

THE ETHICAL REGULATION OF SOCIAL RESEARCH FROM A GLOBAL PERSPECTIVE: AN ANALYSIS OF THE ITALIAN SITUATION

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הרגולציה האתית של המחקר החברתי מנקודת ראות גלובלית: ניתוח המצב באיטליה מרקו מרזנו

Abstract

In this paper, I make a first attempt to conduct comparative analysis of the forms and consequences of the spread of the culture of ethical regulation beyond the borders of the English-speaking countries. In particular, I compare Mark Israel's pioneering analysis on South Africa and Brazil with certain empirical observations on the situation in my own country, Italy. As theoretical tool for the comparison, I employ the category of isomorphism preferred to that of imperialism. From the comparison it emerges that the situation in Italy is to some extent different from that portrayed by Israel with regard to Brazil and South Africa and that this is due in all likelihood a) to the solidity and strength of the Italian domestic scientific community, b) to the reduced importance of funding from countries or international bodies dominated by a regulatory culture and above all,

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c) to the fact that the central Italian State has not yet decided to move decisively in the direction of the rigorous ethical and bureaucratic regulation of research.

תקציר

במאמר זה אני מציג ניסיון ראשון לערוך ניתוח השוואתי לגבי האופנים וההשלכות של התפשטות התרבות של רגולציה אתית מעבר לגבולותיהן של המדינות דוברות האנגלית. אני משווה את הניתוח החלוצי של מארק ישראל לדרום אפריקה ולברזיל, עם תצפיות אמפיריות על המצב בארצי, איטליה. ככלי תיאורטי להשוואה, אני משתמש בקטגוריה של איזומורפיזם, העדיפה, לדעתי, על שימוש במושג אימפריאליזם. מן ההשוואה עולה, כי המצב באיטליה שונה במידה מסוימת מהמצב שמציג ישראל ביחס לברזיל ודרום אפריקה, וכי הדבר נובע, ככל הנראה, מ:
(א) איתנותה ויציבותה של הקהילה המדעית האיטלקית, (ב) החשיבות הפחותה של מימון ע"י מדינות או גופים בינלאומיים, שנשלטים על ידי תרבות רגולטורית. ומעל לכל, (ג) לעובדה כי המדינה האיטלקית טרם החליטה לנוע באופן מכריע לכיוון של רגולציה אתית ובירוקרטית מחמירה על המחקר.

INTRODUCTION

The culture of the ethical regulation of research – that is, the idea that all research activities in every field of human knowledge must be subject to rigorous controls on the part of institutions (committees) specialized in inspection activity – has quite rapidly imposed itself in nearly all research spheres and in every corner of the globe in the course of just a few decades. The concept was developed to limit or completely eliminate the possibility that serious damage might be suffered by patients as a result of research activities in the medical and healthcare fields: that is, in order to secure the hoped-for scientific results of their studies, researchers would fail to respect the dignity and rights of the sick (and people in general), using them simply as means to obtain

their ends. The idea was then transferred from the field of biomedical sciences to social sciences (Van den Hoonaard 2011; Israel 2014). Although there was a lack of clearly significant evidence of the danger of social research, the belief arose in many areas of the social sciences that a level of severity similar to that used to evaluate the ethics of studies in the biomedical field was also indispensable for sociological and anthropological research.

In North America, over the course of just a few years, the entire corpus of social studies, practically all sociological and anthropological work – from university students' degree theses to studies by the most well-established scholars – have been made subject to a thorough "ethics review". The entire community of North American scholars in the social sciences has been obliged to appear before 'ethics juries' represented by committees that every university has formed and provided with extremely wide powers, first and foremost the right to prevent an unapproved research project from being undertaken and completed.

There has been far less investigation – almost none, in fact – of the global spread of the culture of ethical regulation outside North America. The idea of transforming ethics into a standard bureaucratic procedure has been put into effect – or is rapidly being put into effect – in much of the world, but the actual forms that this social and political process takes remain virtually unknown. The only available information relates to English-speaking countries: The United States, naturally (where the entire process began), Great Britain, Canada, and Australia.

