Entangled in an ethical maze

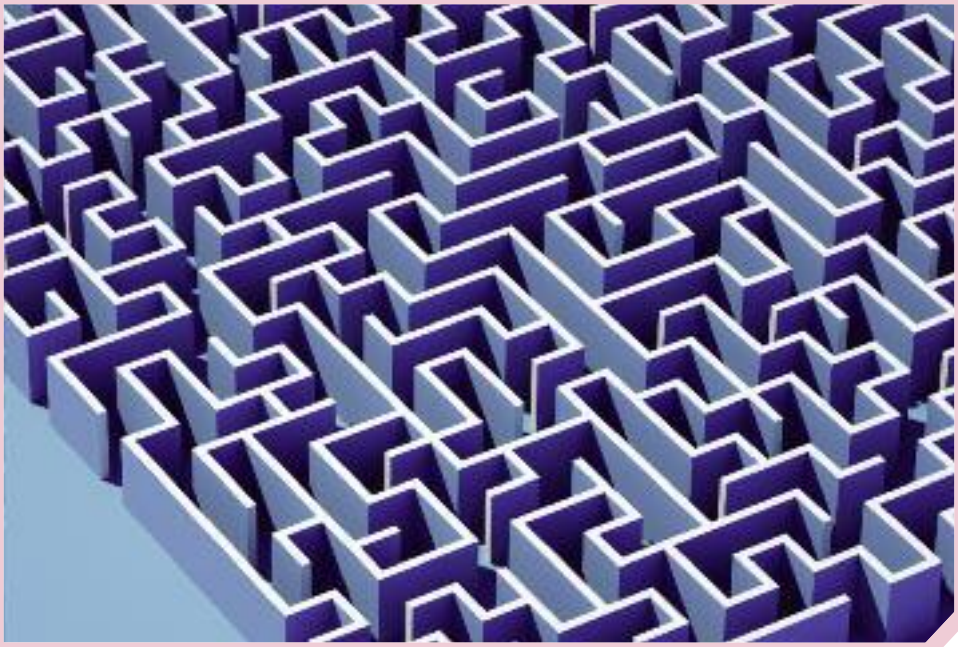
Sergio Della Sala and **Roberto Cubelli** argue that NHS ethics committees hamper ethics

We need ethics in research, we value ethical principles; hence we support ethics committees (ECs). Yet, more often than desirable, the requests by ECs, when vetting studies with patients, don't come across as suggestions aimed at promoting and improving research studies. They are extra bureaucratic hurdles to go through to carry out research.

This is alarming as it creates a hiatus between researchers and ECs, rather than a fertile collaboration. This collaboration is hindered by the partial view that some local ECs seem to take on their role. Singer (1979) stated: 'The justification of an ethical principle cannot be in terms of any partial or sectorial group… Ethics requires us to go beyond "I"and "you" to the universal law, the universalizable judgement, the standpoint of the impartial spectator or ideal observer or whatever we choose to call it' (p.11). Yet the UK NHS Health Research Authority, the body responsible for NHS Research Ethics Committees, states that its 'primary role as an organisation is to protect and promote the interests of patients and the public in health research'. This implies an implicit contraposition between 'them' and the researchers, generating an enduring and unfruitful conflict.

This is not the only aim that ECs should pursue. In the aftermath of the Second World War, ECs have been instituted to implement the principles of the 1948 Universal Declaration of Human Rights. As stated in the Declaration of Helsinki (Fortaleza, Brazil, 2013) and in the 1997 Oviedo Convention on Human Rights and Biomedicine, ECs on one hand 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. ECs ought to guarantee both the researcher's right to investigate and the participant's right to be involved as autonomous agent. ECs should also look after the interests of a third stakeholder, the 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 to propose solutions mediating between them. Unfavourable outcomes, banning individual studies, should be the exception. ECs and researchers should collaborate towards improving research protocols. This collaboration would allow the different standpoints to meet and gel (Cubelli & Della Sala, 2015).

Unfortunately, the interaction between ECs and researchers is not always as



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cooperative as it should be (Baron, 2015). For example, the EC of the West of Scotland Research Ethics Service recently expressed their unfavourable view on an application by a researcher of the University of Edinburgh. He wished to recruit patients with dementia for his funded study on the influence of object congruency within scenes on automatic orienting of attention. The EC invited the researcher to screen for vascular damage to avoid undetermined confounding effects, and at the same time to reduce the sample size to limit the burden on participants. To accept these suggestions would be technically wrong and would undermine the study. Most patients with dementia have some vascular damage; to isolate a specific subgroup would require complex diagnostic procedures and would make recruitment harder by increasing the number of potential participants to be screened. Moreover, the precise aetiology, though important for clinical purposes, is irrelevant in this research addressing a theoretical cognitive question. The sample size had been estimated on the basis of statistical power; reducing it would have made the outcome questionable.

