seen this development as problematic, as the requirement coming from biomedicine may not be suitable for social sciences and humanities [17, 18]. The need to obtain the approval of the ethics committee before starting the research may derive from national legislation, but it may also be required, for example, by research funding agencies or journals where the results of the research are to be published.

At the practical level, the Council of Europe's Steering Committee on Bioethics has worked out a "Guide for Research Ethics Committee Members" [19]. The guide addresses issues related to the appointment of research ethics committee members, emphasizing that the process should be transparent and fair. The requirements for the composition of the committees can be determined either at the level of national law or through guidance documents (e.g. the ETHNA framework) giving recommendations on the number of members of the committee, their qualifications, involvement of lay persons (those whose expertise is not in a specific type of research and who are there to represent the perspective of participants). Having clear policies and making them known is very important for addressing possible conflicts of interest.

However, several critical notes have been addressed to ethics committees. It has been claimed that the requirement of an ethics review is often only formal [20]. From the initial idea to help researchers to balance risks and harms and consider possible benefits of the research and innovation project or proposal [20], the process has boiled down to checking relevant boxes from the checklist or ethics issues table. As such, the "tick the right box" approach does not serve the original purpose of analysing the ethical aspects of one's research and innovation project.

Based on the situation in the United States, it has been claimed that institutional review boards are understaffed, overburdened; that they do not devote enough time, lack sufficient experience, and do not have institutional support [21, 22]. Additionally, there have been discussions on how to define and measure the quality of an institutional review board [23, 24]; how to deal with inconsistencies in research ethics committee review [25]; how to address the disciplinary distinctions in the ethics review process, [26] and the reasons why retrospective review should be added to a prospective one [27].

Although this is quite a tough slate of criticism to be dealt with, these issues can be addressed at the institutional or national level by providing resources, education, and training opportunities. The ETHNA project has given its input by creating a set of guidance tools and a toolbox to help institutions [28]. Additionally, the recommendation has been made that institutional review boards be accredited [29]. Increasing institutional support can mean various things, from hiring more support staff for the ethics committee to providing more training opportunities for members of the institutional review board [21], or requiring ethics committee members to obtain obligatory ethics training.

At the same time, ethics committees can not only review research but also deal with the investigation of possible cases of misconduct. In addition to the ‘ethics committee’, the body may also bear the name of the ‘ethics commission’, ‘integrity committee’, ‘research integrity board’, or ‘misconduct commission’, etc. Also, investigations are mentioned in the Bonn PRINTEGER Statement [2], where it is stated that the integrity committee can function either at the institutional or national level. However, the document does not specify whether appeals can be carried out at the national or institutional levels. Whereas the PRINTEGER Statement focuses on the level of research-performing organisations, the ENRIO handbook “Recommendations for the Investigations of Research Misconduct” [30] provides guidance both at the local and national level, e.g. regarding which decisions should be handled at what level and discusses the advantages of local or national bodies. The mutual learning exercise (MLE) in the research integrity final report gives a recommendation “to create a national research integrity body that could help coordinate, monitor, educate, communicate and promote research integrity in a country” [3]. In addition to establishing a national body, having national-level research integrity officers is important [3]. With regard to oversight, the MLE report suggests having an appeal system for research integrity investigations. This would be especially important in countries where there are no research ethics and integrity bodies at a national level [3].

Since the field of responsible research and innovation covers more than research integrity, the ethics infrastructure at all levels should be adapted accordingly. This should go hand in hand with processes determining that necessary regulations and guidance documents on all types of ethics committees are in place. Firstly, the lack of regulations on ethics committees might be a cause for various misconduct cases. Secondly, the ethics infrastructure should cover all aspects of ethics committees, from ethics review to integrity investigations. Thirdly, both should be in place, a regulatory framework as well as good practice guidance documents. We now turn to ethics (governance) bodies at the institutional level of a research and innovation institution.

4 What Should the Ethics Committee(s) Do?

One of the biggest challenges for a research and innovation institution is to work out an ethical governance system that suits the institution and serves it well. For ethics committees within the ETHNA System [28] the following activities are recommended for consideration.

First, the question should be considered what is the purpose of the ethics committee on research and innovation and how does the committee relate to the RRI Office(r) whose task it is to disseminate the concepts of the ETHNA system, establish performance indicators and monitor the progress of the system in the organization? Different options are available, as the committee can function as a governance committee by keeping an eye on the practical implementation of responsible research and innovation, but it can also create the space for discussions over procedures, commitments, and values.

Second, the question arises of the scope of the ethics committee. Who are the internal and external stakeholders to be involved in deliberations on ethical governance? Does the committee cover one or all of the key aspects of responsible research and innovation:

research integrity, gender perspective, open access, and public engagement, or only one of them?

Third, the main principles of action of the ethics committee should be agreed upon. Having such principles, making them known, and acting on them are of crucial importance for building and maintaining trust, both within the institution and with external stakeholders. Within the ETHNA system, the focus is on the following principles: confidentiality, impartiality, fairness, anonymity, the accuracy of information, and fair, respectful, and mediated agreements [28]. One question that arises is whether it is possible to act based on the principle of anonymity when personal contact and additional queries for information might be needed for mediating and agreement.

