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THE ROLE OF RESEARCH ETHICS COMMITTEES IN STRUCTURING FAIR AND RESPONSIBLE RESEARCH[63]

Jacqueline Fagard, Jacques Py, Agnès Roby-Brami

1. Introduction

In France, research ethics are examined by two types of committees: *Comités de Protection des Personnes* (Committees for the Protection of Persons, CPP), which review the ethics of research projects that are required by law to receive ethical approval, and *Comités d'Éthique de la Recherche* (Research Ethics Committees, CER in French, REC in English), which examine research projects that, although they involve human participants, are not legally required to be reviewed by an ethics committee.[*] The aim of this chapter is to illustrate the operations of the RECs,

[63] This chapter is submitted on behalf of the French Federation of Research Ethics Committees (RECs).

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which are grouped in a federation, and to show how their work contributes to the promotion of honest and responsible research. After mentioning some of the milestones in the creation of the RECs and their federation, we will develop a few examples drawn from our experience: criteria for qualifying projects, relationships and conflicts of interest, compensation of participants, and inclusion criteria.

2. History of Research Ethics Review and Creation of the Recs

The history of research ethics review is marked by scandals the revelation of which has led to growing awareness of the importance of supervising all research involving human beings. These scandals have concerned biomedical research, but also non-biomedical research, such as sociological studies on homosexuals, the social psychology research carried out at Stanford in 1971 on the reconstruction of a prison (Zimbardo, 2007), and Milgram's well-known experiments on submission to authority (Milgram, 1963). These studies were criticized for failing to ask participants to sign an informed consent form and, in some cases, for misleading them or underestimating the risks the research presented for them.

Three milestones in the global history of research ethics review stand out: first, in 1947, at the end of the Nuremberg physicians' trial, 10 principles to be respected in research on humans were enshrined in

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the "Nuremberg Code".[64] The second milestone, 1964, corresponds to the issuance of the first Declaration of Helsinki by the World Medical Association.[65] The Declaration proclaimed the need not only to follow a code of good conduct in medical research but also to have participants sign an informed consent. It should be noted that the Declaration of Helsinki followed the publication of articles by two "whistle-blowers" that drew attention to ethical lapses in biomedical research that could harm participants and discredit the research (Beecher, 1959; Pappworth, 1962). Both Beecher and Pappworth found it very difficult to get published! The third important milestone is the Belmont Report, published in 1979.[66] This report reaffirmed the basic rules of research involving human participants: respect for persons, concern for their well-being, principle of justice, absence of deception, free and informed consent, and consideration of the benefit/risk balance. The Belmont Report was commissioned by the US Department of Health, Education and Human Services in response to what is known as the Tuskegee scandal, which refers to a syphilis study conducted from 1932 to 1972 with predominantly Black participants. No consent was sought from the participants, no appropriate information was given, and when penicillin became an effective therapy in the early 1940s, the participants were not informed that they could receive treatment. Following the Belmont Report, approval by an official ethics committee (Institutional Review Board, IRB) became mandatory for all research in the United States, whether or not it is funded by the government.

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[64] Nuremberg Code: https://muhc.ca/sites/default/files/users/user136/The%20Nuremberg %20Code.pdf.

[65] Declaration of Helsinki: https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/#:~:text=The%20World%20Medical%20Association%20(WMA,identifiable%20human%20material%20and%20data.

[66] Belmont Report: https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html.

In France, legislation initially concerned biomedical research. The first French ethics law, the Huriet-Sérusclat law, was enacted in 1988. It set up committees to regulate interventional biomedical research: CCPPRB committees (advisory committees to protect persons in biomedical research). Researchers in the humanities and social sciences (HSS) did not feel concerned by the Huriet law, and rightly so. However, they became concerned when the international journals to which they submitted their articles for publication began requiring proof of ethics committee approval, in line with the recommendations of the so-called "Vancouver Group". This group of editors has published editorial guidelines, a revised version of which (International Committee of Medical Journal Editors, 2023) includes the need for researchers to declare that their research has been conducted in accordance with the principles of the Declaration of Helsinki and has received the approval of a local IRB-type ethics committee. HSS researchers' concerns became more acute when the agencies to which they applied for funding also began requiring ethics committee approval. The first multidisciplinary ethics review committees were set up in the early 2010s. More and more universities have set up RECs, which have a purely advisory role. To comply with international guidelines, these RECs are based on the IRB model, and some of them are actually labelled IRBs.