In this paper, I will make a first attempt to conduct comparative analysis of the forms and consequences of the spread of the culture of ethical regulation beyond the borders of the English-speaking countries. In particular, I will compare Mark Israel's pioneering analysis on South Africa and Brazil (Israel 2017) with certain empirical observations on the situation in my own country, Italy.

In order to be able to proceed with this comparison, however, we need a clearer and more refined conceptual framework, a main theoretical idea to which we can refer.

One initial possibility is the notion of 'imperialism'. This concept refers to policies of power and supremacy that seek to create a situation of predominance and domination over countries or areas of social life that are believed to be inferior. It has been used by Schrag (2010) to explain the emergence of the culture of ethical regulation in the social sciences. For Schrag, the imperialist is the medical sciences, and the victim is social studies.

Generally speaking, the term 'imperialism' is almost always used in a highly negative sense. Its first use in modern times dates back to the colonial era, especially to the fifty years between the 1870s and the First World War, when the great colonial expansion by European countries was under way in Asia and Africa. Underlying the notion of imperialism is the idea that imperial domination is legitimate and that imperial forces are fully entitled to impose it on weaker countries or social systems. The principal limitation of this notion, in my opinion, is that it refers exclusively to intentional, planned actions by means of which the 'imperialists' seek to establish superiority over their victims. Everything else – i.e. the unintentional, accidental, and involuntary aspects of

the process that leads to the propagation of an idea such as ethical regulation – remains in the shadows. For supporters of the imperialist theory behind the expansion of the practice, there is inevitably a plot hatched by the great powers (whether they be economic, political, or cultural) to take over the rest of the world.

At the opposite extreme to imperialism is the concept of 'diffusion'. According to Rogers's well-known definition, this concept identifies "a process by which an innovation is communicated through certain channels over time among the members of a social system" (Rogers, 1995). Again, according to Rogers, the diffusion effect concerns "the cumulative increasing degree of influence upon an individual to adopt or reject an innovation, resulting from the activation of peer networks about an innovation in a social system ..." (Rogers, 1995). Notwithstanding recent attempts to free it from its mechanistic connotation, the notion of diffusion has remained quite similar to that of 'contagion' and denotes the 'spontaneous' diffusion of a social practice, of a symbol, of a technology, or of a ritual; in short, of any type of innovative element within the body of a social system. Contagion takes place as a consequence of the density of relationships and the volume of social interaction among actors. As exchanges and communications grow, the intensity and velocity of the spread of innovations also increase, and they are then naturally proposed as the most rational, efficient, and economical solutions to the problems that social systems are required to deal with, and this gives them legitimacy. As is obvious, the problems involved in applying the concept of diffusion are precisely the opposite of those raised by the concept of imperialism. Diffusion is apparently well able to explain asocial processes such as epidemics, but it is

far less powerful in explaining social phenomena (Strang and Meyer 1993). For example, why would an increase in the volume of interactions only generate similar and supportive behaviours, and not conflicts, differences, or fence-building (Strang and Meyer 1993)?

In other words, the concepts of imperialism and diffusion appear too simple to grasp the nature of complex social processes like those considered here. It seems to me that the notion of 'isomorphism', which has enjoyed great success in the field of organizational analysis, is far more suitable for this purpose (Di Maggio and Powell 1983; Powell and Di Maggio 2012; Greenwood et al. 2017). Firstly, the concept of isomorphism takes account of both imitative (mimetic isomorphism) and authoritative (coercive isomorphism) processes, as well as those that develop from professional networks (normative isomorphism). Secondly, it includes the relevant pressures, power games, and power balances that exist within every organizational field. The sources of the various forms of isomorphism can be respectively traced back to uncertainty (in the case of mimetic isomorphism), the strength of political (and other types of) authority (in the case of coercive isomorphism), and the density of relations and communications among professionals (in the case of normative isomorphism). Overall, therefore, an institutional analysis that focuses on the concept of isomorphism takes a wide variety of situations and conditions into consideration (to a far greater extent than do analyses based on imperialism or diffusion). For example, all types of mimetic isomorphism spring from the desire on the part of the weaker actors to imitate successful models. It is possible that the organization being imitated has done nothing to warrant such imitation, or that it

