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**The Ethics ‘of’ Research and ‘in’ Research:
the Expanding Role of Committees of Ethics in/for Research**

ABSTRACT

There has been a growing awareness of the needs of 'ethics' in research in recent years. Not only for pragmatic reasons (as requests of Journals to publish or research institutions to complete the application) but also for theoretical increasing awareness. The article distinguishes, inside the ethics ‘of’ research, the ethics ‘in’ research and the ethics ‘for research’, and analysis the main values and principles shared in the European discussion. This article allows to acquire a general vision of the lines of research ethics for each researcher, with a particular focus in the European context, tracing the paths of research ethics with the identification of minimum ethical values in the different contexts in the field of the pluralism that characterizes the current reflection in research on humans, animals, the environment, and machines and raise some challenges for future developments.

1. Introduction

In the area of scientific research, a growing awareness of the needs of 'ethics' in research has emerged in recent years. For various reasons, mainly factual and pragmatic: to publish the results of their research, the journals ask for an opinion of the ethics committee; as part of the request for funding for research, in addition to scientific evaluation, ethical evaluation is also envisaged (for example, for research at the European Commission, a self-assessment questionnaire for research ethics is envisaged; but increasingly also within research centers and universities).

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Researchers who have not received specific training and education in the field of ethics in research (as generally happens, at least in the not strictly biomedical field where ethics, through bioethics, has had a certain diffusion), acquire awareness of it late (already in the phase of publication of the results), or they acquire awareness of them in advance by filling in questionnaires, but without specific skills that allow the appropriate processing of emerging problems.

It is necessary to acquire a general vision of the lines of research ethics for each researcher, with a particular focus in the European context, tracing the paths of research ethics with the identification of minimum ethical values in the different contexts in the field of the pluralism that characterizes the current reflection in research on humans, animals, the environment, and machines and raise some challenges.

2. Ethics 'in' research: codes of conduct

By 'research' in the scientific field we mean human investigation which through the rigorous experimental method has the purpose of generating, increasing and innovating a knowledge of reality (basic, pure or fundamental theoretical research) in a general or specific sense also in view of the technological applications (applied research) in various fields, natural, social and human sciences. By 'ethics' we mean moral reflection on the values that guide human behaviour in the direction and realization of good while avoiding evil².

A conceptual distinction should be made between the ethics 'in' research and the ethics 'for' research, although in reality they are closely interrelated.

As regards ethics 'in' research, we start from the general assumption that scientific research is good as it brings to fruition the intrinsic sense of man's knowledge and reason (it is good for knowledge to know, to expand knowledge), as long as the research is 'good' research and the researcher is a 'good' researcher. It is on

² AA. VV., *Europa. Le sfide della scienza*, vol. II, Istituto della Enciclopedia Italiana Fondata da Giovanni Treccani, Roma 2018.

these bases that the codes of conduct or behaviour internal to the 'profession' of those who carry out scientific research, in general, have arisen. These are ethical codes that make explicit the internal rules and duties of the researcher in scientific research, the so-called '*Good Scientific Practice in Research*'. The codes of conduct, between ethics and law, are generally developed in the institutions where the research takes place (both public and private), they are aimed at researchers, funders, evaluators and concern the research phases (planning, development, publication, diffusion), in a general or specific sense.

Many initiatives arose spontaneously or prompted the development in Europe of a dynamic and flexible self-regulation (also called "soft" regulation) of science in assuming responsibility towards society. As part of the proliferation of initiatives, *the European Code of Conduct for Research Integrity* of the European Science Foundation-All European Academies (ESF-ALLEA) issued in 2011 is of particular relevance. The document identifies the ethical principles of conduct in research without reference to the context of the research and the practices that encourage 'good' conduct in research: honesty, diligence, reliability, objectivity, impartiality, independence, absence of conflicts of interest, transparency, openness, accessibility, effectiveness, efficiency, cooperation, competence, updating, dissemination of knowledge.

