CHICKEN SOUP FOR THE BUSY COORDINATOR

November 2019

How Should Consent Be Obtained From Subjects Lacking Mental Capacity?

Scenario:

Doctor Green has 2 new approved studies. One is regulated by the Human Biomedical Research Act (HBRA) and involves the recruitment of adults lacking mental capacity. The other is regulated by the Health Product Act (HPA) involving the recruitment of unconscious adult subjects. He is unsure on the informed consent process for these groups of subjects. Therefore he asked a senior Clinical Research Coordinator (CRC) what should be done. The senior CRC shared the following information:-

Obtaining consent for subjects of HBR regulated under the HBRA

The **appropriate consent** for the adult must be obtained from the following persons in the following circumstances:

a) Where there is a donee or deputy who is authorised to give consent to the biomedical research on behalf of the adult, consent is be obtained from the donee or deputy;

b) Where there is no donee or deputy who is authorised to give consent to the biomedical research on behalf of the adult, consent is obtained from any of the following persons in the order of priority stated, when persons in prior classes are not available, and in the absence of actual notice of contrary indications by the adult, or actual notice of opposition of a member of the same class or a prior class:

   i. The spouse;
   ii. An adult son or daughter;
   iii. Either parent or a guardian;
   iv. An adult brother or sister;
   v. Any other person named by the adult as someone to be consulted on the matter in question or on matters of that kind.

Obtaining consent for subjects of Clinical Trials regulated under the HPA

Prior to obtaining consent from adults who lack mental capacity:

A. Dr Green who is a qualified medical practitioner will need to find another qualified and registered medical practitioner who is not conducting the clinical trial to certify in writing that –

- ✓ The adult lacks capacity to consent to being a subject, and
- ✓ It is unlikely that the adult will regain capacity within the window period;

A. Dr Green must obtain consent from subject's legal representative:

a) A donee (appointed by the adult before he/she lost capacity) or

b) Where there is no donee or deputy referred to in point a), then Dr Green must obtain consent from any of the following persons in descending order of priority:

   i. A spouse of the adult;
   ii. An adult child of the adult;
   iii. A parent or guardian of the adult;
   iv. An adult sibling of the adult;
   v. Any other adult named by the adult (when the adult did not lack capacity) as someone to consult on the issue of the adult being a subject.

For more information and conditions for applying the order of priority for consent, refer to HSA Regulatory Guidance: Safeguards and Consent Requirements in Vulnerable Subjects.

The senior CRC also reminded Dr Green to:

- ✓ Document the consent process in the subject's source documents (e.g. medical records), which should include an assessment of subject's capacity to give consent and an explanation for the choice of legal representative.
- ✓ Re-consent at the earliest feasible opportunity if subject subsequently regains mental capacity.

References:

- Human Biomedical Research Act 2015, Human Biomedical Research Regulations 2017
- Health Products (Clinical Trials) Regulations 2016 and Medicines (Clinical Trials) Regulations 2016
- Health Sciences Authority Regulatory Guidance (GN-CTB-2-003C-002) - Safeguards and consent requirements in vulnerable subjects 02 May 2017
- NHG Investigator manual 3rd Edition Sept 2017 Chapter 6.3- Research Involving Cognitively Impaired Persons & NHG Investigator manual Addendum Version 1 December 2018 Chapter 6.3 – Research Involving Cognitively Impaired Persons
- NHG Proper Conduct of Research SOP: 501 – C01: Informed Consent Form and Processes

Article Contributed By: Ms Su Jialei, Research Nurse; Ms Lim Boon Khim, Senior Research Nurse; Ms Jolene Ong Jia Min, Research Coordinator, KTPH

Edited By: NHG-RDO

***Proudly brought to you by*: Clinical Research Coordinator Society (CRCS)**
(researchcoord@nhg.com.sg)