Fourth, choosing a suitable model of the ethics committee for the research performing or research funding organization is crucial. In a way, this is the cornerstone aspect of the whole system. The ethics committee, its size, needs and resources should fit the institution and should help implementing the ethical governance of RRI in the organization. Does the institution need a standing or an ad hoc committee? Both have their advantages and disadvantages. Having a permanent committee enables continuous operation, so for large research and innovation institutions this would be recommended. However, if the number of situations to be dealt with is low and resources are limited, it would be advisable to have an ad hoc committee instead.

Fifth, what are the functions of the ethics committee members, and what kind of profiles are needed? The way members of ethics committees are selected or nominated and the period of appointment should be known within the institution and by external stakeholders. Other aspects to consider are: how does renewal take place? For how many terms can a person be a member of the ethics committee? How does replacement or dismissal take place? What are the tasks of the secretary? Is the secretary a member of the committee or a member of the committee's support staff? What IT solutions are there or needed to support the work of the committee?

The solution provided by the ETHNA System is to nominate a committee for 4 years, but there are also other possible solutions, e.g. for a period of three years or five years. The next step is to map what profiles of people are needed in the ethics committee. What are the research and innovation and teaching activities the institution is carrying out? For example, doing research with human subjects, animal research, or research on biobanks or genetically modified organisms requires special expertise and potentially also a separate committee for reviewing these research projects. As such, it can be that in an institution there are separate ethics review boards for health research and biobank research, social sciences and humanities, animal research, and genetically modified organisms. One joint characteristic is that all of these committees should have a representative from the Ethics Committee of the institution and an ethics expert, and a law expert. Depending on how you are building up or changing the system, it can also be that the ethics and/or governance committee consists of representatives of the other ethics committees of the institution (mostly chairpersons). For example, the University of Liverpool in the United Kingdom has a research integrity and governance committee [31] that among other tasks has to oversee the work of other committees.

The sixth activity should be about describing the objectives assigned to the ethics committee. Those can include raising awareness, providing advice, helping with conflict resolution, and updating good practice guidelines, among others.

Seventh, what are the principles of the action of the ethics committee? This means that the frequency and interval between committee meetings should be thought through. For standing committees, it can be once a month, and for ad hoc committees whenever necessary. Compared to review and investigation committees, governance committees with the task of oversight and monitoring, and updating policies, should meet a couple of times a year. The schedule should be agreed upon and the information should be made publicly available (on the website of the institution or the webpage of the committee). How is the quorum for decisions decided? In most cases, this means that half of the members should be present. At the practical level, there can be differences, depending on whether or not the secretary is a member of the committee. Do external experts participate in decision-making? Is voting allowed or should deliberations take place until a consensus is reached? How often will the committee issue various reports? How will the body in the institution approve the establishment of the ethics committee on research and innovation?

Eighth, what are the monitoring indicators for the ethics committee? There should be progress indicators and performance indicators and these should be included and made known in the action plan of the ETHNA system.

5 Implementation of the Ethics Infrastructure

For a research and innovation institution, it is important to take into account whether the creation of committees and ethics infrastructure starts from scratch or if the already existing elements are changed and/or developed. If the existing system is changed and developed further, it is necessary to consider, negotiate and communicate tasks and responsibilities. How do ethics committees relate to ombudspersons and/or good science counselors? Would something be taken away from one committee and given to another? Will any new additional committees be created? Will some of the committees have their duties stripped? It is also necessary to consider how all parties affected by these changes are interconnected and how to involve them in the process, providing them with information about possible changes and asking for feedback.

Implementation of the ethics infrastructure also depends on the size of the research and innovation organization or research funding institution as well as on the size and institutional structures of the country where the institution operates. One way to create or change the system is to think about all the different stages of research and innovation and what is needed there. For example, a committee or committees are needed to review the research proposals in the planning stage, then to handle possible misconduct cases. Alternatively, there may also be a need for a committee governing the whole system and providing counseling at all stages of research and innovation. Additionally, does the governance committee also act as an appeal committee, or are there other committees at the regional and/or national level to manage the appeals?

It also needs to be considered whether it is necessary to do everything by yourself in your institution or whether there is a possibility to cooperate, especially in a small

country and in a small research and innovation institution. Additionally, there might be regulatory aspects to be taken into account, such as the ones specifying that some types of research and innovation activities should be reviewed by a specific body not at the same institution, and should rather be done by a regional or national committee (for example this might be the case for clinical trials in some countries). For a small institution in a small country, it can very well be that all the tasks related to governance, review, and investigations take place in one single ethics committee.

To sum up, it is of crucial importance to think through the following questions. Why does the research and innovation institution need an ethics committee? What should the committee do? Do you change the current system or start anew? How do you involve all stakeholders in the process? Do you have the necessary resources (people, infrastructure, etc.) to implement the ethics infrastructure?