At about the same time, legislation changed in France and the scope of ethical regulation of research was broadened. The Jardé law of 2012, applied in 2016, still primarily concerns biomedical research, but it includes non-interventional research. Any "Research Involving the Human Person" (RIHP) that has the aim of increasing medical or biological knowledge and requires an act outside the usual care of the persons taking part in the research must be presented before a CPP. This definition implies that other research, even if it involves human persons, is not

considered RIHP if its aim is not to increase medical or biological knowledge. This kind of research can therefore be examined by an REC.

3. Qualification of Projects under the Jardé Law and Birth of the Rec Federation

Thus, French law distinguishes between two types of research involving humans: research intended to increase biomedical or biological knowledge and other research. Certain fields such as pedagogy, formal linguistics, and sociology are clearly not covered by the Jardé law; the same applies to studies concerning the *practice* of health care professions. The boundary between the two fields of research is often blurred. At first, it was a real puzzle to qualify research projects as falling inside or outside the scope of the Jardé law. A great deal of research —in the cognitive sciences, the humanities, human-computer interaction, social phenomena such as drug addiction, etc.—concerned with the biological signature of behaviour was situated in what is known as the "grey zone" between CPPs and RECs. This grey area has forced the RECs to reflect on the criteria for designating cases as falling inside or outside the scope of the Jardé law. This qualification represents a particularly sensitive point from a legal and ethical point of view, insofar as the legal status of research that falls outside the Jardé law is not clear. Indeed, a REC's choice to agree or refuse to carry out this evaluation must be reliable, reproducible, transparent, and respectful of the trust of the researchers who submit their projects. The responsibility is great, since approval of the project by an ethics committee is a requirement for publication of the research by most international scientific journals and for obtaining study credits, particularly European credits. But when it comes to approval itself, RECs' primary responsibility is to *research participants*.

To pool their experience and develop tools, the RECs decided to form a federation. The Federation of RECs was created in 2018, and today

includes more than 20 RECs across France. The Federation of RECs provides a forum for often lively discussions, particularly when it comes to structuring qualification criteria. Issues related to information and consent are also the subject of debate within the Federation. The RECs are particularly careful to ensure that information is given in a form that is adapted to the person's ability to understand. With regard to consent, there is sometimes an inherent contradiction that leads RECs into a form of Weberian conflict between an ethics of responsibility and an ethics of conviction. For example, is it necessary to ask for parental consent to interview a young girl who is a minor and has undergone a voluntary interruption of pregnancy? The law obliges the researcher to obtain parental authorization, but it also allows a minor to have an abortion without informing her parents. Which standard or value should be given priority? The law or the spirit of the law? Beyond the study of legal texts, this question requires ethical reflection.

The French RECs have obtained recognition from their supervising university or community of universities; they are now pleading for an amendment to the law that would give them some legal status, which such committees have in many other countries. This development and evolution of RECs has been criticized by some researchers, who see ethics as a problem rather than a solution (Carvalho, 2019). Their position is outlined in Section 4.

4. Debates and Criticisms of the Recs

The evaluation of research projects by RECs raises some interesting questions for researchers. First, ethics committees are criticized for looking not only at ethical aspects but also at scientific issues. RECs focus on the protection of participants and the confidentiality of the data collected. The evaluation of the scientific quality of a research project is not, strictly

speaking, related to the protection of participants, unless one considers that the role of the RECs is to enable participants not to be solicited for research of negligible scientific interest, and that would risk transforming them into censorship committees. Nevertheless, when a REC is labelled as an IRB, it must carry out a scientific evaluation when it assigns an IRB number to a research project. Ethics and science are not separate issues.