The specificity of ethics in research in Europe, in the international context, is awareness of the insufficiency of passive knowledge and extrinsic observance of the code by researchers and the need to promote a culture through education of research integrity, through the acquisition of awareness, critical interpretation, internalization of the code, to become 'good' researchers, exercising the 'virtue' of research, in a constant disposition of mind, in personal active commitment, in the inner motivation to do 'good' research³.

3. Ethics `for` research

³ R. Iphofen (ed.), *Handbook of Research Ethics and Scientific Integrity*, Springer, Dordrecht 2020.

Ethics 'for' research integrates ethics 'in' research. The ethics 'for' research arises from the consideration that research is not a value in itself (regardless of the effects it produces), but that research is 'good' research insofar as in addition to correctness in the conduct of researchers in observing the rigor of the scientific method, it recognizes certain moral values. It is not enough to implement the correct behaviour of researchers to carry out 'good' research: it is also essential to reflect on the potential and limits of techno-science and on the moral values that guide research and the application of research in an era of extraordinary acceleration of scientific and technological progress in Europe. We can speak of progress in general, albeit in the diversification of levels reached in the various countries and in the diversity of the political, economic, social and cultural context in which the research is placed⁴.

Fields of application are: reproductive technologies, new possibilities of intervention on the genome, new frontiers of transplantation, pharmacological experimentation, the possibilities of the technological prolongation of human life, emerging technologies, biometrics, synthetic biology, telemedicine, nanotechnology, robotics, converging technologies, and also biotechnology applied to the non-human life, both animal and vegetable (GMO, hybridization, etc.).

We are facing unprecedented techno-scientific progress in our continent in terms of quantity, quality and speed of innovation, as well as in terms of the scope of application on the synchronic level (including both human and non-human beings, up to the environment in the broadest sense) and the diachronic level (projected to future generations). There is a general ethical question which arises: is everything that is (or will be) techno-scientifically possible also ethically lawful?

It is the question which bioethics asks itself and which inevitably involves ethics 'for' research. It is not easy to answer the question about the limits of techno-science, both in general and specific discussion, due to the pluralism that

⁴ Comstock G., *Research ethics. A philosophical guide to the responsible conduct of research*, Cambridge University Press, Cambridge 2013.

constitutively connotes the European debate. Some orientations and lines of thought expressed in the discussion are identifiable.

In the context of research on the human being, different orientations of thought should be distinguished.

Libertarianism, starting from a non-cognitivist view in ethics (which affirms the impossibility of knowing a moral truth), believes that moral subjectivism should be promoted, defending individual self-determination, within the limits of the search for compatibility between freedoms and absence of damage to others. Utilitarianism, based on the consideration of the instinctive propensity in individuals for the pursuit of pleasure and avoidance of pain, promotes social convenience, measured in the cost/benefit calculation with the maximization of well-being and minimization of pain for the greatest number of individuals

Personalism, in the context of the recognition of the intrinsic dignity of the human person in every human being, supports the principle of protecting human life, freedom and responsibility and justice and solidarity. Communitarianism, within the framework of the recognition of the value of the common good, promotes cooperation in society.

Principlism considers it necessary - given the impossibility of justifying a convergence between the different theories - to refer to general principles that can take on different meanings in different theoretical contexts: autonomy, beneficence, non-maleficence and justice. Supporters of the theory of virtue recognise essential in addition to the principles themselves their concrete realization in disposition to behaviour oriented towards moral values in practice, in addition to the mere extrinsic application of principles, Other ethical theories (ethics of care and responsibility), in different ways, focus on the relevance of taking care of others in conditions of particular vulnerability in the absence of symmetry and reciprocity, also including non-human living beings or not yet living human beings (future generations).

In the context of animal research, other orientations emerge. Animalism, in the various theorizations, aim at the recognition of subjectivity to animals as sentient beings (among which also utilitarianism which focuses attention on the interest of

animals not suffering; other orientations also defend the freedom and life of animals). The radical anthropocentrism that legitimizes the arbitrary use of animals is no longer supported; instead, there is an orientation of moderate anthropocentrism which, while affirming the priority of human dignity, recognizes the need to take due consideration of the interests of animals by prohibiting exploitation and instrumentalization.

