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Ethical Procedures in Scientific Research

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Author's contribution

The sole author designed, analyzed, interpreted and prepared the manuscript.

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ABSTRACT

This work has as its theme the ethical procedures of research and aims to provide a framework of practical guidelines to ensure the protection of all actors involved in the development of scientific knowledge, particularly at the stage of research design and project.
This is a theoretical reflection on the ethical dimension of data collection practices and the limits that the researcher should consciously attend to in the scientific research process. For this reflection, I carried out a literature review and a document analysis of several legal documents, highlighting the European directive on data protection. This led to several questions, namely: what documents should be ensured in the research project design process? What is the scope of informed consent and how can anonymity and confidentiality of data be preserved? These and other questions are answered in a thoughtful way for those who understand that there is no science without ethics, nor ethics without conscience.
Here the hermeneutic method is the natural choice because it allows the interpretation of questions related to values and principles that must be contextualized. This interpretative analysis requires asking questions related to duty, but also to the norm or law. With this questioning it is hoped that the reader will understand in a systematized way the ethical procedures of research and will be able to draw on a documentary listing of the ethical point of view that will protect the informants, but also the researcher himself and affiliating institutions or participants.

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1. INTRODUCTION

The ethical dimension of scientific research is an increasing concern for researchers, but also for institutions and for those who authorize the publication of research results. We are talking about the field of ethical responsibility of scientific work. It is true that virtue ethics has fallen into disuse and Aristotle should understand that ethics is beyond virtue, although he recognized it as the foundation of the exercise of humanity of each one of us.

"The ethics of responsibility is proper to an individual-subject endowed with autonomy (dependent, like all autonomy). However, responsibility needs to be irrigated by the feeling of solidarity, that is, of belonging to a community" [1].

Ethics is the compass that guides us within the boundaries of the responsibility we have for and to others, including in research. Ethics relates directly to the values and principles not only of the individual, as researcher, but to the entire form of the process and development of science. It is also through the ethical responsibility of research that we give meaning and identity to the scientific community [2,3].

Our concern, as researchers, with data protection, the well-being of participants and informants, but also the legal protection of the researcher and the institution to which he or she is affiliated always raises questions about methodological, technical, and ethical guidelines, particularly in the construction process of the scientific project and data collection procedures.

This paper is intended as an ethical reflection on the design and practices of data collection. That is, it is intended to be a questioning of research practices, from their inception.

We know that ethical requirements are the guides of all human orientation. Research, as a process, is not immune to ethical questions.

We can list some considerations about the care of the research process, but we are aware that others will be omitted, not for lack of positioning but because, in some cases, the resolution of ethical issues will depend on the contexts. In other words, there are no closed and finished recipes, but indications of possible solutions.

"The right to privacy or non-participation, the right to remain anonymous, the right to confidentiality, the right to count on the researcher's sense of responsibility" [4] are just some imperatives inherent in the consciousness of scientific freedom.

I believe that researchers are honest individuals and that the integrity of the research is maintained both in the design phase, the data collection, and the presentation of the final research product (report).

Early on, our conscience, like Pinocchio's talking cricket, tells us how to proceed. We may refuse to do what is right, but that does not invalidate the silent voice of the greatest judge we have: our own conscience.

Tiredness and physical adaptation to the place where the researcher is located should also be the object of our ethical reflection. We must be able to critically analyse this context. Apathy in the research process can be an enemy, that is, we should avoid falling into what many call intellectual laziness [5,6]. Of course, we can always present papers and research results to escape some fatigue the research contexts. This can be a strategy to avoid falling into mental lethargy, but we must write the scientific discourse. Writing requires time, but, on the other hand, this time is limited. It is not about writing anything just because it has to be written. The rush of written production has its risks, and we must be careful not to "shred our fingers" [7].

Research is already a moral commitment. That is, not only an agreement or contract that we make with the academy. It is also a commitment to the community. Writing becomes a moral imperative, and we can only do it with others. Therefore, a bibliography of authors, more than guides, forms the set of masters that teach us that we cannot write in a vacuum. "What is written is written. Oh, if it were worth more!" [7].

I will not discuss here scientific ethics in all domains, but rather the ethical procedures for instructing and justifying a scientific project. To do otherwise would be to assume that researchers need lessons in an area that, by its very nature, cannot be taught.

2. THE INSTRUMENTS OF THE SCIENTIFIC ETHICS PROCESS

When I refer to the instruments of the scientific ethics process, I am referring to the material and documentary guidelines and principles that serve as the basis for the conception of the scientific project: Naturally, they also fit the scientific process and results.