This raises the question of the standardization of research, because all the RECs in the world agree that some research is more difficult to evaluate than others. This is generally true of qualitative research (Librett & Perrone, 2010), which is less in line with the orthodoxy of the hypothetico-deductive approach; it is also true of exploratory research carried out on topics that have received little or no attention previously and for which there is therefore no scientific literature on which to base hypotheses.[67] However, researchers have always accepted the principle of peer review. Every researcher knows that, if they want to publish their research in prestigious scientific journals, it will be evaluated by other researchers, with all the limitations that this entails in terms of objectivity, validity, consistency, etc. We admit that the system of peer review may be flawed, but we accept that it is an important part of the scientific process. We accept that, even if the system is imperfect, this is the least bad solution (Py, 2021). So why not admit that ethical evaluation can also be imperfect, since it is also carried out by peers?

Some authors criticize the RECs for focusing exclusively on the protection of participants, thereby ignoring the societal aspects of the research they review (Kitcher, 2011, 2016). Participatory science is then presented as a movement for the democracy of science, distancing itself from the orthodox science (Houllier & Merilhou-Goudard, 2016) for which RECs supposedly constitute an "ethicocracy" (Larouche, 2019),

[67] See, for example, the research by Bringuier et al. (2022) on juries and fake doctoral theses, on which there was no previous literature.

imposing bureaucracy and standardization that distracts researchers from ethical reflections rooted in their research practice (Larouche, 2019).

- First of all, it should be noted that this criticism is based on the assumption that all researchers think ethically about their research. Researchers do indeed seem to be spontaneously concerned with the legal and regulatory framework of their research, but not necessarily with ethics. For example, when children are involved in research, researchers will systematically ask for parental permission, but will not ask for the child's assent, or will do so in incomprehensible jargon. All members of ethics committees can testify that many ethical issues are not spontaneously or fully considered by most researchers, including the welfare of research participants and their information before (consent) and after (debriefing) research, that is, respect for the autonomy and uniqueness of the human subject.
- In addition, evaluating the societal aspects of research means looking at its benefits to society in a complex cost-benefit relationship. It entails taking into account the public or private expenditures on research and the likelihood that it will pay off. This inevitably involves the scientific evaluation of research projects, which is the most common criticism levelled at the RECs.

Another criticism of RECs concerns the geographic scope of their decisions (Felices-Luna, 2016). Most RECs anywhere in the world limit the scope of their decisions to a single nation. The argument for this restriction is both legal and cultural. Legally speaking, a given REC is not familiar with the existing legislation in many other countries and therefore cannot formulate an opinion that might be contrary to legal provisions. Culturally, it is conceivable that certain research materials

presented to participants may be perceived differently in different parts of the world and therefore require appropriate protective or precautionary measures, whereas the REC is not in a position to assess the appropriate course of action. However, there are exceptions; for example, South African RECs and some UK RECs issue advice that is global in scope. The problem of the geographic scope of REC decisions has serious consequences for researchers. It is sometimes an insurmountable obstacle if a researcher wishes to carry out research in a country other than the one in which they are based, especially when working on cross-cultural comparisons. RECs must therefore strive to adopt principles that work for researchers.

Critics of RECs forget that their function is to protect everyone involved in research: this includes researchers and their institutions, and not just research participants. At a time when social relations are often the subject of conflicts that fuel the media and the courts, it is in the interests of researchers and their institutions to be able to point to a favourable opinion by an ethics committee as evidence that the research protocol has been examined and validated by a committee competent to assess the possible consequences for participants.

The debates are far from over, as RECs now face new and complex issues that blur the distinction between research review, scientific integrity, and ethics. We have chosen to present three examples below to illustrate the overlap between these three sources of norms: the issue of relationships and conflicts of interest, which is becoming increasingly acute with the proliferation of grants to researchers by private organizations interested in profiting from research results; the issue of compensation for participants, which needs to be reconsidered, particularly with the increasing use of platforms since the COVID-19 pandemic; and the issue of inclusion criteria for solicited participants.

5. Relationships and Conflicts of Interest

The evaluation of research files by the RECs raises the question of relationships or conflicts of interest, a question on the borderline between ethics and deontology. The most visible conflicts of interest concern ties between biomedical research and the pharmaceutical industry (which are assessed by the CPPs in France). However, they can concern research areas evaluated by RECs, for example for research involving technological or digital devices in various fundamental fields or with a view to applications (in teaching, compensation strategies for disabilities, etc.). These situations are particularly frequent since current research policy encourages collaboration with business organizations, whether the collaboration is initiated by the company or by the researcher wanting to promote an invention.

