CHICKEN SOUP FOR THE BUSY COORDINATOR

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How to obtain informed consent from subjects with cognitive impairment

Scenario:

Principal Investigator (PI), Dr Oliver, is conducting a Human Biomedical Research Act (HBRA) regulated study and a Health Product Act (HPA) regulated clinical trial. Both studies are recruiting adult patients who are cognitively impaired and have obtained the relevant approval (e.g. IRB, HSA). He is unsure of how **consent** should be taken. He consults his Clinical Research Coordinator (CRC) and the CRC shared the following information:

HBRA regulated study	HPA regulated clinical trial
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 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 **REMINDERS** 1. Assessment of subject's capacity HBRA does not prescribe how cognitive assessment is to be conducted but IRBs may impose their own requirements. Please check with your IRBs. 2. Documentation After consent is obtained, document the consent process in the source documents, including the supporting documentation to prove the relationship of the authorised persons giving consent on behalf of the subject and documentation of assessment of the subject's capacity. 3. Consent from Subject Though HBRA does not state the need for consent from subject when he/ she regain capacity, the IRBs may impose own requirements. Please check with your IRBs.	**Consent requirements to be fulfilled prior to enrolment of an adult lacking capacity in a clinical trial**: a. The **investigator who is a qualified practitioner, and another qualified practitioner**, who is not conducting the clinical trial **certify in writing** that – i. The person lacks capacity to consent to being a subject; and ii. It is not likely that the person will regain capacity within the window period; b. **Consent has been obtained from** – The subject's legal representative, who is: a. The donee or deputy appointed pursuant to or under the Mental Capacity Act in relation to the giving or refusing of consent on behalf of the adult to be a subject; or b. Where there is no donee or deputy, 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. c. When assessing the suitability of an individual to act as the legal representative, the study team must also ensure the following requirements are met: i. The order of priority applies in the absence of actual notice of any contrary indication given by the subject or prospective subject (when the subject or prospective subject did not lack capacity); ii. A person referred to in paragraph (b) cannot be a legal representative of the subject or prospective subject if the person is also a donee or deputy and there is an express provision in the lasting power of attorney or appointment by the court that the donee or deputy is not authorised to give consent to the adult being a subject; iii. A person referred to in paragraph b (i), (ii), (iii), (iv) or (v): A. May be a legal representative only if all persons having a higher priority compared to that person are not available or cannot be a legal representative by reason of c (i) or (ii); and B. Cannot be a legal representative if any person having an equal or a higher priority compared to that person [other than a person who cannot be a legal representative by reason of c (i) or (ii)] has objected to the adult being a subject. **REMINDERS** 1. Documentation After consent is obtained, document the consent process in the source documents, including the supporting documentation to prove the relationship of the authorised persons giving consent on behalf of the subject and documentation of assessment of the subject's capacity. 2. Consent from Subject For Clinical Trials regulated under HPA, if the adult subsequently regains capacity to consent to being a subject, the PI must ensure that, at the earliest feasible opportunity: a. The person is given a full and reasonable explanation of the required elements of the informed consent; and b. The person's consent to continue being a subject in the trial is obtained.

References:

1) NHG investigator manual 4th Edition 4 Mar 2022 Chapter 6.3- Research Involving Cognitively Impaired Persons Page 14-19
2) Health Sciences Authority Regulatory Guidance- Safeguards and consent requirements in vulnerable subjects 01 Mar 2021 Page 21-26
3) NHG PCR SOP 501-C01 Informed Consent Form and Process

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