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Drafting of opinions in research ethics committees: foundations, methodology, and good practices

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Abstract

The ethical evaluation of research involving human beings is fundamental to ensuring dignity and scientific integrity. However, a gap persists in the literature regarding practical and structured guidelines for the drafting of opinions, which are often perceived as opaque or bureaucratic. This study aims to provide a conceptual and operational framework for the production of substantiated and transparent opinions. A narrative review was conducted, integrating contributions from recent literature and guidelines from international bodies such as the WHO and the Belmont Report. The results indicate that the quality of the opinion depends on a logical structure that articulates methodological rigour with the principles of autonomy, beneficence, and justice. Evidence demonstrates that the dialogue between the committee and researchers is an essential dialogical process for the improvement of protocols. Collectively, the results underscore that the opinion should function as a pedagogical instrument, avoiding jargon and substantiating every requirement in regulatory standards. From a management perspective, this suggests the need for continuous training of members in practical wisdom (phronesis). This work is original in proposing a specific rhetorical architecture for ethical judgement, transcending mere administrative compliance through a deliberative approach.

Keywords

Ethics Committees, Ethical Opinion, Deliberation, Bioethics, Phronesis

1. Introduction

The ethical analysis of research involving human beings places us before a fundamental interrogation regarding the limits of knowledge and the conditions of possibility of science as a human enterprise. Research ethics committees, known internationally as Research Ethics Committees (RECs) or Institutional Review Boards (IRBs), do not limit themselves to exercising a function of bureaucratic control: they embody the critical conscience of the scientific community, the reflective moment where the impetus to know confronts the requirement not to instrumentalise the other. The ethical opinion represents the crystallisation of a deliberative process that articulates methodological rigour, theoretical density, and communicational clarity, determining not only the effective protection of participants but the very integrity of the scientific project as a search for truth at the service of human dignity.

The responsibility of drafting ethical opinions inhabits the constitutive restlessness between the imperative of protecting human rights and the recognition of research as an existential necessity of the human condition. This article proposes to interrogate the theoretical foundations, the methodological procedures, and the good practices that configure the drafting of ethics committee opinions, integrating

contributions from recent literature and international guidelines. The objective consists of providing a conceptual and operational framework that allows committee members to produce documents of high quality, transparent and rigorously substantiated, recognising that each opinion constitutes, ultimately, a prudential judgement on the conditions of possibility for etically sustainable research.

2. The theory and practice of ethical judgement: institutional architecture, collective deliberation, and opinion crafting

2.1. Ethical foundations of evaluation: guiding principles

The ethical evaluation of biomedical and behavioural research is anchored in a conceptual edifice built upon the historical recognition of the multiple ways science can pervert itself when autonomised from ethical limits. The Belmont Report, published in 1979 by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research of the United States, emerges not as an arbitrary construction, but as a reflective sedimentation on the historical violations of human dignity perpetrated in the name of scientific progress. This document constitutes the ethical basis of North American federal regulations and has exerted profound influence on ethical review systems worldwide, configuring a species of moral grammar shared by the international scientific community (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1979). The Belmont Report identifies three fundamental ethical principles: respect for persons, beneficence, and justice (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1979). The principle of respect for persons incorporates two fundamental ethical convictions: first, that individuals should be treated as autonomous agents; second, that persons with diminished autonomy are entitled to protection (Office for Human Research Protections, 2025). An autonomous agent is an individual capable of deliberation about personal goals and of acting under the direction of such deliberation. Autonomy reveals itself here not as an abstract capacity, but as an existential condition of being-able-to-be-oneself, of self-determination that grounds the dignity of the person. This principle is subdivided into two moral requirements: the recognition of autonomy as an intrinsic value and the protection of those whose autonomy is temporarily or permanently compromised.

