Editorial

The impact of Covid-19 on informed consent

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The last 18 months have seen epochal changes in nearly all segments of our society. The Covid-19 pandemic has brought with itself so many changes also in our way of dealing with emergency in the context of medical and clinical settings.

Through a number of contributions that span the enormous impact that Covid-19 has had on the notion of informed consent, this special issue wants to highlight some of the changes that our society has already faced or will have to take into account in the near future when discussing informed consent, research, autonomy and ethics. Research for the preparation of this BioLaw Journal Special Issue has been conducted within the framework of the European project "Improving the guidelines for Informed Consent, including vulnerable populations, under a gender perspective" (i-CONSENT), project funded by the European Union framework program H2020 (Grant Agreement n° 741856).

To begin with, by analysing the bioethical discussion and in particular the international and national documents with bioethical and biolegal relevance, I introduce the readers to the latest challenges posed to the notion of informed consent in clinical trials within the context of the Covid-19 pandemic, to be immediately followed and reinforced by Fabio Macioce's contribution, where he considers the specific vulnerabilities exposed by a pandemic. By underlining their medical, biological and socio-economical dimensions, Macioce pushes us to rethink the very idea of vulnerability -and its impact on the notion of informed consent for society more at large.

Carlo Petrini, Margherita Daverio and I are the authors involved with the part of this special issue concerned with Covid-19 and biomedical research. Petrini's contribution highlights how, to counter the Covid-19 pandemic, measures have been adopted to facilitate research, including observational research. Yet, some of these exceptional measures taken during the pandemic deserve particular attention as they could be also adopted in ordinary situations -helping us changing the paradigm when needed.

Daverio takes into account ethical and regulatory issues concerning vaccine research in the pandemic context, including a discussion of the controversial case of human challenge studies that have been on the news quite intensely during the first year of the pandemic. These studies need a careful ethical oversight in order to keep balanced risks and benefits for healthy volunteers enrolled in these trials, and the risk and benefits ratio assessment should clearly not result in a jeopardy of the informed consent process.

Lastly, my contribution, focused on clinical trials during Covid-19, provides a comprehensive overview of the main challenges for investigators-physicians and patient-participants, discussing their ethical implications for informed consent.

In the next section of the issue, Mirko Daniel Garasic takes issue with some of the more obscure implications of the widespread use of contact tracing apps during the Covid-19 pandemic. Starting off with an analysis of the increased use of this type of apps worldwide in the past year or so, Garasic questions the boundaries of the state of exception linked to some of those data collecting enterprise, pondering the relationship between public and private actors. Still on the path of technology and

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pandemics, Alberto Tozzi and Giulia Cinelli discuss the role of artificial intelligence when applied to clinical trials in Covid-19 times, arguing that -among other things- given that Covid-19 has promoted the application of digital tools and of AI in clinical trials in order to limit personal contacts, this change might possibly speed up the adoption of AI solutions for clinical trials. This deserves a careful analysis of the potential ethical implications of such a revolution.

The subsequent theme considered is that of biological samples.

First, Monica Toraldo di Francia explains how biological samples, and the genetic personal data connected to them, are subject to special protection; focusing on this issue of great general bioethical importance, particularly in the current context of the Covid-19 pandemic, she highlights some theoretical-philosophical problems which underlie, from the very beginning, the bioethical and bio-juridical debate regarding both the status of biological samples donated for genetic research purposes, and the right of sample donors to choose whether or not to know individual results of potential clinical relevance.

Second, Pablo Enguer-Gosálbez, Jaime Fons-Martínez, Javier Díez-Domingo and colleagues bring to the issue some useful and timely data from the Spanish context, explaining how the Spanish biobanks have reacted to the Covid-19 pandemic, how they have managed the informed consent process during this exceptional time and what -possibly long-lasting- changes have been implemented during the emergency.

Finally, in the last section of the issue, we will engage with the shift of considerations related to the boundaries of health data – questioning how digital technologies (and the resulting rights and duties) might, should or will impact our sense of ownership of private data, hence the resulting need (or not) of our informed consent.

Andrea Parziale, Giovanni Comandé and Denise Amram's contribution maps out the ethical and legal implications of the controversial trend of "cutting corners" for data protection and informed consent in pre-marketing and post-marketing studies on medicines and medical devices in the context of the Covid-19 public health emergency.

In the last article, Federico De Montalvo Jääskeläinen deepens the analysis connected to health data, arguing -through the eyes of the EU Data Protection Regulation- that the pandemic should function as an opportunity to reconceptualize our ethical and legal understanding of personal medical data, privacy and, crucially connected to those, informed consent.

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