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Patient Protection, Engagement & Informed Consent: The Virtual Consent Global Initiative to Enhance Patient Engagement and Reduce Physician Burden

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The broad engagement of patients in medical research is essential for gathering evidence from all parts of society in order to develop innovative therapies and medicines. This assertion has never been more important than today in the era of personalized medicine where efficacy and adverse events are increasingly based on genetic and epigenetic factors. The issue is that research is largely restricted to convenient populations while other populations are excluded for linguistic, cultural or education limitations as many "Informed Consents" require medical literacy. Given that the participation in research is necessarily voluntary, these barriers restrict the voluntariness of Consent and skew the applicable outcomes in favour of participating populations.

This presentation will explore the advantages of a Virtual Consent Platform that can be implemented globally to reduce or eliminatesuch barriers for diverse populations thereby creating greater access for disadvantaged patients to appropriate clinical findings regardless of culture, language, education and literacy globally. Such a platform will increase the understanding and acceptability of potential participants so that the Voluntary Consent is more of a truly "Informed Consent" and less subject to legal challenge for clinicians. A Virtual Consent Platform developed as a "Transactional Consent Process" where participants interact with the consenting process over timeand Consent is tracked, verified and stored for later retrieval. As clinical studies inevitably are amended over time requiring patients to be informed of such changes, such a Platform allows convenient and timely access to patients to inform them of changes that may alter their willingness to voluntarily participate in a study. This presentation will provide a concrete example of a Virtual Consent for neurodegenerative diseases to illustrate how such a simplified system would work to better inform participants considering enrolling in clinical research trials. At the same time, physicians are better protected legally as a result of a documented, transactional Consent process.

Biography:

Ronald J Heslegrave is currently the Corporate Chief of Research at William Osler Health System in Toronto, Ontario, Canada. He has built a vibrant research and innovation program for one of the largest Community Hospital Systems in Canada focusing on the evaluation and implementation of innovative healthcare delivery both in hospitals and the community. In 3-4 years he has grown the research studies conducted from a few interested investigators conducting a very limited number of studies to over 200 studies with budgets totaling more than $5+M. This innovation is designed to provide transformational and integrated health care delivery systems of care through technology in an evidenced-based, system-based approach to care. Previously, he was a Senior Scientist in Research Ethics at the University Health Network, University of Toronto where his interest is in new models of ethics review oversight and developing new processes for protecting and informing participants of research. Previously he was appointed as the Inaugural Executive Director of the newly formed non-profit corporation in Canada called Clinical Trials Ontario supported by the Ministry of Economic Development and Innovation. This is a government-supported initiative which had the mandate to make the Province of Ontario a preferred location for global clinical trials. He also established a single Research Ethics Board for Cancer Research in 2004 which continues to thrive in Ontario. He also served on the Canadian Expert Panel on Research Integrity to establish the way forward for improving research integrity for the oversight of scientists in Canada.