The second principle, beneficence, establishes that persons must be treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being. Beneficence comprises two complementary rules: do not cause harm and maximise possible benefits while minimising possible harms (Brothers et al., 2019). The Hippocratic maxim of doing no harm traverses the history of medicine as a categorical imperative. As the Belmont Report observes, Claude Bernard extended this principle to the domain of research, arguing that one should not cause harm to a person regardless of the benefits that might result for others (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1979).

The third principle, justice, requires that the benefits and risks of research be distributed equitably. This principle interrogates not only who participates in the research, but above all who bears the risks and who will obtain the benefits. Sample populations should be selected for reasons related to the problem studied and not because certain classes of people are easily accessible, manipulable, or convenient for researchers (Office for Human Research Protections, 2025). Justice thus reveals itself as a structuring principle that questions the power asymmetries inscribed in research relations.

The application of these principles to the practice of ethical review frequently involves irreducible restlessness and contradictions that summon deliberation as a method of navigation within complexity. As Resnik (2021) observes, ethics committees must, in most cases, base their decisions on empirical evidence, although other sources of knowledge, such as intuition, emotion, and rational reflection, may play a role in decision-making, given that ethical decisions involve a value component not reducible to science. This irreducibility of the normative to the factual constitutes the condition of possibility and the permanent challenge of ethical deliberation.

2.1. Structure and composition of ethics committees: architecture of collective deliberation

Research ethics committees constitute independent bodies composed of members with both scientific and non-scientific competencies, whose function consists of ensuring the protection of human rights and the well-being of research participants. The independence of these structures does not represent a mere administrative formality, but a transcendental condition of their legitimacy: ethical judgement loses validity when contaminated by interests that precede or determine it. This independence is critical to guarantee that the interests of participants are always prioritised and not secondary to other interests, such as scientific advancement or economic gain (European Patients' Academy on Therapeutic Innovation, 2021).

The multidisciplinary constitution of committees reflects the philosophical recognition that ethical truth does not emerge from the mechanical application of rules, but from the dialogued confrontation of diverse perspectives. A study conducted by Mehta et al. (2023) on 146 national ethics committees revealed that 82.7% included a philosopher or specialist in bioethics amongst their members. This presence is not justified by the need for academic legitimation, but by the recognition that ethical questions summon a way of thinking that surpasses techno-scientific rationality, demanding reflection on concepts such as dignity, autonomy, vulnerability, or distributive justice.

The functioning of committees is governed by standard operating procedures that specify quorum requirements, review criteria, and decision-making processes. The Declaration of Helsinki, in its most recent revision, proposes for the first time the submission of research protocols to an ethics committee prior to the commencement of studies (Mehta et al., 2023). This requirement for prior review has become an international standard for research involving human beings, institutionalising the reflective moment as a necessary condition of scientific action.

2.2. Ethical deliberation process: phenomenology of collective decision

Ethical deliberation constitutes the core of the committees' work and reveals itself as a hermeneutic praxis where the research protocol is interpreted in light of ethical principles and the concrete experiences of the deliberators. This process refers to the careful reflection and discussion of research projects, considering ethical principles and values arising from relevant local and international guidelines (European Patients' Academy on Therapeutic Innovation, 2021). During the discussion, all members present should contribute and provide their competencies and perspectives, configuring an interpretative community that collectively constructs the ethical meaning of the project under analysis.

For each member to participate meaningfully, all documentation relevant to the review must be received and analysed by all members before the discussion, allowing the time of the meeting to be effectively a time of deliberation, not merely of information. Members must have sufficient time to communicate their points of view during deliberation. When different norms and ethical concepts appear relevant but lead to contradictory conclusions, the aporetic nature of applied ethics manifests itself, demanding a reflection that is not satisfied with the logical subsumption of the particular case to the general norm (European Patients' Academy on Therapeutic Innovation, 2021).