In the context of environmental research, the debate is between the eco-centrism and antropocentrism. The eco-centric and bio-centric orientations, which argue in favour of the subjectivity of all forms of life in an equal and undifferentiated way, such as expressions of interest in living elements. Orientations inspired by responsible anthropocentrism, while recognizing a hierarchy between living elements and the priority of human dignity, justifies the principle of responsibility and precaution towards plants and the environment in general, in function of the protection of present and future human generations.

In the field of engineering and computer research, several theorizations are emerging, which oscillate between radical orientations of transhumanism and posthumanism and human-centrismo. Transhumanist and post-humanist hypothesize a man/machine equivalence in the "infosphere" where inanimate computer objects have a status comparable to living beings, including humans; where robots and cyborgs can acquire the status of 'electronic persons' endowed with 'autonomy' and in the future even substitute human beings, considerate vulnerable. The human-centric or human-centered orientation recognizes the primacy of human being over artificial entities, calling on the artificial to collaborate (help, support) with human beings but not to replace them.

4. The framework of shared values and principles in Europe for technoscience

In the context of a considerable heterogeneity in theoretical reflection, only synthetically outlined, a shared awareness emerges in a general sense in the European discussion of the distance-taking from extreme positions between: bio-optimistic technophiles and bio-pessimistic techno-phobes, between techno-scientism that

believe that the promotion of science is always good (the so called 'technological imperative) and anti-techno-scientific obscurantism which unconditionally considers it an evil. The commonality which emerges is that on the one hand an excess of liberalization risks exposing the individual and humanity to possible serious, invasive and irreversible risks and damages and on the other hand an excess of prohibition hinders and prevents the dynamic innovation of the progress of techno-sciences and does not adequately consider the social transformations that are taking place.

In this sense, a path is also outlined on the theoretical level in the direction of pondered, reflective and balanced bioethics that seeks, beyond rigid contrasts, with dialectical reflection in the arguments, an 'ethical mediation' on the theoretical level that is not reduced to a mere compromise or pragmatic agreement, identifying a minimum level of shared ethics (or a maximum level of sharable ethics, where possible) in balancing the principles and values at stake in the face of real complexity.

It is in this horizon that the ethics 'for' research of European culture is outlined. In Europe, despite the heterogeneity of ethics and cultures, there is a need to identify a table of common values, inscribed within the international horizon of human rights and articulated in a cultural sensitivity that has common historical and cultural roots. Europe is characterized by diversity: the plurality of its traditions, histories, ethnic groups, religions; the heterogeneity of political and legal systems and socio-economic contexts. The recognition of these differences is compatible with the search for harmonization, which is based on the recognition of common values⁵.

Even in the context of the ethical pluralism that has always characterized the international discussion, some minimum common principles and values of European ethics for research can be identified, including the perspectives of Anglo-Saxon bioethics, of Central and Mediterranean Europe. Each area retains some specificities, but some common general elements that make up the moral reference horizon for research are recognizable. These are principles mainly expressed with reference to biomedical research, but which can be applied to the ethics of research in general.

⁵ R. Huxtable, R. Ter Meulen (eds.), *The voices and rooms of European Bioethics*, London 2017.

In the context of human research, some shared principles emerge, at least at a general level, albeit with different meanings (in different theoretical contexts) and a different equilibrium between the principles⁶.

1. *The dignity of the human being*. It is a principle and a value that is loaded with different meanings: it oscillates from a vision that recognizes dignity to the human being in a strong, intrinsic and unconditional sense (in the personalist vision and ethics of responsibility) to a weak vision that attributes dignity in an extrinsic way based on the situation (the capacity for self-determination or social convenience). Dignity is an expression that is explicit in international documents even if it is not possible to clearly and precisely deduce the specific meaning with respect to the different applications, requiring an interpretative integration, in light of the state of ethical discussion and rules of the different countries. In a general sense, human dignity concerns the protection of the physical integrity and safety of the body, the prohibition of manipulation, exploitation also for commercial purposes, definition of the limits of physical-psychic invasiveness (e.g. use of devices, experimental treatments). The principle of dignity is often connected to that of vulnerability which justifies a particular attention towards persons in conditions of particular fragility and incapacity, as minors, the physically and mentally disabled persons, the elderly, women of childbearing age/pregnancy/breastfeeding, prisoners, soldiers, migrants, individuals from developing countries, people in poverty.

