



Taking the high road retroactively: flexible and robust framework of ethical thoughts over time

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Published online: 7 February 2024

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In 2017, we went through a drastic change in legal regulations when conducting clinical research in Japan. One of the most significant, and therefore influential changes made to the Clinical Trials Act (CTA) was the limitation of patient-derived materials exclusively for the approved purpose. Specifically, one cannot use the materials for any other purposes other than those explicitly stipulated beforehand in the protocol. This prevents us from re-cycling the specimens and genetic materials for other purposes that were not approved by the Institutional Review Board (IRB). The amendment highlights at least two important points that should also be reconsidered in our expertise. One is the concept of ‘ownership of the body’, and the other is much more complicated and diversified viewpoint or mindset of ‘compromise to the contemporaneity’, which means uncritically following the social atmosphere. These can be interdependent and hard to be considered separately.

In Japan, cadavers used for educational purposes in medical and dental schools are donated by volunteer individuals with a living will. The system is legally defined by the Act on Body Donation for Medical and Dental Education (ABD), which is further supported by the Post-mortem Examination and Corpse Preservation Act (PECP). As dead bodies are donated to the educational institution, the ownership of the body is automatically transferred to the universities and colleges, while, in principle, ashes are returned to the bereaved families after the incineration, to comply with the Japanese traditions. With recent upsurge in cadaver surgical training (CST), some volunteers agree to the use of their body toward CST. In such cases, we take written permission from those who do not deny the use of body for the purpose of CST.

No matter how the cadaver is ‘donated’, the ownership appears to be still alive after the body donation, as the

purpose of body donation was limited to the educational activity to the students as well as the trainees of surgical expertise. Therefore, in case we plan to conduct a systematic survey or research based on the cadaver, we have to prepare a protocol that must go through the IRB to judge whether the submitted research proposal is legally, ethically, and scientifically sound. Although the proposed study may be different from the clinical trial, and never invoke any harmful event to the donor, we have to respect the philosophy of the CTA.

Let us consider a situation where collections of cadavers or body parts were curated for longer periods before the current legal and ethical fundamentals had been implemented. In almost all cases, cadavers had been ‘donated’ in the original sense of the word, or in some cases, acquired without any unequivocal permission under the customs of medical community in these periods. If the term ‘acquisition’ sounds too strong to be unintentionally taken as violating the law, we prefer to use more euphemistic term, such as ‘automatic transfer of ownership through medical routine’. For example, collections of human embryos and fetuses gathered from obstetrics department and maternity hospitals are representative of the issue. In this case, how can we reconcile with the concept of ownership pertaining to the cadaver? While the bodies were acquired, at least without violating the law in those days, times have drastically changed, both in terms of regulations, and social and ethical atmosphere prevailing worldwide. In this sense, the process of acquiring the foetus was in accord with the consensus upon contemporaneity, but at present, it would be judged as ethically incorrect.

Contemporaneity, undoubtedly, plays an important role in building a consensus on the manner by which one behaves in the society and sets a standard of ethical viewpoint. In this perspective, the collections are legitimate in both legal and social sense in the light of contemporaneity of the time when the collections were established. However, consensus based on the contemporaneity do not always take the right path. One example dates back to the era of Nazi dominance over 80 years ago in the Third Reich. Distinguished anatomist

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Eduard Pernkopf, renowned for his meticulous atlas of topographic anatomy (*Topographische Anatomie des Menschen, Atlas der regionär-stratigraphischen Präparation*), was criticised later by Edzard Ernst (1995) for his usage of cadavers (executed person by Nazi), which were directly delivered to his institution at the University of Vienna. I have no intention to explain this case in detail here and to report the ethical issue in terms of the crime against humanity; however, it certainly draws our attention on the results brought about by compromising the common sense of contemporaneity or dominant atmosphere of the age, as stated by Weizsäcker in his historical speech (1985): “*Es gab viele Formen, das Gewissen ablenken zu lassen, nicht zuständig zu sein, wegzuschauen, zu schweigen* (there are many forms to distract the conscience, not to be responsible, to turn their gaze and to keep silent) (Weizsäcker 1985).

The bottom line is that Pernkopf was not at all extremely deviated in terms of contemporaneity at the time of Third Reich. However, he had to flexibly have a universal sense of humanity and robust ethical framework on human beings. Compromising with the trend of contemporaneity may make us somewhat blank-over and blind to the sensitive and critical matters that will be condemned in later eras. We can see an allegory in *mouton de Panurge* by François Rabelais (Rabelais et al. 1994), which symbolises those who follow others without foreseeing the consequences or disaster.

It would not be pertinent to criticise the behaviours of the past era simply based on the current legislation and ethical codes. If this is applied to all the cases in the past, the social system would neither go well nor be sustained. Contrarily, if there is a significant gap in the code of ethics between the

not-far away past and the present day, we have to take care not to violate the universal framework of ethical attitude over time. This may be true in considering the handling of anatomical heritage obtained from human body and curated for longer durations. Taking the high road in a retroactive way may pave the *bona fide* way to a new horizon of biomedical research.

Acknowledgements The author would like to thank Prof. Takaichi Fukuda, Executive Director of the Japanese Association of Anatomists (JAA) and Dr. Toshio Miyashita at Teikyo University for their critical reading, valuable comments, and discussions.

Data availability Not applicable.

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