The decision phase succeeds deliberation as a moment of practical synthesis. Ideally, the committee deliberates and arrives at a collective opinion or consensus that all members consider ethically satisfactory. The consensus reached by a committee is valid provided it emerges from honest, fair, factually well-informed deliberations that follow standard operating procedures (European Patients' Academy on Therapeutic Innovation, 2021). However, in reality, this convergence is not always reached. Sometimes, a decision is not completely acceptable to some members, but they agree that their concerns were heard and discussed, thus considering the process of deliberation and decision-making fair. This procedural acceptability configures a form of legitimacy that does not depend on substantive unanimity.

Decisions by voting, in opposition to consensus, should be restricted to exceptional circumstances. Voting privileges the number of people who defend a certain opinion but does not consider the reasoning underlying the opinions defended (European Patients' Academy on Therapeutic Innovation, 2021). The vote quantifies positions but obscures arguments. Consensus, conversely, privileges the quality of argumentation and requires that each position be rationally defensible before others. The chairperson of the committee assumes responsibility for the decision-making process, particularly in determining when consensus is necessary to reach a decision, exercising a species of deliberative prudence that navigates between the need for decision and respect for complexity (World Health Organization, 2010).

2.3. Structure of the opinion: rhetorical architecture of ethical judgement

Based on what is described in the literature, highlighting the contributions of the European Patients' Academy on Therapeutic Innovation (2021), the opinion of an ethics committee should follow a logical structure that facilitates understanding and allows for the verification of the substantiation presented. Although no single internationally accepted format exists, the literature identifies essential components that must be present in any quality opinion. The structure of the opinion is not a mere formal matter: it configures the very possibility of ethical judgement becoming intelligible and criticisable.

The document should commence with the clear identification of the research project under analysis. This section includes the full title of the study, the name of the principal investigator, the proposing institution, the reference number assigned by the committee, and the submission date. The clarity of this identification is fundamental for traceability and proper archiving of processes, but also to establish the reading contract: upon what does this opinion pronounce itself. The methodological section of the opinion presents a synthesis of the research project. This synthesis does not intend to replace the full protocol, but rather to demonstrate that the committee has adequately understood the objectives, methods, target population, and proposed procedures. The capacity to synthesise the project evidences the quality of the analysis performed: to understand is already to interpret, and to interpret adequately presupposes having apprehended the essential structure of what is interpreted.

The core of the opinion consists of the ethical evaluation properly speaking. This section must systematically address the established evaluation criteria, demonstrating how the project respects or fails to respect fundamental ethical principles. The evaluation should be structured logically, sequentially addressing different dimensions of the ethical analysis, configuring an argumentation that offers itself to rational verification and critical scrutiny.

2.4. Evaluation criteria: hermeneutics of applied principles

The ethical analysis of a research protocol involves multiple dimensions that must be systematically considered, recognising that each dimension opens a specific interpretative horizon regarding the project. Respect for the principle of autonomy materialises primarily through the informed consent process. Committees must examine the process through which informed consent will occur, as well as the information that will be provided (World Health Organization, 2010). Committees may waive the requirement for informed consent only when such is consistent with international guidelines and national standards, recognising that the waiver of consent constitutes an exception that lacks particularly rigorous substantiation.

A study conducted by Martín-Arribas et al. (2012) on the experience of an ethics committee in the evaluation of research protocols revealed that approximately two-thirds of the projects presented contained some type of ethical or administrative deficit. The majority of the committee's observations related to the principle of autonomy, mainly to informed consent, but also to the principles of beneficence and non-maleficence. This statistic suggests not so much the incompetence of researchers as the intrinsic difficulty of anticipating all ethical implications of a protocol, confirming the need for the external gaze of the committee.

