

# Ethics committees for non-clinical studies with humans: an unmet need

*Comitati etici  
per studi non clinici  
sull'uomo:  
una necessità  
da affrontare*

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## **ABSTRACT**

Ethics Committees (ECs) play a crucial role in the scientific endeavour. However, while animal research and clinical studies on patients are precisely regulated and duly submitted to ECs for ethical approval, projects in Social Science and Behavioural Research involving non-clinical research with humans fall in a legislative vacuum. We posit the request for the institution of local ECs dealing with Social and Psychological non-clinical research which would benefit from undergoing the process of ethical approval to support the well-being of participants and researchers alike.

## **ABSTRACT**

*I Comitati Etici (CE) hanno un ruolo importante per la conduzione della ricerca scientifica. Eppure, mentre studi con animali e studi clinici sono regolamentati minuziosamente e devono essere sottoposti ad approvazione etica, gli studi in scienze sociali e in quelle del comportamento, che coinvolgono l'essere umano in ricerche non cliniche, cadono in un vuoto normativo. Sosteniamo la richiesta di istituire CE locali che si occupino specificamente di ricerche in questi campi al fine di tutelare al contempo i ricercatori e il benessere dei partecipanti a questi studi.*

## **KEYWORDS**

Ethics committees  
*Comitati etici*

Non-clinical studies  
*Ricerca non clinica*

Social sciences  
*Scienze sociali*

Psychology  
*Psicologia*

Introduced in the Tokyo's (1975) version of the Declaration of Helsinki (1964) and confirmed in the Oviedo Convention on Human Rights and Biomedicine (1997), Ethics Committees (ECs) play a crucial role in the scientific endeavour. On one hand, they should ensure the accretion of scientific knowledge via new empirical evidence; on the other hand, they should warrant the human rights and dignity of the participating individuals, both researchers and volunteers.

The updated version of the Declaration of Helsinki (Fortaleza, Brazil, 2013, Article 23) states:

The research protocol must be submitted for consideration, comment, guidance and approval to the concerned research ethics committee before the study begins. This committee must be transparent in its functioning, must be independent of the researcher, the sponsor and any other undue influence and must be duly qualified. It must take into consideration the laws and regulations of the country or countries in which the research is to be performed as well as applicable international norms and standards but these must not be allowed to reduce or eliminate any of the protections for research subjects set forth in this Declaration. The committee must have the right to monitor ongoing studies. The researcher must provide monitoring information to the committee, especially information about any serious adverse events. No amendment to the protocol may be made without consideration and approval by the committee. After the end of the study, the researchers must submit a final report to the committee containing a summary of the study's findings and conclusions.

The task of ECs is to make sure that these principles are implemented and to assist researchers to acquire awareness of their responsibilities. They should vet the experimental design of the study, including specifying inclusion and exclusion criteria, as well as its scientific relevance and the competence of researchers. They should also ascertain that consensus is acquired appropriately; that potential and actual risks are assessed thoroughly and prevented or dealt with properly; that anonymity of the participants is guaranteed and that procedures to log data are watertight.

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The well-being of the researchers conducting their studies should also be safeguarded.

In practice, a researcher or a team of researchers apply to the appropriate EC to be granted approval to carry out their proposed research. In this application, the researchers are required to report all relevant information demonstrating the full awareness and fulfillment of the scientific and ethics standards in scientific investigation. Information should include the theoretical basis and the empirical questions of the planned studies; the methods, procedures and instruments that they will employ; the way the participants will be involved and informed about their rights in refusing or withdrawal from the study; any possible risk or adverse effect that the study could entail for both participants and researchers.

ECs should not be perceived as a bureaucratic hurdles or as quangos hindering research. On the contrary, ECs and researchers should collaborate towards improving research designs and bettering the study paradigm.