What documents must be secured and attached to the body of scientific work?

What information should be available to anyone intending to evaluate a research project? I believe the simplest way is to make a list of key documents.

Data collection is probably the moment where ethics is most pressing. Issues such as privacy and anonymity of the information collected and the autonomy, in terms of participation, of the informants lead to the discussion on the transparency and equity of the scientific investigation process.

“Respecting the autonomy of participants means recognizing their ability to make choices and decisions about their participation in the research, without any kind of coercion or manipulation by the researcher. This implies ensuring that participants receive clear and objective information about the research, to understand its objectives and consequences, and ensuring that they can refuse or interrupt their participation at any time, without suffering any kind of retaliation or harm” [8].

The question of the participants' autonomy arises at the level of professional secrecy as a fundamental indicator of public trust in scientific research. "Scientific research is a socially constructed activity, and public trust in its integrity is fundamental to its success. Those who engage in research must always keep in mind that their actions have consequences not only for the scientific community but for society as a whole" [9].

Thus, scientific research is not an isolated act of the researcher, but a work that has a social and public dimension due to its impact on the daily lives of citizens.

3. INFORMED, CLEAR AND FREE CONSENT

It is a document that concerns the informed authorization signed by the informant and is mentioned by the National Health Council in Resolution 510/2016. Anyone who participates in the research as a data provider has the right to know in a simple, objective, and clear way the objectives of the study.

In the informed consent, the identification of the researcher, the title and framework of the study should be included. The objectives, method, and techniques that will be used in data collection should also be clear in this document.

"This cooperation agreement, properly clarified, including the agreement of the participants and the confidentiality of the data obtained, should be made before the research procedures are initiated. In the case of students, the agreements require not only the consent of their parents but also of the school management (...), properly explaining the research objectives, the procedures to be developed, and the contents of the questionnaires, tests, and other instruments to be used" (Sousa, B. A, 2005, p.3).

The participant should be informed of the location and time he or she will have to be available, and his or her participation should be voluntary. It is also wise to state whether participation is paid or free. The researcher should also inform the participant of the deadline for the destruction of the collected material.

Another important issue is to state whether the study is financed, and if so, it is mandatory to refer to the funding entity. Whether it is a public or private entity, or both. If the project has been submitted to an ethics committee and requested an institutional data protection opinion, then this information should be included in the informed consent. Don't worry if the document ends up being bigger than expected. This is the way to protect everyone involved in the research process.

The greater importance of informed consent rests on issues of anonymity and data confidentiality. Anonymity protects participants, ensuring that informants' identity data is not identified. The confidentiality of the data must guarantee that they will be used exclusively for this or that study only.

Thus, as researchers, we should never, at any time, ask for personal, professional, or institutional contacts of those who have allowed us to collect data. We can leave the contact details of the researchers and their identification

to the participants. In case of doubt, after data collection, participants can contact the researchers, not the other way around.

In the case of surveys using online questionnaires, a section must be included at the beginning of this data collection instrument, which requires the respondent to indicate that they are over 18 years old and who freely and consciously consent to participate in the study. In all cases, whether face-to-face or online, the informant has the right to withdraw from participating in the study at any time and without having to justify his decision to the researcher or the research team.

4. DATA COLLECTION INSTRUMENTS

As for the list of documents, the data collection instruments must be attached without being completed. It should be a validated scientific instrument, or a zero-phase data collection instrument. Typically, phase zero refers to a pre-test or a testing of survey instruments.

The variety of data collection tools is so extensive that there is not enough space to list them all, but some of them are familiar to all of us: scales, individual or focus group interviews, questionnaire surveys, ethnographic notes, journals, observation grids, etc.

"The use of research techniques should be guided by the same ethical principles that guide the research itself. Researchers should be sensitive to the cultural values and social norms of the groups they are studying and should ensure that research participants are treated with respect and dignity. This includes respect for participants' privacy, anonymity, and confidentiality, as well as obtaining their informed consent to participate in the research" [9].

The rights of participants must be guaranteed and respected, and it is our duty to pay more attention to techniques that expose participants more, such as participant observation or ethnographic records. This is even more important when these data have implications for the publication and dissemination of the results.

"Borg and Gall (1989) suggest two processes to safeguard the confidentiality of research data:

1. Collect research data in such a way that no one, not even the researcher, can link the data obtained to each of the subjects who produced it. For example, delivering questionnaires on identical sheets, without any identification, in identical, sealed envelopes returned by mail or deposited in a location where their reception is not recorded.
2. Using a linking system, for example, replacing names with a numerical code that is only known to the researcher" (Sousa, B. A. 2005, p. 37).

