Editorial

# Why informed consent requires attention once more?

**Laura Palazzani**

At the end of WWII, through an analysis of the atrocities committed by so-called doctors and men of science, the world had to face the cruel reality that torture and dehumanization had led humanity to cross lines that should never be trespassed. Trials and experiments made on prisoners without their consent -and with a masochistic level of cruelty- pushed the international community to increase the centrality of individual autonomy and the right of the patient to say "no".

Yet, despite the noble intention, individual autonomy cannot be (and has not been) the answer to all problems. At times, the (benevolent) interference of third parties (family members, doctors, spouses) might be the ethical way to go. In other situations, we might have to assess how much our consent is in fact "informed" when we thick a form online.

In addition, recent social and cultural changes in European and extra-European countries, as well as changes in technology and science, have called for more attention for informed consent. A notion in need of some restyling in line with such changes.

As a result, the European Union has decided to fund "i-CONSENT", a Horizon 2020 project aimed at improving the guidelines for informed consent so to improve the information that patients receive from clinical studies -with particular attention given towards vulnerable populations under a gender perspective.

The i-CONSENT project is first presented in this special issue of the journal by Jaime Fons-Martínez, Cristina Ferrer-Albero, Rosanna Russell, Elizabeth Rodgers, Linda Glennie, Javier Díez-Domingo. Straight after that, I illustrate the emerging ethical problems related to the presence (or absence) of informed consent in experimentation. The philosophical analysis is then carried on with the contribution by Fabio Macioce, who stresses the importance of the interconnection between autonomy and trust in all the procedures involving informed consent.

Of course, this is particular evident and sensitive with minors. For this reason, first, we have Jaime Fons-Martínez et al. analysis of the differences between the scientific literature and the legal requirements in terms of contents of the minor's assent in medical re-search. Second, Leonardo Nepi looks into the European guidelines and recommendations on minor's assent and parental permission -with particular attention on the informed consent process in paediatric clinical trials.

Minors are not the only particularly vulnerable group that our project takes into account. Women, as well as religious and cultural minorities have also much relevance in the trajectory of our investigations. As a result, Loredana Persampieri begins this part of the special issue by talking about the specific ethical -and other- challenges of gender in the conceptualization of informed consent in clinical research.

A challenge on how we might change our conceptualization of informed consent is also at the centre of Alberto Garcia and Mirko Garasic's contribution -with their article stressing the connection between neuroscience, new (possible) human rights, religion and culture.

The impact of culture and religion on informed consent is further expanded by the contribution made by me and my team at Lumsa University, where we bring forth an argument in support of new strategies for increasing participation of patients from diverse cultural and religious backgrounds in clinical trials.


ISSN 2284-4503

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The last two contributions are also the result of the work carried out at Lumsa University. With her paper, Margherita Daverio focuses on informed consent in translational/clinical research, paying particular attention to the ethical issues according to international guidelines. Valeria Ferro instead, takes into account the legal aspects of informed consent in clinical research -with a particular emphasis on vaccines.


ISSN 2284-4503