In Italy, and in most Western countries, animal research and clinical studies on patients are precisely regulated and duly submitted to ECs for ethical approval. However, with few exceptions, like the possibility for Italian National Research Council (CNR) researchers to ask for ethical clearance independently of the nature of their study<sup>1</sup>, Social Science and Behavioural Research projects with humans fall in a legislation vacuum almost everywhere. Behavioural, cognitive and social sciences (Sociology, Anthropology, Behavioural Economics, Educational Science and Psychology) lack the benefit of precise procedures allowing them to identify and access suitable ECs partners.

The Declaration of Helsinki though was mainly geared at medical research. However, overlapping principles are laid out also in documents from Social Sciences and Behavioural societies. For instance, the Economic and Social Research Council<sup>2</sup> and, in Anthropology, the European "Research Ethics in Ethnography/Anthropology"<sup>3</sup> or the American "Ethical Guidelines of the National Association for the Practice of Anthropology"<sup>4</sup>. In Psychology also there is acute awareness of the need for ethical codes and procedures for ethical approval. The Italian Association for Psychology<sup>5</sup>, The American Psychological Association<sup>6</sup>, the British Psychological

Society<sup>7</sup>, all strongly promote ethics for all types of studies. Yet, research by psychologists is required to be inspected by ECs only when the proposed studies involve animals or patients or use neuroimaging tools or invasive techniques. This creates a hiatus within the discipline – part of which will habitually share with ECs whereas other members of the same discipline, or even the same members in different contexts, cannot capitalise on institutional partners dealing with ethics in research. An increasing number of Psychology journals, grant awarding bodies and international research calls require a certified ethical approval to vouch for funding or to accept manuscripts for publications. This practice induces researchers to seek ethical approval *ex post*, forcing ECs into the unsuitable situation of having to endorse a study without the possibility of asking for modifications.

Therefore, there is an unmet need, which has to be addressed; we endorse the proposal that experimental studies in non-clinical populations should also benefit from interacting with ECs (see e.g., Wassenaar and Mamotte 2012). Individual institutions have attempted to enforce their own procedures, different from one another; Common ad hoc regulations are required.

ECs which will deal with non-clinical work in humans ought to pay particular attention to:

- vulnerable groups (children, frail older participants, prisoners);
- sensitive topics (political views, religious matters, emotional stimuli);
- use of deceit within the experimental paradigm;
- efficacy and appropriateness of the debriefing session;
- sample size (both in terms of "no more than" and "no less than").
- non diagnostic use of neuroimaging with particular reference to incidental findings;
- involvement of students as experimental participants in exchange for academic credits.

Establishing ECs to evaluate behavioural and social sciences studies presents with organisational issues. All projects should be assessed by a local EC. However, to avoid conflicts

of interest and possible interference due to personal interactions and the relative hierarchical status of applicants and members of the EC, it is advisable that the EC be organised at Faculty or College level and be composed mostly of trained non academics. The demand for a swift turnaround of the applications cannot be solved by institutionalising departmental ad hoc ECs. Rather, fast track procedures managed by independent staff could be conceived and guided by the use of carefully thought through checklists and by classing the different projects relative to their a priori complexity or the presence of problematic issues. It is important to stress that the notion of minimal risk (Baron 2015; Mayer 2013) is specious and should be avoided. Firstly, ethical considerations should not be limited to protect the physical and emotional well-being of the participants. Secondly, it should not be requested of researchers to decide on whether or not their own project should undergo ethics approval.

As stated above, all behavioural sciences need ECs. This is particularly relevant for studies proposing methods of participatory research based on direct field observations, interviews and exchanges with particular groups of individuals (Malinowski 1922). By using these methods, researchers may incur risks, the evaluation of which cannot be left to their good faith or to the vouching of their close colleagues working in the same department. Two recent, unfortunate instances from Anthropology and Sociology exemplify the need for an ethics appraisal of these studies.

On May 2016, a researcher of the university Federico II in Naples, Enzo Alliegro, has been formally accused of public disturbance as he was amongst rioters protesting against the chopping of olive trees affected by the bacterium *Xylella*. However, he was there to investigate the dynamics of the demonstration as part of his field research by means of participated observation. His ensuing problems with the law could have been moderated, or even prevented, had he been able to demonstrate that his study received previous ethical approval.