The evaluation of the risk-benefit balance constitutes a critical dimension of ethical analysis that questions the very rationality of prudential weighing. Before seeking committee approval and conducting a study, researchers must analyse potential risks and benefits for participants. Examples of possible risks include physical harm, loss of privacy, unforeseen side effects, emotional suffering or embarrassment, monetary costs, physical discomfort, and loss of time. Possible benefits include access to a potentially valuable intervention, increased understanding of a medical condition, and satisfaction from helping others with similar problems (Capili & Anastasi, 2024). The weighing of risks and benefits is not an arithmetic operation, but a judgement that mobilises Aristotelian *phronesis*, the practical wisdom that discerns the just mean in each concrete situation.

The fair selection of participants relates directly to the principle of justice and interrogates the structures of power that traverse scientific research. The committee must analyse whether inclusion and exclusion criteria are appropriate regarding the study objectives and whether they do not reflect prejudice or the convenience of the researcher. Vulnerable groups deserve special attention. Vulnerable populations include pregnant women, children below the age of consent, terminally ill individuals, institutionalised persons, and those with mental or emotional disabilities (Capili & Anastasi, 2024). Vulnerability configures itself here not as an intrinsic property of certain groups, but as a relational condition produced by the intersection of multiple social, economic, and political factors.

2.5. Drafting the opinion: clarity, objectivity, and substantiation as ethical imperatives

The quality of the opinion's drafting determines its practical utility and credibility, but also its very validity as an act of rational communication. The document must be written in clear, objective, and accessible language, avoiding unnecessary jargon. Each relevant statement must be substantiated, whether through reference to ethical guidelines, applicable regulations, or pertinent scientific literature. Substantiation is not a rhetorical ornament, but a condition of possibility for the intersubjective verification that distinguishes rational judgement from arbitrary opinion.

Transparency constitutes a fundamental requirement that is not reduced to a technical issue, but assumes an ethical commitment to the possibility of public scrutiny. A central criticism of ethics committees throughout the literature has been their lack of transparency and failure to associate clarifications with a corresponding regulation or ethical position (Serpico, 2024). Researchers may perceive opaque requests as a fishing expedition, or worse, research administration as a burden and a barrier. Researchers expect an ethical review supported by clear explanations and regulatory standards, legitimately demanding that the power of approval or rejection be exercised in a rationally justifiable manner.

The language used should be neutral and impersonal, but clarity should not be sacrificed for neutrality. The opinion communicates a decision that has a direct impact on the researchers' work and, potentially, on future participants. Terminological precision is essential to avoid ambiguities that might compromise understanding, recognising that language is not a neutral instrument, but a *medium* wherein ethical thought itself is configured. When the committee identifies ethical problems in the protocol, the opinion must clearly specify which modifications are necessary and for what reason they are required. The justification must reference specific ethical principles or applicable regulatory requirements. This specificity allows researchers to understand the committee's concerns and effect appropriate corrections, transforming the opinion into a pedagogical instrument that contributes to the ethical training of researchers.

Committees have historically had a reputation for hiding behind a veil of anonymity, not providing justification or foundation for their decisions and seeking arbitrary reviews that fundamentally alter the scope of the research (Serpico, 2024). This opacity not only compromises the legitimacy of decisions but perverts the very nature of ethical deliberation, which requires publicity and the possibility of rational contestation. The careful and substantiated drafting of the opinion contributes to modifying this negative perception, restoring to the ethics committee its dignity as a rational instance.

2.6. Types of opinions: modalities of ethical judgement

Ethics committees may issue three main types of opinion: favourable, unfavourable, or request for modifications. Each modality configures a different relation between the committee and the protocol, between ethical judgement and the scientific project. The favourable opinion indicates that the research protocol complies with ethical requirements and may proceed as submitted. This type of opinion must clearly specify that approval applies to the revised protocol and associated documentation, identifying the specific version of the documents approved. Approval is not a blank cheque, but the validation of a specific protocol at a given moment.

