NOTES ON STATISTICS AND RESEARCH

Ethics in Qualitative Research

María F. Grande Ratti[1], Delfina Murature[2], Agustín Sánchez Del Roscio[2], Salomé Frei[2] y Sonia E. Benítez[3]

1. Área de Investigación en Medicina Interna, Servicio de Clínica Médica. Hospital Italiano de Buenos Aires. Buenos Aires, Argentina
2. Instituto Universitario Hospital Italiano de Buenos Aires. Buenos Aires, Argentina
3. Área de Investigación e Innovación tecnológica, Departamento de Informática en Salud, Hospital Italiano de Buenos Aires. Buenos Aires, Argentina

ABSTRACT

Ethical considerations are essential to ensure that any research project takes place responsibly, respecting the rights and well-being of participants and maintaining scientific integrity. This article presents the safeguards of qualitative research, emphasizing bioethical principles and the handling of personal data. Researchers must implement rigorous measures to ensure confidentiality. That includes obtaining informed consent from participants before collecting personal data, using secure methods for data storage and transmission, and ensuring that data protection measures prevent data from being used in a way that could identify identity. When interviews are the collection method, they should consider the implications of audio recordings (voice recognition) and video recordings (image protection). The collected data may be sensitive and reveal delicate information

Key words: Research Ethics, Qualitative Research, Confidentiality, Informed Consent Forms, Personal Autonomy, Argentina.

Ética en la investigación cualitativa

RESUMEN

Las consideraciones éticas son imprescindibles para garantizar que todo proyecto de investigación se lleve a cabo de manera responsable, respetando los derechos y el bienestar de los participantes, y manteniendo la integridad científica.

Este artículo presenta los resguardos de la investigación cualitativa, haciendo hincapié en los principios bioéticos, y el manejo de los datos personales. Los/as investigadores/as deben implementar medidas rigurosas para garantizar la confidencialidad. Esto incluye obtener el consentimiento informado de los participantes antes de recopilar datos personales, utilizar métodos seguros de almacenamiento y transmisión de datos, y garantizar que los datos no se utilicen de manera que puedan identificar la identidad. En caso de utilizar entrevistas como método de recolección, deben contemplar las consecuencias de audiograbaciones (reconocimiento de voz) y videograbaciones (protección de la

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Author for correspondence: maria.grande@hospitalitaliano.org.ar, Grande Ratti MF.

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imagen). Los datos recabados pueden ser sensibles y revelar información delicada sobre las personas, por lo que el uso de verbatims debe ser anonimizada.

Palabras clave: Ética en Investigación, Investigación Cualitativa, Confidencialidad

INTRODUCTION

Ethical considerations in any research project (quantitative, qualitative, or mixed) are essential to ensure they proceed responsibly, respecting the rights and well-being of the participants while maintaining scientific integrity.

What is the difference between guidelines, norms, and principles?

Universal ethical principles are based on guidelines, norms, and principles, which should be applied in the ethical review of research protocols.

Guidelines. They are recommendations provided to guide behavior or decision-making. They are less rigid than norms, thus allowing some flexibility in their interpretation. They are used to establish quality standards or to provide guidance on how to address specific situations. For example, the CIOMS Guidelines of the Pan American Health Organization, in Guideline 10 of the 2016 version, include modifications and waivers of informed consent, establishing when a research ethics committee could approve them[1].

Norms. They are specific and detailed rules that regulate behavior or activity in a particular area. They do not only indicate what is considered acceptable or unacceptable for a given context but are also more concrete. For example, in scientific research, there is a norm for accurately citing the sources used to avoid plagiarism. This basic rule involves listing the sources relied upon with precise, complete, and coherent references. The Vancouver style is the most widespread in health: it uses numbers within the body of the article that refer to the formatted citations in the reference list at the end of the work.

Principles. They are fundamental and general statements that guide behavior, decision-making, and actions in a specific area. Unlike guidelines and norms, they are more abstract and broad.

What are the four bioethical principles?

Medical ethics is often confused with bioethics, but they do not mean the same thing. Bioethics is a branch of ethics whose purpose is to try to respond to the conflicts that arise from scientific advances, ensuring the well-being of life (human, animal, or plant), and therefore it goes far beyond medicine.

In health sciences research, the four bioethical principles are undoubtedly fundamental (Table): Beneficence, Non-maleficence, Justice, and Autonomy[3].

What are the ethical safeguards of qualitative research?

