

Marion DANIS, Emily LARGENT, David WENDLER, Sara CHANDROS HULL, Seema SHAH, Joseph MILLUM, Benjamin BERKMAN and Christine GRADY. *Research Ethics Consultation. A Casebook*. New York, 2012. Pg 259

"What must I do?" is, according to Kant, one of the questions –alongside "what can I know?" and "what can I expect?"– to which Philosophy must attempt to provide a response. And while doing so, in response to that question, Philosophy unravels the strange method and personal style of Ethics, understood as philosophical-moral reflection. Ethics, therefore, always faces an extremely laborious and challenging task: to attempt to shine light on the praxis using principles and general criteria, more or less abstract; in other words: to reasonably guide concrete decisions in light of dilemmas and perplexities of real life in the different spheres and fields of human activity. In the matter at hand, this reflection summons us in what the title –somewhat ambiguously, in theory– anticipates: *research ethics consultation*.

The title, *Research Ethics*, surely, can cause certain confusion given that, pars pro toto, it without doubt promises more –or perhaps, something else– of what it effectively implies. The work focuses its attention on Research Ethics in *Bioethics, Health Ethics and Clinical Ethics*. In fact, the field encompasses even more: the most recurrent *consultations* with regard to moral problems which emerge in those spheres of reality. I will justify this claim in the following paragraphs. After all, this would be the only *minor "but"* that could be detected by whomever endorses this review of a work that, in all respects, I would not hesitate in rating as exceptional and worthy of reading.

The reality is multifaceted and submits different *ontological fields* for research. If we take research to be a systematic project of intellectual stimulation, directed towards the aim of grasping the reality, for essentially practical purposes; we will have to accept that the research process would have to be guided to find its place regarding the peculiar nature and quality of The Real which is sought to be understood. As such –beyond the accuracy entailed in Formal Sciences; in other words: Logic and Mathematics– in Natural Sciences and Physics, research into how to expound the *ability to be* which lies within the reality –veiled– is expressed as *fixed*, like a statue form, *subject to laws* and regularities that can be precisely identified and verified. However, things somewhat change when we move from Physics to Biology; and even more so when in realms

formerly known as the Sciences of the Spirit and which nowadays we associate with Human and Social Sciences. In Biology, the *ability to be* –the practical application of theoretical knowledge– after that which research seeks to discover –to unveil–, appears *regulated* instead of *fixed*. Therefore, *a fortiori*, in Social Sciences, knowledge will rise from the reality of things and the relationships between things, with a much greater dose of vagueness. Or if necessary, with a greater burden of freedom. This circumstance, as a matter of fact, is that which hinders the precision of this type of knowledge. Thus, indeed, the reality of this level of being, more uncertain, is more difficult to simplify to objective mathematical formulae and to elegant predictive models...

Ultimately, the following statements, at the very least, would have to be kept separate. Firstly, we must thoroughly recognize that, a large part of current development of Applied Ethics is owed to the reflection that has been gaining momentum in the medical field and Bioethics, at least, after the Second World War. The principal milestones are well-known: The Nuremberg Code (1947), the Declaration of Helsinki (1964), the Belmont Report (1979) and the *International Ethical Guidelines for Biomedical Research Involving Human Subjects* 1982, 1993, 2002, known as CIOM, acronym for the Council for International Organizations of Medical Sciences.

Meanwhile, the biomedical research paradigm which seems to occur in the collective imagination, through a sort of *analogatum princeps* of all research work –irrespective of the field of study and the applicable methodology– does not mesh at all with the reality. It is precisely from that theoretical budget where stem many of the controversies and a large part of the discrepancies which are observed in the current discussion on Research Ethics *sensu lato*. It is usually emphasized, from this critical view regarding the dominant paradigm, that Research Ethics should somewhat vary depending on the different scientific disciplines. And for such, rather than just thinking of a one-size fits all approach of the ethical suit to cater for all disciplines, the method of implementing it with ethical quality criteria should be left to the judgement of research professionals. The biomedical model, in effect, is not entirely harmonized with Social Sciences.

Nevertheless, independently of the foregoing reflections, the book that we are reviewing is, at the very least, three things: firstly, it is an excellent example of applied ethical reflection, whereby the reader develops their own analytical and reflective ability. Secondly, it represents a remarkable practice of deliberative and prudential argumentation. Lastly, it represents a pragmatic approach, –interdisciplinary,

provisional and in group, where relevant–, to the resolution of grave moral dilemmas where the conflict of interests and values is not entirely out of the ordinary.