The unfavourable opinion results when the committee determines that the protocol presents fundamental ethical problems that cannot be resolved through modifications. This decision must be carefully substantiated, explaining the specific ethical reasons that prevent approval. The unfavourable opinion does not necessarily mean that the proposed research lacks scientific merit, but rather that, in the form presented, it does not comply with the ethical standards necessary to protect participants. Rejection configures itself as a limit that ethics imposes on science, recognising that not all possible knowledge is legitimate knowledge.

The type of opinion most frequently issued requests modifications prior to approval. The committee identifies aspects of the protocol that require alteration or clarification. The opinion must specify with precision which modifications are necessary and why. This specificity allows researchers to respond adequately to the identified concerns, configuring a dialogical process where the protocol is perfected through critical confrontation. A study on ethics committees in the United Kingdom revealed that ethical review may involve multiple iterations. The median number of versions presented was two, and the process of evaluation and approval lasted a median of 13.5 days (Martín-Arribas et al., 2012). These data suggest that the dialogue between the committee and researchers constitutes a normal and expected part of the process, demystifying the idea that ethical approval is obtained in a single submission or that requests for modification represent serious failures.

2.7. Deliberation and decision: collective processes of judgement construction

Decision-making in ethics committees involves complex considerations that are rarely resolved through binary lines, revealing the fundamentally aporetic nature of applied ethics. There is a considerable grey area in ethical decision-making. More than one set of norms, values, principles, and habitual practices may legitimately apply to the issues involved (Markham & Buchanan, 2012). It becomes difficult to formulate judgements on which set applies, especially when one conflicts with another in some way. This difficulty represents not a defect of ethical thought, but its structural condition.

Consistency in ethics committee decisions has been the subject of academic debate interrogating the very nature of practical rationality. In response to growing concerns regarding inconsistency in ethics committee decision-making, Friesen et al. (2019) introduced the decision-maker's dilemma, which arises when complex normative decisions must be made regularly. Those facing such decisions can develop an algorithmic decision-making process, in which consistency is ensured but many morally relevant factors are excluded from the process, or embrace discretionary decision-making, which allows space for morally relevant factors to model decisions but leads to inconsistent decisions.

Based on an exploration of the similarities between criminal sentencing systems and ethical review of research, Friesen et al. (2019) argue in favour of a discretionary system of decision-making, even if it leads to more inconsistency than an algorithmic system. This defence of discretion recognises that ethics cannot be reduced to calculation, that prudential judgement requires considering the irreducible particularities of each situation. Committees must have space to exercise informed discernment and consider the particularities of each protocol, recognising that absolute consistency is achieved at the price of moral blindness.

The chairperson of the committee assumes responsibility for the decision-making process, namely in determining when consensus is necessary. Researchers, funders, or others directly associated with the protocol in question are not present during committee deliberations, preserving the space of deliberation free from external pressures. Committee members recognise the limitations of their knowledge and seek external contributions when necessary, particularly regarding research involving people whose life experiences may differ significantly from those of committee members (World Health Organization, 2010). This recognition of epistemological limitation configures a form of intellectual humility that qualifies the exercise of judgement.

2.8. Documentation and communication of the decision: writing as the concretisation of judgement

The committee's decision must be communicated in writing to the applicant and relevant authorities in accordance with national requirements. The appropriate archiving of records also promotes due process. The committee must ensure it retains, and is prepared to make available, relevant records of its decisions, procedures, etc., for the required period of time (European Patients' Academy on Therapeutic Innovation, 2021). Documentation is not a mere bureaucratic formality, but a condition of possibility for accountability and historical verification.

The written opinion constitutes the official document that formalises the committee's decision, materialising in text what previously existed as oral deliberation. This document must clearly identify the trial, the documents reviewed, and record the dates of approvals, modifications required prior to approval, disapproval of a proposed trial, or termination or suspension of any prior approval. Continuous review of ongoing trials is required at intervals appropriate to the degree of risk to human subjects, but at least once per year (European Patients' Academy on Therapeutic Innovation, 2021). The temporality of approval recognises that the research project develops in time and may diverge from the initially approved protocol.