Qualitative research is an approach that focuses on deeply understanding and exploring people's experiences, perspectives, meanings, and contexts, as well as phenomena. Unlike quantitative research (based on numerical data), it relies on collecting and analyzing data such as texts, images, observations, and narratives. Therefore, the data collection instruments most frequently used are interviews, observations, documents (e.g., diaries, letters, reports, complaint books, photographs, and other written or visual materials), journals or records (which document daily experiences, thoughts, and emotions), narratives (e.g., stories, life histories, or testimonies), or focus group discussions[4]. Even multiple methods can enrich the understanding of the studied phenomena and provide a more complete and profound picture of the participants' experiences.

We describe some ethical safeguards to consider in qualitative research in particular(Fig. 1).

Ethical approval. Although it is not a mandatory condition for presenting scientific work at congresses (or even in some scientific journals), it is important to know and respect the regulations. Ethical approval implies the review of the protocol by a committee. It is a fundamental process that must be carried out for any project before the study itself begins.

The purpose is to ensure the research takes place ethically, respecting the rights and welfare of the participants involved. This committee will guide how to safeguard the rights and welfare of the participants. It is responsible for evaluating various aspects of the project to ensure that it complies with ethical and legal standards (e.g., Law 3301/09 of the Autonomous City of Buenos Aires, on the Protection of the Rights of Subjects in Health Research), as well as with principles of integrity and protection of human rights.

Informed Consent. It is a communicative process that certifies the decision of an individual (or their legal representative) to participate in an investigation voluntarily and free of undue influence, incentives, or coercion. For this, it is necessary to inform an autonomous and competent person who can understand the purpose and nature of the research, about the risks they will face and the benefits they might receive, and who knows their rights as a participant[5]. The understanding of the information depends on the individual's maturity, intelligence, and education but also on the ability and willingness of the researcher to convey it.

Table. Cuatro principios bioéticos en investigaciones de ciencias de la salud

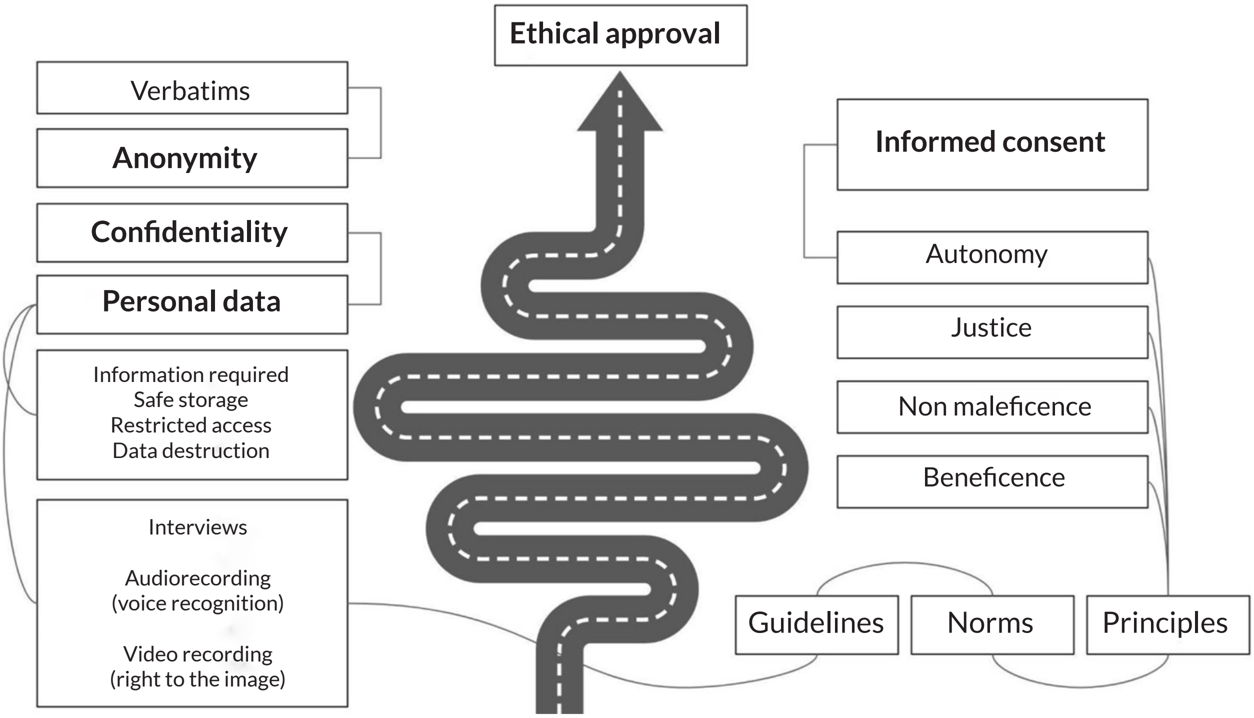
Beneficence[3]	A moral duty that involves acting for the benefit of others, promoting the well-being and best interests of individuals, which we commonly refer to as "doing good." For researchers, this translates into the responsibility of considering the well-being of the subjects at all times and taking the necessary measures to minimize any possible risks associated with participation in the research.
Non-maleficence[3]	A principle based on respect for others and the environment. This principle can easily be summed up by the Latin phrase "primum non nocere" which translates to "first, do no harm." Researchers must identify and mitigate any possible risk/harm to participants (whether physical, emotional, or psychological) before starting the research and be ready to handle situations where unexpected emotions or reactions arise.
Justice[3]	It involves treating people fairly and equitably without discriminating or showing favoritism. It means giving everyone what they deserve, applying equality criteria, and trying to reduce the causes of discrimination as much as possible. The selection of participants should avoid discrimination or unjustified exclusion of specific groups, and research should not increase existing inequalities.
Autonomy[3]	Autonomy is the capacity of individuals to make their own decisions and act on them freely, without interference or personal limitations generated by external aspects. In bioethical and scientific language, informed consent is the concretization of the principle of autonomy, an act by which a patient agrees (or rejects) the indication or medical proposal after receiving complete, adequate, clear, and precise information.

