Legal and Ethical Considerations of Brain Organoid Technology

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Organoids enable the study of organs in 3D models, allowing modification of genetic and environmental factors that influence ultimate function.[1] Organoids are essentially microcosms of organs, recapitulating organ function. Derived from stem cells, organoids are propagated in culture in three-dimensional cell clusters for later experimentation.[2] Organoids develop upon the culture of pluripotent cells - meaning that organoids may develop into any of a variety of different mature cell types when placed in an amenable environment for growth- hES (human embryonic stem) and hiPS (human induced pluripotent stem) cells.[3] The stem cell origins of organoids enables them to develop into a multitude of different organoid types.[4] In this fashion, organoids are capable of regenerating and modeling development and disease in organs such as the liver, pancreas, lung, intestine, stomach, prostate, breast, and brain.[5] [6] [7] [8] [9] Thus, biomedical

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research *in vitro* and *in vivo* using organoids has potential uses for diagnostics, precision and personalized medicine, tissue regeneration and transplantation.[10] [11]

Yet, ethical considerations are increasingly debated as demand for brain organoid technology increases and clinical trials progress.[12] [13] [14] [15] Concerns regarding the potential sentience of cerebral organoids have left neuroethicists and bioethicists in a quandary regarding the morality of their creation and use.[16] Recently, scientists detected brain wave activity which mimicked that of whole brain specimens in brain organoids. [17] The brain wave activity was positively correlated with the age and maturity of the brain cells.[18] Although many scientific entities, including EuroStemCell, a research initiative supported by the European Union's Horizon 2020 program, currently deny that brain organoids are capable of consciousness or higher-order thinking, this does not mean that brain organoids will remain incapable of such

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activity.[19] As brain organoid technology becomes more sophisticated, clinical and research teams must consider how they will adeptly weigh legal and ethical concerns of informed consent, human rights, and a host of other relevant issues. This research project will examine how clinicians, ethicists, policymakers, and legal scholars may address some of these future brain organoid concerns.

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