CHICKEN SOUP FOR THE BUSY COORDINATOR

OCTOBER 2018

OBTAINING CONSENT FOR ADULTS LACKING MENTAL CAPACITY IN HUMAN BIOMEDICAL RESEARCH

Case Scenario

An activity tracker had been designed by a local research centre and IT industry partners (the consortium partners) to assist researchers with the collection of data from elderly participants with moderate to severe Alzheimer's Disease, to monitor their daily activities. The tracker is a wearable device which allowed researchers to track the patients' daily activities and sleep pattern. The participant are required to sync the device to a central website with assistance from the caregiver weekly. The consortium partners stated that the data collected would be anonymised, and no identifiers would be collected or stored. On the other hand, researchers will be collecting other health indicators such as vital signs. The collected data will enable researchers to create targeted self-help interventions.

Is Informed Consent Required from the Participant and How Should it Be Obtained?

Yes, informed consent is required as the researchers would be collecting identifiable health indicators of participants and this is a human biomedical research involving individuals with diminished capacity. The informed consent process should be obtained in accordance to the HBR Act (HBRA) requirements *(Refer to the diagram below for the consent taking hierarchy for adults lacking capacity.*

NOTE:

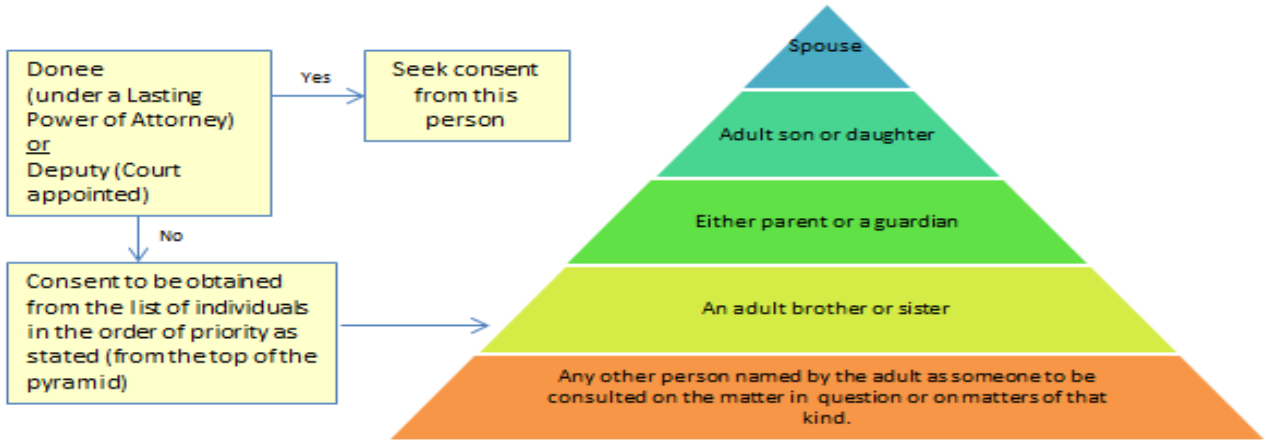
(i) According to the Mental Capacity Act (Chapter 177A) Section 4, "a person who lacks capacity is one who lacks mental capacity in relation to a matter, if at the material time, this person is unable to make a decision for own self in relation to the matter because of an impairment of, or a disturbance in the functioning of, the mind or brain".

(ii) The DSRB may require independent assessment of capacity for such research and the investigator may also use the NHG DSRB Sample Language for Documentation of Capacity template for this purpose.

(iii) HBR that are determined to be not invasive and not interventional, subject to the determination of the DSRB, may be exempted from the requirement for witness.

Consent Hierarchy for Adults Lacking Capacity

(HBRA 2015, Part 3, Section 7: Consent for research involving adults who lack mental capacity)



Note: If consent had been refused from the individual on the highest list, consent may not be obtained from the rest of the listed individual (e.g. if the spouse had refused consent, the consent cannot be obtained from the adult son/daughter).

Reference:

- Mental Capacity Act (Chapter 177 A), Part II Persons Who Lack Capacity (https://sso.agc.gov.sg>Act>MCA2008)
- NHG Investigator's Manual 3rd Edition, Chapter 6.3: Research Involving Cognitively Impaired Persons
- NHG Proper Conduct of Research SOP, 501-C01: Informed Consent Form and Process
- NHG DSRB Sample Language for Documentation of Capacity (www.research.nhg.com.sg > Home> Resources> Ethics Forms and Templates

Article Contributed By: **Ms. Jaclyn Ong, Senior Clinical Research Coordinator, Institute of Mental Health**
Edited By: NHG-RDO

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(researchcoord@nhg.com.sg)