The data collection instruments themselves should anticipate not only the risks and benefits of participating in the research but also those of the research itself. For example, one thing is the inherent risks of measuring heart rate during exercise. Another is understanding the importance and added value of a study aimed at assisting the scientific field of cardiology. To minimize the risks of participation, a contingency plan (CNS, Resolution 510/2016) and security measures must be adopted. Here, extra attention is more common in the general health field [10].

"In any medical research involving human subjects, each potential patient must be adequately informed of the objectives, methods, sources of funding, any conflicts of interest, disruptions and foreseeable risks that the research may entail, and any potential health or societal benefits that may result from the research. The potential patient must be informed of their freedom to refuse to participate in the research or to withdraw their consent for participation at any time. After being informed of all of this, the patient's informed, free and clear consent in writing must be obtained" [11].

5. ACCEPTANCE LETTER AND SCIENTIFIC SUPERVISION

In the case of advanced training, master's, doctoral or post-doctoral degrees, a scientific supervisor is required. Whether in master's, doctoral or post-doctoral programs, there is a scientific supervisor who must sign an institutional letter showing their availability to ensure the good functioning of these works from both a scientific and procedural and ethical point of view.

Regarding research projects that do not lead to an academic degree, they always have a main coordinator and local coordinators. They should be the ones to sign the letter of responsibility for the research to be carried out. One way to write this letter is in the form of a commitment of honour.

This commitment is a term of responsibility that implies a real understanding that ethical norms in different contexts [12] give rise to different responsibilities. That is, those who commit to research, and here the area of social sciences must be very cautious, must be very aware of the implications of their work on vulnerable groups, especially when sensitive data such as gender, sexuality, mental health, etc. are addressed.

6. INSTITUTIONAL DECLARATION OF DATA PROTECTION

With the Data Protection Directive (Directive (EU) 2016/680) it was assumed by the entire European Union that "the protection of natural persons in relation to the processing of personal data is a fundamental right" (OJEU, EU Directive, Consideration 1, 2016) and, in this sense, all Member States of the European Union had to transpose this directive into their national legislation. The deadline was 2019. With the improvement of this directive, the internal legal order of directives (EU) 2022/211 and (EU) 2022/228 relating to the protection of personal data, in this case in the criminal domain, was spilled into national law.

It is important to understand that failure to protect data, including in research, has criminal consequences. Therefore, all projects must be accompanied by a data protection statement from the researcher or institutional research teams, which is what is assigned to the Data Protection Officer under the law.

We all know the famous cases of fines imposed on technology giants. One of them was fined 745 million euros. These fines can range from 10 to 20 million euros per violation of the General Data Protection Regulation (GDPR). In Article 83 of the directive, we can find the sanctions defined based on criteria such as:

- "The nature and size of the breach.
- Precautions taken by the company to limit risk
- Whether the company notified affected individuals of their breaches
- The type of personal data affected
- The company's history regarding data privacy issues
- The level of company compliance with its DPA during the remediation period
- How the company responded to GDPR warnings
- The intention regarding the misuse of data, and whether there was negligence
- How much mitigation exists to limit the harm caused to data subjects." from https://www.visitor-analytics.io/pt/blog/quais-sao-as-penalidades-para-o-nao-cumprimento-do-gdpr/

Given the importance of the institutional Data Protection Officer statement, we move on to research partners.

7. RESEARCH PARTNERS

Data collection often takes place in third-party institutions, i.e., outside the researcher's affiliated institution. This means that data collection can occur in public or private institutions, government or non-governmental organizations, associations, companies, etc.

Wherever it is, the researcher must ensure a written document with a favourable opinion from the entity or entities where they will collect information. If the institution where the data collection will take place is under regional or national government, the researcher must ensure this favourable opinion in a formal document. For example, if data collection is done in a school, then the Ministry or Department of Education should be aware and authorize it through a written document. This does not preclude a favourable opinion from the school's management and parents in cases of working with minors.

8. CONFLICT OF INTERESTS

If applicable, a declaration of no conflict of interests must be made by the researcher and all members of the research team. A situation of conflict of interests is generated between two or more parties, namely by access to privileged information, which may compromise the impartiality of the interpretation of scientific information and/or may affect or influence the collective interest. Conflict of interest can even lead to corruption and crime.

The most effective ways to control conflict of interests, in addition to individual awareness, are through Codes of Conduct and Ethics, or Good Practice Manuals. By providing declarations of specific situations and requests for abstention from a role, it is possible to prevent conflicts of interests. Most institutions have global policies for the prevention and management of conflicts of interests.