has obtained any advantage from it. In this case, the relevant form of power is completely different from that which exists for the types of coercive isomorphism deriving, for example, from the imposition of domestic laws that oblige all actors to comply with them. Different from the other two are the types of (normative) isomorphism that originate (for example) from research by universities and research centres (attended by students from all over the world) that produce theoretical and practical models later adopted in every corner of the earth.

Let us now return to our topic – the globalization of the culture and practice of ethical regulation – and get to the core of the analysis.

ETHICAL REGULATION CONQUERS THE GLOBAL SOUTH.

Mark Israel (2017) has carried out interesting comparative analysis of the development of ethical regulation in Brazil and South Africa.

In Brazil, the ethical regulation of research has been entrusted to a National Commission for Ethics in Research (CONEP), which operates according to radically positivist criteria that are only appropriate to medical research. All forms of cultural pluralism are radically rejected. The consequences for human and social sciences have been dramatic: large numbers of research projects have been cancelled or hugely delayed due to the 'working style' of the overbearing and inefficient CONEP bureaucratic organization. "For example, one researcher has been asked by a committee to obtain signed informed consent from individual participants using documents translated into Xavànte, an indigenous language. The requirement compromised a strong tradition among Xavànte of community decision-making through ritualized daily

meetings and, ignored the lack of standardized written form for their language, and a relatively high level of bilingualism among the population "(Israel 2017, 4). Until now, all attempts at resistance on the part of Brazilian social scientists have been futile. In South Africa, the system of regulating ethics operates more or less in the same way, and the overall result has been reinforcement of the "asymmetrical power relationship that already exists between predominantly white researchers and predominantly black participants" (Moodley and Meyer 2007, quoted in Israel 2017, 5).

Overall, as Israel (2017) maintains, the propagation of principlism forms just one part of a very substantial flow of financial and cultural capital, ideas, and persons between the global North and South. Persons travel in both directions, but ideologies, values, rituals, and money go in only one way – towards the South. Even if we limit consideration to the case of research ethics, the vehicles for its exportation (which Israel (2017) thoroughly analyses) are numerous. An important part is played by the generous American research grants that oblige all parties receiving them to apply the ethical standards in effect in the United States, regardless of their nationality. Similar instructions are given by many of the large international organizations that fund programmes for the Third World (for example, the World Health Organization). A second vehicle of the imperialist globalization of ethics, according to Israel, consists of professional networks, individual "epistemic communities" (Haas, 1997). These communities (for example, of doctors or psychologists), backed by the power of the scientific and cultural legitimacy that derives from the role given to their members, promote what I would call a form of 'normative isomorphism' to which the peripheries

are obliged to yield willy-nilly if they do not wish to be completely marginalized, to 'remain behind' in the processes of global transformation. In the area of research ethics, it is also often the case that the young people who move from poor communities to the rich countries of the global North to study import the culture and values of the dominant countries when they return to their homelands.

Often, and once again it is Israel (2017) who points this out, the arrival in an African or South American country of values, rituals, and procedures (such as those of research ethics) destroy and replace local values, rituals, and procedures.

The net result is that "researchers who fail to comply with imported ethical requirements risk forfeiting funding, having their papers rejected by publishers, or losing their jobs (Israel 2017, 11). Even where social scientists have mobilized, changes in the imported regime may be difficult to achieve". (Israel 2017, 11).