During our work at an REC, we found that researchers were often unaware of the need to declare relationships of interest to the committee and to participants. Incomplete, erroneous, or untimely declarations of relationships of interest constitute a breach of ethics (INSERM, 2014). In addition, researchers sometimes have difficulty distinguishing between a *relationship* and a *conflict of interest*. However, not every relationship of interest necessarily leads to a conflict, whereas declaring relationships of interest is simply an obligation.

A conflict of interest (financial or otherwise) is defined as such if it creates a significant bias for the research. For example, funded research has been shown to have a favourable evaluation bias (Lundh et al., 2017). Preventing conflicts of interest theoretically involves simple rules: separation of powers, separation of public office and commercial activity, and refusal of an assignment if there are risks of conflict. However, these rules come up against the complexity of reality, and it is often difficult to distinguish between them. In France, official guidelines for academic research do not address the practical ethical conduct of projects (Askenazy

et al., 2019). Yet, the transparency of agreements is far from being a given (Mulinari et al., 2021) and there is a lack of student training (Scheffer et al., 2017).

The main objective of the ethical review is to protect the participants. This requires the fullest possible information on relationships of interest so that they can participate with full knowledge of the situation. A conflict of interest is especially likely to arise if a researcher is both judge and party to a study: situations of coercion could arise and influence participants' decision-making. Particular attention must be paid to doctoral students, whose theses may be funded by private players, particularly in industry. The REC may require measures to reduce the risks, for example by asking the person in a conflict of interest situation to withdraw from the research project or requiring important responsibilities such as recruiting and informing potential participants and obtaining consent to be entrusted to other members of the team. The legal and ethical aspects of a collaboration are often governed by an agreement, but it is rare for this agreement to be attached to the file submitted to the REC.

It is also important to pay particular attention to the protection of data confidentiality, which is often difficult in the case of collaboration with private organizations. The right to participants' image and voice must be particularly respected. However, in the digital age, data also have economic value; participants must therefore be informed of what will be done with their data, even if they are anonymized. This last point requires close collaboration between each REC and the Data Protection Officer who ensures compliance with European legislation on personal data protection.

6. Participant Compensation: Ethical and Deontological Issues

Participants' consent must be free and informed and they must be at arm's length from the researcher. Ideally, participation in research should be motivated by altruism, a wish to advance knowledge, or a sense of community (Russell et al., 2000). In practice, however, researchers often offer incentives in the form of cash, gift cards, or course credits to enhance recruitment. This common practice remains ethically controversial (Permuth-Wey & Borenstein, 2009), as it casts doubt on whether the relationship is at arm's length, but there are few written recommendations and standards vary widely across contexts (Dickert & Grady, 1999).

In France, it is forbidden to pay participants in the form of a salary: this could lead to the admission of a class of "professional healthy volunteers" (Anderson & Weijer, 2002). Moreover, it would eliminate the possibility of withdrawing from a study without having to justify it. However, compensation is defensible if participants are active partners in participatory research (Gross & Gagnayre, 2022; Houllier & Merilhou-Goudard, 2016). In general, it is accepted that participants should be compensated to adequately honour their contribution or to offset the loss of earnings that results from the sacrifice of their time. This form of payment involves less dependence than a salary but could give rise to inequality if, for example, the amount varies with people's social status. Compensation might influence a participant's decision to accept risks or unusual discomfort that they would not otherwise have accepted. There is also a risk of biasing recruitment towards financially disadvantaged populations, which violates the principle of justice. To avoid these pitfalls, compensation, whether in kind (gift cards or benefits) or in cash, should be low enough that participants are not encouraged to sign on for primarily financial reasons. However, even a small amount of money can be an undue incentive for financially disadvantaged people: "Faced with

this dilemma, researchers are at a loss, torn between a utilitarian sense of guilt and the service they provide to society" (Rémy-Jouet et al., 2021, our translation). When compensation is offered, it is frequently in the form of gift cards, the amount deemed reasonable is around €10 to €12 per hour. However, there is some hypocrisy insofar as this amount is close to the minimum hourly wage in France, even though it is not called a wage.

