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Marietjie Botes

Dyason Inc, Republic of South Africa

Material transfer agreements for human biological material: Successful sample and data sharing in the framework of European and South African privacy laws

Insurance companies in South Africa are increasingly developing insurance products which will enable patients to afford genetic testing for purposes of personalized medicine, specifically in the oncology fields. But because South Africa does not currently possess sufficient local capacity to sequence and/or test genetic samples, these services will have to be outsourced to laboratories in foreign countries. South Africa is also home to the San, an indigenous population with the oldest living genes on earth, which make this population highly sought after for GWAS and other genomic research. It is thus clear that South Africa scientists and medical practitioners will increasingly engage with their foreign counter parts by means of Material Transfer Agreements, as these are only two examples of areas where the cross border transfer of human biological material will be imminent. In July 2018 South Africa has adopted its first formal Material Transfer Agreement for Human Biological Materials in terms of its National Health Act 61 of 2003 which, amongst others, addresses issues such as benefit sharing, informed consent, publications and publicity. However, this agreement sorely lacks substance when it comes to the management of intellectual property, which often constitutes the lifeline of biotechnology companies. It also does not deal with material ownership, as opposed to possession, or privacy, further considering that genetic material and genetic sequences resulting there from cannot really be de-identified to comply with the recently enacted European GDPR and the South African Protection of Personal Information Act 4 of 2013. Further considering the vulnerability of both sick patients and an indigenous minority group, coupled with the sensitivity of the medical and population data that may be gathered from the genetic testing and/or sequencing of these persons, the value of Material Transfer Agreements (MTA) and the ethics and legal issues surrounding it is of critical importance to ensure a balance between the rights and protection of patients or research participants and easy access to biotechnological services, samples and data by scientists and medical practitioners to aid biomedical innovation.

Biography

Marietjie Botes is the Founder and Managing Director of Biolawgic, a private company focusing on the promotion of Bioethics and Director at Dyason Inc in Pretoria where she specializes in Health-tech, Fin-tech and Bio-tech Contracts, Biotechnology Law, Health Care and Life Sciences Law and Insurance Litigation. She is particularly interested in and passionate about genetic, genomic and stem cell research and has published numerous articles in both national and international journals on these topics.

marietjie@dyason.co.za

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