ETHICAL REGULATION IN ITALY

In this third section, I will address the topic of the diffusion of a regulatory culture in the country in which I live, namely Italy. No systematic data are available on this phenomenon, and what follows is therefore a largely incomplete and merely initial construction that has been predominantly carried out on the basis of interviews with key informants. I will focus on the regulation of social research, leaving regulation in the biomedical field, on which I have very few data and to which I will make just a few brief references at the end of this section.

I will begin by noting that the Italian university system is largely public, and therefore dependent on laws enacted by Parliament and regulations issued by the

extremely powerful Ministry of Education, Universities and Scientific Research (MIUR). To date, the Ministry has issued no directives on the need to obtain the approval of an ethics committee in order to access the allocation of the funds that are granted each year to universities, and by the universities to individual researchers.

Given the extremely centralized nature of the system, two lines of text in a law would be sufficient to change the entire scenario immediately. In other words, binding ethical regulations (a form of clear coercive isomorphism) could be introduced in Italy overnight in a meeting of the Council of Ministers or in a session of Parliament. This is what happened in the case of assessments of scientific research, which the Ministry unexpectedly decided to introduce at the same time as it established new rules for hiring academic staff. A further source of possible coercive isomorphism (with regard to Italy) is the European Union, which also allocates considerable funds to Italian scholars. As a part of its most significant research funding programmes, the European Union can ask scholars to certify their compliance with the ethical standards in force in their country. Since Italy does not currently have any specific standards, Italian scholars are authorized to declare that they have no obligations in this regard. In some cases, where they are judged by European bureaucrats to be especially risky from an ethical standpoint, further systems of control are implemented. For example, researchers working on a population subject to strong social stigma were asked to modify a questionnaire by strictly avoiding the use of certain terms, which was good for political correctness but seriously damaged the effectiveness and scientific appropriateness of the study (the

specific purpose of which was to unmask the racism implicit in many commonly used definitions).

However, the spread of ethical rules for social research in Italy is not only taking place through domestic or supranational political authorities.

Another channel through which the ethical regulation model is being imposed in Italy consists of professional associations and international English-language scientific journals.

Some of these journals, which are the most important in many areas, also require Italian scholars who want to publish their articles to cite references to a document certifying approval of the research project on which the article is based by an ethics committee from the institution to which the scholars belong.

Those subject to this requirement are most often, at least in Italy, psychologists, i.e. members of a community that more than any other in the human sciences belongs to the international community and is very close to the methods and styles of research in natural and life sciences.

This phenomenon forms the basis of a type of coercive isomorphism that has a very serious impact. The process begins with the strict requirement on the part of an international journal that ethical certification be provided. The publishers of these journals are not in the slightest interested in verifying whether this requirement is reasonable: whether an obligation to provide ethical certification is imposed by the laws of the country in which the researcher works is not checked, let alone the existence of an ethics committee at the university to which the author of the article belongs. This

requirement on the part of journals is non-negotiable: there is no publication without ethical certification, full stop. The fact of the matter is that for psychologists, being published in prestigious international journals has become an indispensable requirement for career advancement and the ability to be members of selection committees or doctoral colleges, and in short to be able to work serenely, while also harbouring some form of career expectation. This is why we see the occurrence of highly paradoxical effects of 'research ethics' such as exemplified by what happened to an Italian psychologist at a university in the south of Italy (who has asked me not to reveal his identity, and whom I shall call Alberto). A couple of years ago, he received the usual request from the journal to which he had sent an article to produce a document attesting to the approval of his research project by his university's ethics committee. The journal's editors also told the colleague in question that in order to publish his article, they needed him to send them the written informed consent form that he had provided to the participants in his study. In the event that this form had not been provided, the researcher was obliged to explain the reasons, and at the same time to provide a document evidencing the consent of the local ethics committee. The journal's publisher reserved the right to reject the article in any event if it decided at its sole discretion that "high ethical standards" had not been complied with.