2. *Autonomy*. Autonomy indicates the recognition of freedom and responsibility, understood as respect for a person's ability to make personal choices. The autonomy of those participating in research is generally expressed by informed consent. Informed consent should not be reduced to a procedure or fulfilment of a bureaucratic measure as a contract between two subjects in a condition of symmetry:

⁶ The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, Office of the Secretary, *The Belmont Report*, Ethical Principles and Guidelines for the Protection of Human Subjects of Research, 1979; D.B. Resnik, *The ethics of research with human subjects. Protecting people, advancing science, promoting trust*, Springer, Dordrecht 2018.

sick or healthy subjects participating in research, are in any case in a condition of vulnerability, if only for the fact that they do not have the same competence as the researcher. The information should be understandable with reference to the chronological, existential, cultural and accurate conditions of the research (procedures, purpose, risks/benefits), explaining the consequences of the choice and the revocability of the consent. Those who participate in research should be explicitly informed of the freedom to withdraw at any time without giving a reason and without any negative consequences and on the right to have relevant research information 'returned'. Participation in research should never be 'coercive' or 'induced' either directly or indirectly: financial compensation is considered an induction to research, which alters (ethically) the gratuitous intention. Precise and complete information on specific research requires the reformulation of consent each time the research modifies its object of study. Total consent (or 'blanket consent'), is 'blind' consent that does not ask to know the itineraries of future research, it leaves the types of research unspecified and the period of time indefinite, it does not even include the receiving of research results: albeit comprehensible in the logic of gift and solidarity, it may be understood as uninformed naivety that forgets the individual, with a series of negative consequences, for the individual and the research itself. Partially restricted or general consent allows specific present and future research only if directly associated with the original research⁷. In the case of subjects unable to give consent (minors, individuals with disabilities), guardians (parents, support administrators) must be appointed to give substitute consent to the research.

3. *Proportionality or appropriateness*. It is the principle that makes explicit the need, in every action and field of application, for a balance of risks and benefits, orienting towards the maximization of objective benefits and the minimization of physical-psychological-social damages (be they possible, probable or potential). The risks should not be disproportionate to the potential benefits in assessing the comparative risk. The benefits include: the scientific quality of the research design,

⁷ The use of the (sensitive, personal) data of the participants in research (how they are used, who keeps them, for how long) for reasons of confidentiality and privacy must be specified.

the correctness of the method, relevant statistical analysis, publication of the positive/negative results, the competence of researchers, compliance with professional obligations and standards, adequate protection for participants. The risk should be minimized: research is not justified if there is a high risk of serious irreversible damage (even if the subject expresses consent), because it is a specific duty of the researcher to protect research participants. Risky research can be conducted when there is no alternative that can give comparable results and when there are already significant results from animal testing prior to entering human testing. The measurement of the risk of damage/discomfort should be put in reference to the participants in relation to the direct or indirect benefits for participants (indirect when the benefits do not concern the actual subject, but at least a group of individuals with the same characteristics). Risk should also be understood as psychological damage or socio-economic damage. In the case of incapacitated subjects and minors, the risk and discomfort should be minimal⁸.

4. *Justice*. Justice means ‘giving each person his or her due’: it is the principle that is based on equality and equity in the distribution of scarce resources and in the access to treatments, or to the results of scientific discoveries and technological applications. This principle has implications for the selection of participants and equity of access: participation should not be calibrated on the basis of the purpose of the research or even on the ease of obtaining consent. Groups that can benefit from the results should not be excluded. The exclusion and inclusion criteria should be justified on an objective and scientific basis. The distribution of benefit sharing to research participants should also be considered, with specific attention to the most vulnerable. In this field, the close connection between justice and solidarity emerges within the context of international cooperation.