Effective communication between the committee and researchers facilitates the resolution of ethical issues and promotes the quality of research, configuring a dialogical space where knowledge is perfected through critical confrontation. Chirico and Bramstedt (2022) propose that the feedback mechanism for ethics committees be expanded for additional purposes related to the understanding of research proposals, as well as stakeholder opinions and community impact. This proposal recognises that the committee should not function as an isolated instance, but as a node in a wider network of social deliberation on scientific research.

2.9. Training and capacity building of members: the education of ethical judgement

The quality of opinions issued by ethics committees depends directly on the training and capacity building of their members, recognising that ethical judgement is not a natural gift, but a competence that is cultivated. The literature review reveals that the lack of scientific competence of reviewers can affect the quality of research (Mehta et al., 2023). Regular training in research ethics and good clinical practice, together with adequate consultations with external specialists, becomes necessary to maintain the quality of the committees' work.

The training of ethics committee members is conducted in various regions under different frameworks. Programmes seek the training of members regarding good clinical practice, bioethics, establishment of ethics committees, review processes and standard operating procedures, selection of independent consultants, and confidentiality agreements (Mehta et al., 2023). This systematic training contributes to improving the consistency and quality of ethical analyses, although it cannot replace the effective exercise of deliberation as a praxis through which prudential judgement is formed.

The American Society for Reproductive Medicine (2023), through its Ethics Committee, regularly produces opinions on complex ethical dilemmas in reproductive medicine. These opinions serve as models of good practice, demonstrating how contemporary ethical questions can be analysed and communicated in a clear and substantiated manner (American Society for Reproductive Medicine,

2023). The existence of exemplary models does not dispense with the work of interpretation in each concrete case, but provides references that guide deliberation.

3. Final considerations: drafting opinions as an exercise of practical prudence

The drafting of ethics committee opinions constitutes an intellectually demanding activity that requires the integration of ethical, scientific, regulatory, and practical knowledge, but also, above all, a form of practical wisdom that cannot be reduced to the mechanical application of rules. The opinion represents more than an administrative decision: it constitutes an act of judgement that articulates the universal of principles with the particular of concrete situations, exercising that capacity for discernment that the Aristotelian tradition designated as *phronesis*.

The quality of an opinion is measured by its clarity, substantiation, transparency, and practical utility, but also by its capacity to honour the complexity of the issues at hand without getting lost in paralysing indecision. A well-drafted opinion does not limit itself to communicating a decision: it explains the reasons for that decision, references applicable ethical and regulatory principles, and provides constructive guidance to researchers. This approach promotes not only the protection of participants in the specific project under analysis, but also contributes to the training of researchers and the development of a culture of integrity in research.

The restlessness between the need for consistency in decisions and the importance of considering the particularities of each protocol remains as a conceptual and practical challenge that admits no definitive resolution, but requires prudent navigation. The solution does not lie in the search for absolute uniformity, which would sacrifice the consideration of morally relevant factors, but in the clear articulation of the principles and reasoning that substantiate each decision. This transparency allows different committees, although they may reach different conclusions in complex cases, to do so through rigorous and duly substantiated deliberative processes, maintaining the possibility of rational dialogue between different instances of ethical review.

The future of ethical review will benefit from international dialogue between committees, the sharing of good practices, and the development of training resources. The growing complexity of ethical issues emerging from technological innovations and international collaborations requires that ethics committees maintain a capacity for adaptation and continuous learning. The ethical opinion, as a product of this collective work, must reflect not only the mechanical application of rules, but the practical wisdom that emerges from careful deliberation on how to protect human dignity in the context of the search for scientific knowledge. This wisdom is not taught through manuals, but cultivated through the reflective exercise of deliberation, recognising that each opinion constitutes, simultaneously, a judgement on a specific protocol and a contribution to the collective construction of a research ethics that honours both the need to know and the imperative not to instrumentalise.

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