Sadly, the rebuttal was disregarded and the request for further clarification and advice was ignored. After some nagging the Scientific Officer for that Ethics Service clarified that the EC's ruling was based on the view that 'Alzheimer's is a white matter disorder whereas stroke is due to vascular events with ischaemic damage to the cortex/grey matter and therefore have different pathophysiology/pathology'. Even a cursory look at Wikipedia would show how inaccurate this statement is. And so the view of members of the ECs is vented acritically, yet it influences their verdict, quite independently of ethical issues.

ECs' requests can be not only questionable but sometimes illogical. Another colleague in Edinburgh, aiming at investigating memory performance for English words, was asked by the NHS EC to provide a direct translation of the testing material in other languages to avoid discrimination in the recruitment procedures by excluding non-English speakers. This suggestion would have meant transforming a memory experiment into a cross-linguistic study, which would have required more than a simple translation of the stimuli.

Academic blogger Dorothy Bishop has invoked Charles Dickens's Circumlocution Office in her description of the 'contemporary problem' of NHS ethics committee bureaucracy, and anecdotes have become the object of sly remarks at psychology conferences. A colleague in Nottingham was summoned to explain why they used Times New Roman font for their information sheet rather than the apparently much clearer Helvetica. In Oxford, another project was rejected because the EC wanted the researcher to use electrophysiology rather than a validated clinical psychology questionnaire to assess anxiety, as if electrodes provided 'more scientific' data that structured surveys.

Erratic and gratuitous requests such as these harm the collaboration between researchers and ECs (Jansari et al., 2015). The outcome is a critical conflict. ECs offer the impression that rather than supporting basic research on patients they tolerate it (Kumar & Pilling, 2015) or even stigmatise it (Kim, 2015). Researchers, requested to fill in an exorbitant, often incomprehensible or inappropriate, amount of forms, conceive ethical procedures as an extra autocratic loop they have to go through to carry out their studies.

This is dangerous for both parties. It curtails freedom of research as it makes it difficult for some types of studies to be considered (Della Sala et al., 2015), it induces the idea that ethics bureaucracy causes research waste (Al-Shahi Salman et al., 2014), it forges the prejudice that ethics is a form-filling exercise rather than a set of principles shaped by the scientific community. It is dangerous also for ECs as it produces knee-jerk reactions aimed at reducing their impact, thus favouring individual interests and soliciting fraudulent behaviours as well as decreasing the competence and overview that members of the ECs could accrue with experience. The conflict between ECs and researchers is also unfit for society's needs, as research will not be stimulated and it would be potentially of poorer quality, thus reducing knowledge acquisition and impoverishing development.

> "The interaction between ethics committees and researchers is not always as cooperative as it should be"

Basic and clinical research

One of the major causes of the potential conflict between ECs and researchers resides in the lack of clear demarcation between basic and clinical research. This lack of clarity penalises in particular psychology and neuropsychology studies.

To return to the example above, the issue of sample size has different approaches according to the nature and aims of the investigation. All studies need a solid statistical power to be valid and reliable. Therefore, in a research addressing a theoretical cognitive question, it is good practice to recruit a sample large enough to fulfil the statistical demands of the study. However, in a clinical study, like a trial to establish the effects of a drug, given the potential risks embedded in the procedure, it is good practice not to exceed recruiting the minimum number of participants to obtain a clinically significant outcome. That is, all studies need 'no less than', but only clinical studies should recruit 'no more than'. In basic research with patients, it is often impossible to establish *a priori* the number of participants, as these decisions depend on the initial screening. The EC ruling that all studies should recruit participants according with the 'no more than' principle, is hampering basic studies, hence, making them potentially unethical as underpowered, therefore wasted.

Animal research or clinical trials are precisely regulated. Psychology studies recruiting healthy volunteers or children with typical development are usually regulated by university ECs, which in our experience are efficient and helpful as they operate with a clear mandate (although in the experience of others they are not without controversy). Psychology studies on patients instead meet with a normative vacuum. Psychology studies on clinical populations cannot be examined by university ECs. On the other hand, NHS ECs do not seem adequately equipped to evaluate ethical issues connected with non-clinical research projects recruiting patients. This is due to the idiosyncrasies of this kind of study compared to clinical trials.