As is the case in very many other Italian universities, the university to which this psychologist belonged had nothing that resembled an ethics committee. At this point, Alberto, who until that time had never thought about the need to comply with such a request, in desperation because of the risk that he would have to throw away work that

had cost him many months of effort, turned first to the Vice-Chancellor responsible for research to explain his situation, without obtaining anything, and then to his Head of Department. The Head of Department was sympathetic and came up with a solution that might help Albert circumvent the problem: he promised him that he would produce a document certifying that the research from which the article took its data, a study which the Head of Department had in fact never actually seen, had been carried out in accordance with the requirements of the Code of Ethics of the university to which both belonged. In actual fact, the only code of ethics that existed at this university at the time of the request related to the rules of conduct and ethics that applied to professors and students. Nothing in it had anything to do with research. Naturally, the psychologist and the Head of Department avoided clarifying this point and drew up a draft of the document to be sent to the journal.

Following an initial moment of great relief at perhaps having found a solution that would completely satisfy the journal's 'imperial' requirements, Alberto thought of another, possibly insuperable, stumbling block: the date of the document! Because the certification naturally referred to research that had been carried out before the paper had been written, in order for the certification to be deemed valid, it became necessary to backdate the document and pretend that it had been approved in advance by the Head of Department. This was done, and the certificate was sent to the journal on the headed notepaper of the Department in question.

What moral should we draw from this whole story? Like his Head of Department, the young psychologist might be considered to have committed a venial sin because

he told a lie in order to have his article published. It is also true, however, that from a practical standpoint, the study had not caused any type of damage to the interviewees, and that for this young scholar, publication of the article meant having the opportunity to work and commence a normal academic career: that is, to realize his legitimate professional and intellectual aspirations. As far as the Head of Department was concerned, a sense of solidarity towards a young colleague who was seeking to find a way around an idiotic regulation prevailed. In any event, what is certain is that in this entire matter, it was the journal that gave the worst account of itself because of its imperialist attitude, its arrogant and obtuse ignorance of local specifics, and its pretension that in addition to the language, the methodological format, and the theoretical and epistemological references, it could also impose a procedure that could not possibly be complied with honestly in a country where the situation was so different from that in the United States.

More generally, the situation in Italy in this area is decidedly uneven and chaotic, and cases such as the one recounted involving Alberto are probably not particularly rare. In some universities, in the absence of a university ethics committee, the task of producing the certificates required for publication in international journals is performed by the ethics committees in hospitals and health authorities. In other cases, faculties have equipped themselves with their own ethics committees, which are nearly always composed (and this is the most frequent complaint among academic psychologists) of professors who are members of the same departments as the colleagues that they are required to assess, and who are not neutral as regards the customary academic games.

In reality, the episodes I have gathered on this topic are not at all numerous overall, and in any event they are similar to those that have previously been reported by North American scholars who have been critical of the research ethics system: committees produce observations that researchers find highly questionable, and which they believe to be the result of ignorance of the specific literature or a wish to criticise, or worse, a desire to slow down and obstruct the work of a rival colleague.

In certain cases, the Italian members of these committees have spent many years studying in an English-speaking country (the United Kingdom, the United States, or Canada), where they have learned how the committees work and the results that they can obtain if they become members of them. In addition to stating the extreme importance of the function that they perform of promoting the development of greater 'ethical awareness' in researchers, some of the committee members that I interviewed firmly maintained that the task of these committees should also be to ensure that the money universities provide to researchers is actually used 'in an ethical manner': that is, for seriously 'important' studies. I had the impression that, perhaps unwittingly, these individuals wanted to be able to establish what was and was not important in the work of their colleagues, and which studies should be carried out and which blocked. It seems to me that the end result of all of this may a restriction of the actual freedom to carry out research and the institution of an authoritarian system that obliges scholars only to study topics that are of relevance to the members of these committees, using the methodologies they prefer, all in the name of public ethics.