Far more gruesome are the atrocious events of January 25th 2016 which resulted in the torture and death of Giulio Regeni. He was a Cambridge PhD student in Politics and International Studies; his aim

was to use participated observation to investigate how independent trade unions were changing their organisation and relationship with the governmental authorities in Egypt after the 2011 revolution. Who or which body granted ethics approval for his study? The student's supervisor and the authorities at the University of Cambridge have been rather unforthcoming on the case, hence we do not know for sure which path to ethical approval his study underwent. However, given the common practice in Social Sciences and the information gleaned from newspaper reports, we doubt that the cost-benefits of the project were discussed within an external and independent EC.

Would his horrendous fate have been the same had his proposed field work been scrutinized by an independent EC? The perils embedded in his research would have been fully considered and probably reduced, had the project undergone a thorough perusal by an EC rather than the risk evaluation having been arbitrated by the researcher himself and his supervisor. Researchers directly involved in carrying out a project, due to their own passion for their studies, may not be in the best position to determine the real risks that a field work may entail. An independent panel should be involved to offer both an impartial, unbiased opinion on strategies to collaborate with local referents and recommendations for devising a careful acting plan.

ECs ought to guarantee both the researcher's right to investigate and the participant's rights when recruited to partake in research. ECs should also look after the interests of a third stakeholder: society at large, which invests human, instrumental and financial resources and demands scientific merit of research aims in terms of enhancement of basic knowledge or potential applications. When these rights and interests conflict, ECs are called on to propose solutions which mediate between them.

ECs work at cross-purpose with researchers more often than is desirable and they are hence perceived as a hindrance to research rather than team players whose remit is to better it (Baron 2015; Cubelli and Della Sala 2015; Della Sala and Cubelli 2016; Jansari et al. 2015). This perception has often been used as a reason to oppose widening the scopes of ECs to encompass both

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behavioural and social sciences. However, the wrong-doing or the slowness of some ECs should be addressed on individual bases and not be an argument strong enough to deter us from developing a sound collaboration between social scientists and ECs.

We maintain that all research should benefit from the advice of an EC. Social and behavioural sciences do not entail moral standards different from those required in biomedical research (Wassenaar and Slack 2016). The collaboration between social scientists and ECs could improve the study protocol on several aspects. Some of these aspects are common across disciplines, some are specific to particular experimental approaches: how to handle individual reactions to the proposed tasks and stimuli is relevant to Psychology or Behavioural Economics; field work in possibly hostile environments characterises some Anthropology or Sociology studies. Some degree of deceit may be essential in Psychology experiments, participated observation is one of the research paradigms used in Anthropology and Sociology. In either case, yet for different reasons, to acquire consensus may be problematic or even unattainable.

All studies carry some level of risk, conceived as the need for cost-benefit analyses; even seasoned researchers may overlook them when focussed on their own targets. We all need ethical advice. We uphold the request for introducing a legislation which institutes local ECs dealing with Social and Psychological non-clinical research which would benefit from undergoing the process of ethical approval to support the well-being of participants and researchers alike. This process should be concerned with assisting researchers in their endeavour and should avoid the pitfalls of being perceived as yet another bureaucratic hoop scientists should jump through to carry out their studies.

## NOTE

1. <https://www.cnr.it/it/ethics>
2. (ESRC: <http://www.esrc.ac.uk/funding/guidance-for-applicants/research-ethics/>)
3. [http://ec.europa.eu/research/participants/data/ref/h2020/other/hi/ethics-guide-ethnog-anthrop\\_en.pdf](http://ec.europa.eu/research/participants/data/ref/h2020/other/hi/ethics-guide-ethnog-anthrop_en.pdf)
4. <http://practicinganthropology.org/about/ethical-guidelines/>
5. AIP: <http://www.aipass.org/node/11560>
6. APA: <http://www.apa.org/ethics/code>
7. BPS: [http://www.bps.org.uk/sites/default/files/documents/code\\_of\\_human\\_research\\_ethics.pdf](http://www.bps.org.uk/sites/default/files/documents/code_of_human_research_ethics.pdf)

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