We are, without doubt, faced with *a book of Ethics* in the true sense of the word, even though the subheading makes reference to the content that the reader will come across throughout the book, with the simple and terse "*A Casebook*". It is indeed a Casebook. However, a Casebook that entails a lot of very profound moral theory. Precisely that which, through discussions on the Bioethical issue and those regarding the cited Medical Ethics, began to emerge in *principlism*; a philosophical-moral approach whereby a set of principles rigorously appear which, to the strand of theoretical development, are assuming and proposing almost like a *mantra* of Applied Ethics: the distinguished principles of *do not harm* and *beneficence*; of *autonomy* and *informed consent*; as well as the principle of *justice*. The practical problem, beyond the elegant wording of the previous principles, is pinpointing on a day-to-day basis how those principles must be understood and applied in complex situations, faced with clashing interpretations and guides. According to the authors: "The belated attention to clinical research ethics consultation means there has been little discussion of how clinical research ethics consultants might translate conceptual ethics principles into meaningful, actionable advice, and many substantive and procedural questions remain unanswered" (3).

The book at hand systematically exhibits the wealth of experience spanning more than a decade of the Clinical Centre Bioethics Consultation Service at the National Institute of Health (NIH). This institution, found in Bethesda, Maryland, is the largest clinical research hospital in the USA. It connects 27 centers and institutes from around the country which, regardless of the fact that they collaborate and attempt to coordinate among themselves, have their own idiosyncrasy, priorities and its personal research agenda.

The introduction –pages 1 to 20–, gives an account of how the Clinical Center Bioethics Consultation Service operates. Its philosophy is outlined –providing an opportunity to discuss the moral dimension of clinical research, from the commitment to openness and inclusivity–; the role it is assigned –consultation and recommendations; faced with monitoring and correction of bad praxis–; the structure of its members –attendings,

fellows, etc.–;as well as the profiles, skills and knowledge required in that interdisciplinary team.

Of special practical interest is the section devoted to explaining how the consultation process is conducted, the steps which are taken and the "standardized" sequence which is usually followed from the moment in which someone initiates the consultation, to the moment in which the report is issued and a record of such, where applicable, is made in the database; covering stages of clarification, analysis and recommendations along the way. The importance of addressing aspects such as maintaining confidentiality is highlighted...and several items open for discussion are indicated, which urge the reader to address several interesting ideas: Who should define the scope of the consultation question (12); how should consultants handle conflicts between regulations or policies and their analysis? (13); how should requests for anonymous consultation be handled? (14); should study participants be included in consultations? (15).

The book's content establishes a flow –using *real cases*, with the names of people appropriately concealed, except on occasions otherwise indicated– of the ethical dimensions of each one of the key moments in the research process –“ Starting Research” (chapter 1); “Enrolling Research Participants” (chapter 2); “Protecting Research Participants” (chapter 3); “Ending Research (chapter 7)– or in reference to some of the most controversial aspects of the research *stages*, such as, by case: “Conducting Research with Vulnerable Populations” (chapter 4); “Balancing Clinical Research and Clinical Care” (chapter 5); or “Navigating Interpersonal Difficulties” (chapter 6).

The structure of the piece, therefore, in addition to a Foreword by Benjamin S. Wilfond (XI-XIII); comprising seven appendices (219-250) and an Index of concepts (251-259); consists of the seven cited chapters which, we assume, would have to have been written by one of the seven signing authors and those mentioned in each section when the "author's commentary" is attached to each one of the studied cases.

Each chapter, in turn, follows the same framework: An initial introduction of the aspect subject of study and title of chapter, is followed by a set of themes –between 6 and 8 headings related to the general statement of the chapter–, out of a selection of cases, chosen by the authors, concerning consultations which were resolved and collected in the Center's database. The discussion and analysis is always carried out in accordance

with the following pattern: Reason for Consult; Narrative; Analysis and Recommendations and Author's Commentary.

As stated above, I believe it is a piece of compelling interest; which enables various levels of reading and which, undoubtedly, will be of value to many different readers: indeed, to researchers in the medical-biological field; to members of Bioethics Committees and Clinical Ethics Committees; to those involved in consultations similar to the ones outlined throughout the piece...Having said that, the volume that we have just introduced could also be used as a textbook for Ethics and Moral Philosophy students.

In fact, it creates a very stimulating exercise by stopping the reading of each case at the end of the "Narrative" section so that, by not offering the authors' analysis in continuation, the reader draws up their own well-founded response as best as possible. This type of deliberative regime makes whoever carries it out fine-tune their moral discernment and good practical judgment. Therein lies the challenge for the interested reader.

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