

The Front of "Life Science and Law": Focusing on Human Gene Editing and Mitochondria Replacement

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The area of life science, medical science and medicine is very dynamic and flexible. Now we are confronting with two advanced issues; **human gene editing** and **mitochondria replacement**. How should we response to these difficult issues from the viewpoint of medical law.

In the post genome era, it may be disadvantages for mankind that the law regulates too strongly scientific and medical activities of this field because it can obstruct the progress of life science or medicine. Therefore on the one hand, it is true that the freedom of study and research should be guaranteed by the Art.23 of the Constitution in Japan. On the other hand, however, we must carefully examine whether this freedom is unlimited or not.

We must consider the balance between the promotion of life science or medical science and protection of human right in this field. Thus we must rethink how we should regulate illegal misconducts in this field. In connection with these perspectives, I have proposed "**the Legal Doctrine of Medical Due Process**" as a Fundamental Model of Medical Law since 2002. As a result of comparative study, in Japan, we should aim at this mixed type between hard law and soft law. And yet, we should consider into "**the Legal Doctrine of Medical Due Process**". This is the legal theory on which I have insisted for a long time. According to this theory, as a rule, medical

innovation/medical research without due process is unlawful. And Medical Due Process contains (1) informed consent, (2) balancing between risks and benefits, (3) due review by appropriate ethical committee, and (4) compensation to human subjects system because of impossibility to foresee concrete risks. And furthermore (5) it contains some exceptional various legal sanctions to extreme abuses. Due to this doctrine, we can build a bridge between law or bioethics and medical and scientific research and practice. I think that we can realize it by enacting the Fundamental Law of Bioethics in Japan.

In my opinion, this theory is meaningful also in the field of like **human gene editing** and **mitochondria replacement**. In this paper I try to present the legal framework on the ground and the way to regulate these new techniques.