However, isomorphic practices are not limited merely to the creation of ethics committees and the proliferation of certifications as a consequence of coercive pressures from international journals. The Italian Association of Psychology has issued – we are in the sphere of normative-professional isomorphism here – a ‘Code of Ethics for Psychological Research’ that directly copies the underlying philosophy of the codes of similar British and American associations. For example, among the ‘rules of conduct’ suggested for its members, the absolutely central importance of the ‘dogma of informed consent’ is restated. "Those who conduct research activities", we read in the Code, "must provide sufficient information to participants, and must obtain their prior written consent to their participation [...]". Subsequently, the Code mentions the need in all cases to provide participants with forms in which the following are identified: a) a description of the study; b) the manner in which the results will be returned; c) the right to refuse or suspend participation; d) the means provided for protecting anonymity; e) the personal particulars of the research manager; and so on. All aspects of the research process are regulated in this code in exactly the same way as they are in the countries that dominate the global research panorama.

Moreover, in the world of the Scientific Psychological Societies, there is talk of creating ethics committees that operate as ‘one-stop counters’: that is, at the request of individual researchers. The aim here is to provide members of those universities that do not yet have an ethics committee (and perhaps also those with excessively severe committees that ‘halt’ many studies) with the certifications they require in order to satisfy

the demands of international journals. Of course, implementation of this system would involve not insignificant costs.

One final aspect that I shall briefly consider before setting out my conclusions concerns the operation of ethics committees for biomedical research, which in Italy are established within local health authorities and hospitals.

The limited, and only partial, information that I have managed to gather on the operation of these bodies furnishes a depressing picture. Judging from the evidence provided by two key informants (who are long-serving members of numerous committees), many of these bodies, which are supposed to protect patients from the risks of clinical trials that fail to respect their rights and dignity, are dominated by medical personnel, and perform a decidedly secondary role, substantially limiting themselves to approving research projects that have previously been elaborated by the various doctors proposing them. In turn, again according to my key informants, these research projects are a direct expression of the interests of certain large pharmaceutical companies that fund the medical researchers. A few courageous reformers have attempted to change the situation over the years, for example by creating a national discussion round table involving the various committees, or by seeking to separate studies from the interests of pharmaceutical companies, or by trying to understand whether patients are in fact properly informed about the trials they are asked to take part in, but their efforts have all been in vain. One gains the impression that where the economic and political interests of pharmaceutical companies and doctors are truly powerful, the ethical aspect is merely a fiction. This is a paradox: where real risks exist

(and not imaginary ones, as in the case of psychological studies), ethical controls become a merely pro forma phase that masks the realities of actions taken by the powers-that-be, which remain unchanged compared with the past.

CONCLUDING REMARKS

In this paper, I have attempted to outline a comparative analysis of the exportation of a culture of ethical regulation beyond the borders of English-speaking countries. The situation in Italy seems to some extent different from that portrayed by Israel (2017) with regard to Brazil and South Africa. In the former case (as long as episodes such as those that I have described are not also occurring in the countries Israel writes about), coercive isomorphism is less pronounced, and forms of adaptation prevail that *de facto* significantly attenuate the efficacy of the constraints, making them softer, and less binding. This is due in all likelihood 1) to the solidity and strength of the Italian domestic scientific community (which makes it able more effectively to resist pressures to conform with the rules laid down by English-speaking countries); 2) to the reduced importance of funding from countries or international bodies dominated by a regulatory culture; and 3) above all, to the fact that the central Italian State has not yet decided to move decisively in the direction of the rigorous ethical and bureaucratic regulation of research. What does appear to have been truly sacrificed in this entire process is ethics, in the sense of reflections on the optimal conduct to be adopted towards one's fellows. The path to forced regulation imposed from the outside by journals or by the creation of committees has revealed all its limitations and inadequacies. It would be better to

attempt a different route before any more damage is caused (Van den Hoonaard and Hamilton 2016).

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