Compensation can be offered to students in the form of validation of a part of their curriculum (Miller, 1981): participating in experiments is considered to have pedagogical virtues. But it is necessary to make sure that the students are not dependent on the researcher and that they have a choice (other experiments or alternative work). It is also important for researchers to commit to spending some teaching time explaining the rationale of the research at the end of the experiment. On the other hand, it is more difficult to argue that participation in research should be credited with points on an exam. It has been noted that the option to compensate students in course credits has a negative influence on the quality of outcomes, unlike cash compensation, probably because of interactions with motivation (Nicholls et al., 2015).

Another issue facing RECs is internet-based micro-work platforms used to answer questionnaires or participate in online experiments. These platforms, particularly Amazon Mechanical Turk (MTurk), use micro-jobs parcelled out to exploited, underpaid workers whose primary occupation this becomes (Casilli, 2019). The use of MTurk is considered unethical by most RECs, which recommend using academic platforms that comply with the GDPR (data protection regulations). However, the operation of internet platforms is not transparent and demands thorough investigation so that RECs can give relevant recommendations. The use of these platforms also raises the question of data quality since participation in research is motivated by money. Recent testimony from MTurk users is instructive: they estimated that 3% of participants provided

usable data (Webb & Tangney, 2022). Thus, ethical and scientific integrity considerations can be inextricably linked.

7. Inclusion Criteria for Research Participants: a Call for Greater Inclusivity

Haphazard application of exclusion criteria can be problematic. Researchers have developed habits based on procedural considerations that are not always well thought out and have no ethical basis. For example, in psychology, some researchers, influenced by medical studies, exclude pregnant women from research protocols. Obviously, it would be risky to test molecules on pregnant women, but it is not clear what ethical consideration should lead to the exclusion of a pregnant woman from research using questionnaires or interviews, or even experiments if the physical constraints of the research are limited.

On another note, research conducted in France often requires participants to be "native French speakers", even though millions of people are perfectly capable of understanding and responding to instructions or questions without being native French speakers. In fact, only qualitative research, in which the analysis of the data goes beyond the signifier (the material form of a sign as opposed to the idea or concept indicated, the signified), should methodologically distinguish between native speakers and people who are usually dominant in that language, even if it is not the language they acquired in infancy.

Similarly, most studies in movement and sport sciences and those based on brain activity measurements exclude left-handed people, who make up about 13% of the world's population, on the grounds that their brain functions are different. So why not include laterality as an explanatory variable instead of excluding a modality? Or do some research only on left-handed people? And what about research on people who do not identify as either male or female?

In fact, there are many reasons for exclusion. They raise the question of equal participation in research, which is an ethical issue. They also raise questions about the validity of the results obtained, which is a matter of scientific integrity. Once again, ethics and scientific integrity are intertwined, making it all the more necessary for researchers to reflect on these issues.

8. Conclusion

The work of the RECs focuses on issues that combine ethics and scientific integrity. The link is quite deeply rooted. Indeed, RECs can make several fundamental arguments in favour of participating in science with integrity and responsibility. Submitting an application to an REC leads researchers to reflect on their duties towards the participants in their research, but also on their responsibilities towards their institution, their funders, and even society as a whole. This requires them to define a protocol *a priori* and to submit a version of it before carrying out the research. This protocol includes general and operational hypotheses and a methodological approach; it also defines the analyses to be carried out. According to Haiech (2022), this guarantees the rationality of the research approach (how can the research strategy be reconstructed?), the reproducibility of the research (how can the results and their interpretation be reproduced on the basis of the methodology used?), and the replicability of the data (how can a new set of data be reconstructed by following the research protocol and its data analysis methodology?).

The RECs are destined to play an active role in the vast global movement to promote scientific integrity. When researchers using human participants submit their research files to an REC, it helps to build participants' trust in researchers, researchers' trust in peer review, academic institutions' trust in the researchers they employ, research funders' trust in the research they fund, and, in short, society's trust in science.

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