5. *Precaution*. This is the principle applied to technologies of particular complexity: it consists in the possible decision to abstain from possible/plausible, non-quantifiable, potentially serious and irreversible damage in the absence of

⁸ S. Simonsen (ed.), *Acceptable risk in biomedical research: a European perspective*, Springer, Dordrecht 2012.

certainties, taking into account the scientific and technical knowledge available, with the aim to avoid, decrease or control the damage to humans, animals and the environment. It presupposes scientific risk assessment (risk assessment in terms of entity-probability), the identification of the risk as an estimate of the level and extent or the danger with respect to other risks and the political management of the risk (risk management). The need emerges for man, for every action, to rationally evaluate the negative consequences for other human beings, but also for the environment and future generations.

In the field of animal research⁹, despite the context of a diversification of theories, there is a shared stance on the protection of some values and principles:

1. *animal safety and well-being*: in consideration, also in the context of research, of the need to safeguard the integrity and quality of life and reduce suffering as far as possible;

2. *the protection of biodiversity*, even in terms of genetic diversity;

3. *the 'Ethics of the 3 Rs'*, *replacement* of animals to the greatest extent possible by adopting alternative and inanimate models to animal experimentation, *reduction* with particular attention to reducing the number of animals used for research and reduction of suffering, *refinement* of the experimental procedures in order to reduce the incidence or invasiveness of 'inhumane' procedures for animals which should in any case be used for research.

In the context of environment, the ethical principles generally evoked are:

1. *non maleficence*, or avoid or minimize damage and ensure long-term benefits to the greatest extent possible, considering the effects on present and future human generations, as well as on animal life;

2. *naturalness*, understood as minimization of human interference and modification in nature, in particular if interventions are irreversible, having long-term effects, and interacting with biodiversity;

⁹ M.J. Kuhar, *Research ethics in the life sciences*, Amazon Italia, Torino 2022; M.Z. Schrag, *Ethical Imperialism*, Johns Hopkins University Press, Baltimore 2010.

3. *sustainability*, as the safeguard of sustainable development understood as development that satisfies the present needs without compromising the possibility of future generations to satisfy their own; sustainable development involves respect for limits in the use of technologies and in the consumption of resources taking into account the capacity of the biosphere to absorb the impact of human activities; sustainability includes equity considered in the present time dimension and in the future projection;

4. *the precautionary principle*, indicates the need for responsibility and prudence stressing that humanity (both present and future) has the right to respect and to general ethical protection, as a condition for the defence of existence itself, and that the earth, as the home of human and living beings, should be safeguarded in accordance with the principle of sustainability.

In the field of engineering and computer science research, certain ethical principles of reference for research on big data, algorithms and artificial intelligence are emerging:

1. *meaningful human control* in the interaction with machines, in the critical awareness of man in the modality of the interaction and relationship with the machine in order to keep an oversight, without losing capacities (de-skilling) e decreasing responsibilities (de-responsabilisation);

2. *autonomy*, as an expression of human freedom with respect to the intelligent machine in the mode of control on the so-called "autonomous systems", or better to be called "automatic" systems; this implies the relevance of the predictability of "autonomous" systems, without which the user would not be able to decide whether to intervene or not when the action is deemed morally appropriate or inappropriate;

3. *responsibility*, translates into the need for the development and use of "autonomous" systems to be functional to the common good (the good of individuals and of society at large), responsibility should be transformed into precaution and prudence in the face of the potential abuse of technologies when high risks and potential unacceptable damage to humans and humanity emerge; in this sense,

research in this sector should be guided by an authentic awareness of the ethical requirements of "trustworthiness" of engineers and developers;

4. *quality of data*, with appropriate tools to verify the accuracy and correctness in the gathering, cataloguing and use of data, in particular those used for research purposes;

5. *transparency* of information to the user on the opportunities and limitations of technologies so that they gain awareness of them; the transparency (versus opacity) of algorithms as regards profiling, the sharing and using of data;

6. the promotion of *interaction* between engineering-IT operators and ethics experts for collaboration both in the information technology design phase and in the application phase, in order to ensure safety and privacy conditions from the outset (*safety-by-design* in addition to *privacy-by-design* and *privacy-in-design*);

7. *inclusivity*, as a guarantee of eliminating biases in the design and of ensuring equal access to new technologies in a global sense, so that everyone can benefit from them: discriminatory prejudices in this context should be identified and prevented, recorded and neutralized to the extent possible and in the shortest possible time.