In a qualitative project using prospective collection methods, researchers must provide relevant information and the opportunity to give voluntary and informed consent to participate or refrain from doing so. This consent can be indicated in several ways: verbal or written with a signature sheet6. Usually, the consent should be in writing unless an ethics committee approves an oral waiver under certain conditions or grounds.

However, even when consent has been granted verbally, investigators must: a) provide documentation of the process (e.g., having a witness present at the time consent was obtained, recording the waiver as part of the interviews, or leaving a record/recording in the electronic medical record) and b) all participants should receive a committee-approved information sheet that they can take with them (brief, no more than two or three pages, in understandable language).

Confidentiality. The data may involve the participant's identity, but we take measures to protect that information. That implies protecting the study subject's identity and personal information, ensuring that only authorized persons have access, and taking the necessary measures to ensure that it is not shared or disclosed to unauthorized third parties. On the one hand, it is advisable to apply the precautionary principle, and *unnecessary information should not be made available* (e.g., date of birth, ID card number, name, and surname, which can be recognized by simply consulting the electoral roll and other similar sources). On the other hand, *it is essential to plan the destruction of the data* once used for the purpose requested.

There has long been a persistent paradigm of the postal code as the personal health destination of individuals[7]; however, there are also studies that mention the *risk of re-identification of individuals* based on three



Source: Own elaboration using Google Slides(®)

Figure 1. Ethical safeguards in qualitative research.

simple demographic variables: the complete postal code, date of birth, and gender[8]. Thus, health data should remain stored in a secure system with guarantees and backup. Also, with structured permissions according to user role, passwords, encryption, and secure servers[9].

Anonymity. The terms are often confused and assumed to be synonymous; however, anonymity refers to a situation in which the participants' data/responses cannot relate to their identity, even if the principal investigator does not have access to information that would allow participants identification.

Generally, anonymity is not feasible in qualitative research with prospective collection through interviews because they use audio or video recordings, where one must also be careful about *voice recognition and care of the image* (Article 53 of the Civil and Commercial Code on "Right to Image")[10]. It is advisable to destroy these recordings as soon as possible, once transcribed into text, and to keep these files unidentified (e.g., "Interview 1", dd/mm/yyyy).

Verbatims. These are an essential tool in qualitative research, as they allow researchers to present the voices and perspectives of participants authentically and directly. They refer to verbatim quotations or exact fragments of subjects' responses or comments. When using them in a report, it is critical to ensure that quotes appear in a way that is accurate (true to the original words) and contextualized (allowing readers to understand the meaning).

CONCLUSIONS AND REFLECTIONS

Qualitative research protocols must be subject to independent review by a committee to ensure they achieve the maximum benefits, have clinical and scientific value, and respect ethical principles.

Informed consent guarantees the provision of pertinent information and the opportunity to participate voluntarily and knowledgeably (or to abstain from doing so), respecting autonomy. Conventionally, it should be in writing unless a committee has approved an oral waiver.

However, there is a growing number of studies using *electronic informed consent*. Undoubtedly, current principles and regulations cannot cover all conceivable situations in light of new advances in science and technology[11]. A systematic review mentions that the perspectives of various domains (ethical, legal, regulatory, and user interface) must be addressed using six concepts: format, impact on understanding, acceptability, security and trust, storage, and content. It will be necessary to avoid extreme positions and maintain a context of dialogue and respect for these challenges imposed by innovations.

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