In cognitive research with patients, it is sound to refine the assessment according to actual findings. In this field, a precise protocol, to be scientifically fruitful and clinically coherent, cannot be fully framed in advance. Moreover, a cognitive symptom may be fleeting, thus time is crucial. These idiosyncrasies require flexibility within an agreed frame; such flexibility is not envisaged by ECs, which conceive it as giving way to low standards rather than the ability to handle discipline specificities. The ECs' mindset appears to be forged on clinical trials. Basic research is descriptive, it devises theoretical models aimed at explaining observed phenomena; clinical research is

prescriptive, as it defines therapeutic protocols according to predetermined procedures and methods. Basic research moves slowly and changes often; clinical research is for immediate use and it is rigid. Different research needs call for specific ethical issues. The current operating of ECs is instead to apply a single model to assess each and every issue.

We are not suggesting that, given the apparent low risk for the physical wellbeing of participants, psychology studies should not undergo ethical scrutiny. We maintain that all research should benefit from the advice of an EC, which could improve the study protocol on several aspects, including the adequacy of information offered to participants, ways of using deception, how to handle individual reactions to the proposed tasks and stimuli, ways of applying inclusion and exclusion criteria, the duration of the testing sessions, the availability of first aid, and the relevance of the question posed. All studies carry risks, even seasoned researchers may overlook them when focused on their own target. We all need ethical advice. It is the advice that we currently receive that is sometimes inadequate. The outcome is the risk that researchers consider ECs not as part of their team but as a barrier to overcome, jeopardising the ideals of the founding elements of ethical principles and procedures as established in the wake of the Second World War.

We do not expect omniscience from ECs, not even familiarity with each specific project topic; indeed, a committee of experts in each discipline is unfeasible as it would always be partial and it would configure a conflict of interests. ECs should implement ethical principles, avoiding taking to task researchers by imposing their own views. They should be disposed to explain and convince the researchers of the reasons for their demands. In turn, they should also be prepared to listen to the researchers with the attitude of being convinced by them about their full appreciation of the possible ethical pitfalls in their experimental design and procedures. If the EC's ruling is debatable, the researcher should have the opportunity of openly challenging the EC's deliberation, and this hearing should be handled by the same EC. The EC's deliberation should be accountable, not undisputable; the relation is akin to a knowledge exchange, even in a setting whereby one party is called to approve the other party's application.

On the specific issue of psychology studies with clinical populations, ECs should be open to the possibility of establishing procedures addressing the needs of such studies, which vary in terms of response promptness, methodology and aims. NHS ECs might take advantage of a formal interaction with university ECs, which seem to have forged more efficient and less contentious procedures addressing ethical issues within psychology research, complying with the needs of both the participants and the researchers.

Finally, not only should ethical issues be part of the formal training of students and researchers, but they must also enter the public debate exactly as any other scientific matter holding societal relevance.

Danger that ethics is seen as a form-filling exercise rather than a set of principles

A defeat of ethics

Korotkov, the main character of Mikhail Bulgakov's *Diaboliad*, in his quest for an answer, finds himself entangled in the maze of Soviet bureaucracy inculcating in him the feeling of guilt for predestined misdeeds. Eager to share his reasons, he was sent to the Grievances Office, on the 'Seventh floor, Corridor Nine, Apartment Forty-one, Room 302' but failed to locate it. Researchers dealing with ECs share his feelings. A beautifully crafted example is told by Dorothy Bishop on her blog. Within such a context, in the absence of cooperation, the researcher has little choice: either accept his or her fate and comply with arbitrary requests or try to cheat the system. Either solution would be a defeat of ethics. Researchers delegate their own responsibilities to the ECs, missing the opportunity to become more aware of ethical concerns in their studies. ECs, taking only a partial view and adopting rigid mental algorithms, miss the opportunity to appreciate the diversity inherent in individual projects, hence ignoring important and specific issues of research ethics.

> "We all need ethical advice. It is the advice we currently receive that is sometimes inadequate"

In conclusion, researchers should be more aware of ethical matters involved in their own studies and should welcome the advice offered by ECs. ECs should conceive of the relationship with researchers as a way to facilitate research and better study protocols. Good ethical principles spring from the collaboration between all parties concerned. We know that the view we have expressed is partial and does not apply to all ECs. However, the current impermeable operating modes of some ECs and the intricate bureaucracy entailed by the application procedures is endangering this collaboration, hence hampering ethical principles. We would invite ECs to open a discussion to find a shared solution that would reinstate ethics at the centre of basic research with vulnerable populations.

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