5. *The increasing role of committees of ethics in/for research*

The objective of the committees for research is to implement an ethical reflection that balances the needs of scientific innovation with moral values in the context of the common horizon of human rights, the values of dignity and vulnerability, autonomy and responsibility, justice and solidarity, precaution and social and economic sustainability¹⁰.

¹⁰ *Ethical Assessment of Research and Innovation: A Comparative Analysis of Practices and Institutions in the EU and selected other countries* Deliverable 1.1 This deliverable and the work described in it is part of the project Stakeholders Acting Together on the Ethical Impact Assessment of Research and Innovation - SATORI - which received funding from the European Commission's Seventh Framework Programme (FP7/2007-2013) under grant agreement n° 61223.

In the “*Position of the European Network of Research Ethics Committees (EUREC) on Ethics Reviews of Research Projects involving Persons outside Biomedical Research to the attention of the the European Commission, the Council of Europe and the European Research Institutions*” (March 15, 2021), EUREC would acknowledge the increasing importance of ethics committees for research and ethics reviews of research projects inside and outside the field of biomedical research, and encourages research institutions to carefully take it into consideration.

EUREC, as the representative body of research ethics committees in Europe, underlines that in some jurisdictions it is difficult for researchers (above all outside the medical field) to find an ethics committee that will review their projects, having a necessity to have if for publishing or for applying research projects. The experience gained by medical research ethics committees during the last decades can support the establishment of ethical review procedures outside the field of biomedical research, considering and applying the general principles and values of reference shared, interpreting and adapting them in the different context¹¹. Knowledge and experience gained with existing medical ethics committees for research may be helpful to consider the problem both theoretically and practically: the common general principles and values should guide the evaluation, even always considering the specificity of the field of application¹².

Ethics committees for research may be established in different ways and by different institutions, like Universities, Research Institutions, and others, clarifying their independence, the scope of their legal competence, and the specific mandate. This should be clearly established, by the statute of the committees. The duty of researchers to submit research projects for a review should be clearly fixed by appropriate provisions, also identifying strategies to help researcher to gain

¹¹ E.A. Anderson, A. Corneli, *100 Questions (and answers) about Research Ethics*, Sage Pub. Library of Congress 2018; N. Jacobson, R. Gewurtz, E. Haydon, *Ethical Review of Interpretive Research: Problems and Solutions*, “IRB: Ethics & Human Research”, 2007, 29 (5), pp. 1-8; N. Jacobson, R. Gewurtz, E. Haydon, *Ethical Review of Interpretive Research: Problems and Solutions*, “IRB: Ethics & Human Research”, 2007, 29 (5), p. 3.

¹² J.D. Resnik, K. C. Elliott, *The Ethical Challenges of Socially Responsible Science*, “Accountability in Research”, 2016, 23, 1, pp. 31-46.

awareness of ethical problems (for example, self-evaluations questionnaires). A clear system for the appointment of members should be established, including an indication of bodies entitled to appoint the members and the duration of membership. Clear conditions for the qualifications of members of committees for research should be shared as well as initial and continued training of members in view of their professional qualifications and experience. Given the interdisciplinarity of the research and the dynamic innovations of technologies, also external experts may be involved in order to integrate competencies for the evaluation¹³.

EUREC recognises the importance to encourage in Europe the development of ethics review system also beyond biomedical research in front of the rapid development and applications of techno-science in different fields and the need to develop an ethics for research that could guide and orient researchers and committees' members in order to develop research always as having the priority to protect research participants¹⁴.

¹³ C. Beyrer, N.E. Kass, *Human rights, politics, and reviews of research ethics*, "The Lancet", 2002, 360/9328, pp. 246-251.

¹⁴ <https://www.emerald.com/insight/publication/issn/2398-6018>.