9. SCIENTIFIC PROJECT DESIGN

Creating a work map and designing a research project requires many hours of work and deep dialogue between us, others, and our conscience. Scientific and critical debate tends to be the least difficult because, once trained, the method takes care of our scientific doubts.

But "ethics for oneself can be defined as ... resistance to our own inner barbarism. No civilization has been able to reduce the inner barbarism of the human being" [1]. Science quickly realized that it cannot survive without ethics and that ethics must be its ally to be respected.

"In the preparation phase, research is planned and designed, specifying objectives, delimiting the research field, and developing an initial outline that becomes a project when all planning is properly thought out and defined" (Sousa, B. A., 2005, p.79). It is also in this phase that ethical procedures are delineated.

Basic precautions such as identifying the type of study, whether there are external institutions participating in the work, if there is a data sharing agreement signed between different institutions, it allows great steps to be taken in the confidence of the community in general.

We must be honest about whether the project involves humans, animals, biological materials, etc., and describe the research protocol. This attitude not only strengthens confidence in research, but also guides us as researchers throughout the process in terms of theoretical and scientific foundations. Data security and destruction procedures should also be mentioned in the research project. Data cannot remain in investigators' hands forever, as the research period has a beginning and an end.

Ethics in research also allows us to correct methodological and technical procedures, identifying who can participate and who should be excluded. Minors, migrants, pregnant women, people with special needs or mental health problems, prisoners, animals, etc. The criteria for inclusion or exclusion of informants are scientific, but they also bring an ethical and, in some cases, a deontological definition. These criteria allow us to define samples or groups of informants.

Attached to the initial project and the final research report should be the Curriculum Vitae of the researcher, or all members of the research team if applicable. It should be clear who the leader or principal/local coordinator of the research is. In the case of advanced training, master's, doctoral or post-doctoral degrees, in addition to the investigator's CV, the CV of the scientific supervisor or mentor should also be included. The identification of the researcher(s) should include the following information: name, affiliation institution, email address, and telephone contact. If it applicable a link to the project or webpage or the researcher.

10. RISKS AND BENEFITS IN RESEARCH

Those who are willing to provide information and data must be aware of the risks inherent in their participation in the study. It is true that filling out a survey can take 20 minutes of our lives, but a blood sample can take much more. Therefore, clear indications should be given by the researcher about what is at stake in the participation of third parties in scientific work.

It is advisable to know, if applicable, what compensations will be given, how much, and how that return will be made. Compensation is a mechanism used to correct or balance something.

In the process of experimental scientific research, compensation can be understood in another way. It means as a technique for controlling experimental groups, that is, as a guarantee that the experimental group and the control group receive identical treatments except for the factor being tested. This ensures that any differences in the results are due to the factor being tested and no other variables.

11. CONCLUSIONS

Those who participated in the research are an integral part of the results. In this sense, the question is simple: if the researcher guaranteed anonymity and confidentiality of the data (Silva, L. O. M., & Nunes, M. D. M. [9], and how will he/she return the results to the participants?

This can be done in different ways: scientific articles, online publication of dissertations and theses, lectures, conferences, websites for projects or studies. But the return must happen. It is our duty. It is an ethical demand of gratitude.

Without the informants and the data, the theory would be empty.

That is why we have an obligation, as researchers, to sign a responsibility statement. Responsibility for scientific progress, but essentially for humanity.

The Declaration of Helsinki of the World Medical Association Ethical Principles for Medical Research Involving Human Subjects serves not only the health scientific area. It is a fundamental guide and combined with Data Protection and the recommendations of the European Union, it reshapes our projects and studies and shows us how far Science can go.

Everything that is alive deserves our respect and our deepest admiration. In fact, what use is science without ethics? Knowing is being able to think, and thinking is respecting the world and everything that inhabits it.

The ethics of knowledge is the deepest struggle we have against despotism, blindness, and lies. Through it, it is possible to understand scientific uncertainties and contradictions, but also those inherent in ethics itself. It is ethics of knowledge and research because she is a constant dialogue between the one who thinks and builds knowledge with the one who is the real possibility of existence of that knowledge. Respecting the subject and the objective, this pair of the cognitive act, ensures scientific freedom and its quality. But there is another equally important dimension here: the greater the perception of what science does, the greater the cognitive democracy (Morin, 2002).

CONSENT

As per international standard or university standard, Participants' written consent has been collected and preserved by the author(s).

COMPETING INTERESTS

Author has declared that no competing interests exist.

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