When creating a system of ethical governance, it is especially important to avoid making all researchers and innovators feel like their primary task is to constantly prove that all is done by regulations and guidelines of good practice.

Rather than only expecting compliance with codes and regulations, policies should be supportive and aim toward good outcomes. For example, Zwart and Meulen [32] are of the opinion that only using bottom-up processes can foster ethics and integrity in research, and that integrity work must take place in everyday research settings. This should be done by research institutions by facilitating open dialogue and fostering a culture of deliberation, e.g. by creating a safe space for discussing issues from everyday practice. Nevertheless, Zwart and Meulen are of the opinion that the focus should be at the institutional level, not on the level of an individual researcher; not on exposure and punishment, but rather on having a supportive ecosystem. Therefore, a supportive culture is needed, and creating it is the responsibility of the leaders. Furthermore, there should be a variety of training available, for various stakeholders. In this process, not only ethics committees for review and investigation of possible misconduct are needed, but in addition, there should also be persons in the research and innovation institution to whom people can turn to get advice (before handing in an application to get research ethics approval or an application that a misconduct investigation should be started). This can be a good science counselor, ombudsperson, ethics officer, research integrity office or officer. Such persons should also act as mediators giving advice, as well as listening to feedback and the reactions of the users of the ethics infrastructure to further enhance the system.

To implement ethical infrastructure and to help leaders of institutions, another project funded by the European Commission, SOPs4RI, has also worked out templates and guidelines for writing research integrity promotion plans, both for research-performing organizations and research funding organizations [33–35]. The name “promotion plan” might be misleading, since the actual focus is broader, covering preparation (diagnosis, assessing readiness, finding the right people, creating the plan), execution, and monitoring. This is similar to the ETNHA action plan as the plan has to be concrete and contain concrete actions, listing specific responsibilities and deadlines.

At the practical level, it should be thought through how the dissemination of the role and functions of the ethics committees in a research and innovation institution should take place. Furthermore, will there be educational activities provided about the ethical

infrastructure in general for members of different ethics committees (new and current) and for researchers and innovators? Whose task will it be to provide them? The plan should have a concrete bearer of responsibility, be it the ethics officer, the research integrity officer, the ethics committee chair, or someone else.

If the earlier questions remain unspecific, let us consider two concrete examples. First, since the framework program Horizon Europe, the European Commission changed the table on ethical issues by adding the category artificial intelligence [36]. Who in the research and innovation institution should be aware of this requirement and who has to organize educational activities and the communication plan for those to whom it is relevant? Furthermore, does this require that the duties of the ethics review committee members have to be updated and the members educated, so researchers and innovators can submit research protocols encompassing AI to the ethics review committee of the research and innovation institution? Does the institution need to update its policies? For more specific debate about issues related to AI, see the chapter “Ethics and Development of Advanced Technology Systems in Public Administration” by António da Costa Alexandre and Luís Moniz Pereira in this book.

The other case is about chatbot ChatGPT, the AI tool that can create sentences and, in some cases, has been listed as an author of a research paper [37]. Who has to provide information about the possible threats of this development? Should the guidelines and policies about investigating possible misconduct be changed? What can the governance committee do regarding this challenge? Do the institution and ethics committee members have the knowledge to assess whether a text (e.g. research project submitted for ethics review) has been written by a researcher or a chatbot? Would it be possible to provide training about this matter for members of the institution (including members of the ethics committee)?

In these cases, it is not possible to provide a solution that would be suitable to all research and innovation institutions, but each institution should have a bearer of responsibility that fits its ethics infrastructure. Additionally, for successful implementation, a transition period is recommended to carry out communication activities and to enable the institution members to take part in the educational activities.

To sum up and return to the action and implementation plans, a question that needs further elaboration -- and not just being marked in proposed plans -- is whether the writers of the plan are in a position to write down the specific bearers of responsibility for each task and area or whether the bearers of responsibilities have to be specified by leaders of the institution at a later point. Additionally, it should be realized that there might be some issues that can only be dealt with to some extent at the institutional level as they may also require being addressed at the national level (e. g. national policy). Limitation of consideration to only one level may hinder the impact of creating and maintaining a culture of ethics and integrity.

6 Conclusion

Ethics infrastructure and governance are needed to safeguard trust in science. Ethics committees have an important role in the ethics infrastructure ensuring ethical research and innovation. The infrastructure must function at the institutional level and there should

be cooperation with the national level. The tasks of the ethics committee(s) within the research and innovation institution can vary, from issuing approvals to investigating (possible) misconduct to governance of the system. An example of an ethical system of governance for research and innovation in organizations developed was introduced based on the results of the H2020 ETNHA project, with a special focus on activities related to ethics committees. Additionally, for successful implementation of the system of ethical governance in a research and innovation institution, an action plan should be followed. Through involvement, and communication of policies and procedures, the plan should safeguard that both researchers and the public have trust in ethics infrastructure and ethics committees.

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