Guidance for Ethical Research with People that have Cognitive Impairment

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A. General

One major principle in research ethics is ensuring that participants have the capacity to make autonomous choices and decision about their participation in research. Cognitive impairment in general, makes affected persons lose the capacity for autonomous decision-making, thus the need to provide them additional protection when being considered for research participation.

This document provides guidance to Health Research Ethics Committees (HRECs) to ensure ethical participation of persons with cognitive impairment in research.

Definition(s)

Cognitive impairment - Cognitive impairment is present when an individual is unable to think, remember or reason, and this negatively affects the individual's ability to concentrate or make decisions that affect their everyday living. The impairment may be permanent or temporary, transient, or progressive.

B. Specific Guidance

1. HREC responsibilities in approving research in cognitively impaired individuals

1.1 The National Code for Health Research Ethics (NCHRE) subsequently referred to as the Code herein, provides overarching guidance for the ethical conduct of health research in Nigeria. All the provisions of the Code apply to protection of human research participants.

1.2 Persons with cognitive impairment shall not be needlessly excluded from participating in research.

1.3 HREC must determine the type of cognitive impairment in consideration, whether permanent or temporary, transient or progressive; and ascertain whether proposed research needs to be conducted during the period of impairment.

1.4 HREC must determine whether the informed consent process provided by researchers is adequate for the specific characteristics of potential participants with cognitive impairments.

1.5 Participant's assent may be sought when sufficient cognitive capacity is presumed to be present. In such circumstances, non-response must not be construed as assent.

2. Capacity assessment

2.1 Researchers must describe an adequate method for assessing the capacity of potentially cognitively impaired individuals to make and communicate informed choices that is commensurate with participant's cognitive state, research risks, complexity of research, degree and duration of participant's involvement.

2.2 HREC shall ascertain that research proposals that would include cognitively impaired individuals have adequate methods for assessment of cognitive capacity prior to enrolment in research

2.3 HREC shall make the final determination on the appropriateness of the method for assessment of cognitive impairment of the participants and the professional competency of the assessors.

3. Informed Consent

3.1 Researchers must propose informed consent process that is appropriate for the nature of proposed research and its associated risks.

3.2 Cognitive impairment may fluctuate therefore a process for re-consenting research participants during the course of research may be required and mandated by HRECs.

3.3 Where participant is sufficiently impaired that they cannot give informed consent, consent may be given by:

i. Legally authorized representative
ii. Individuals previously designated as surrogate for decision-making purposes by the participant.
iii. First-degree relative (other orders of relatedness can be considered hierarchically) with consensus from other primary care givers.
iv. Health institutions and legal authorities.

3.4 Research may be conducted under a waiver provision if none of the above options are practicable.

3.5 HREC may request implementation of an independent consent verification and/or research participation monitoring mechanism commensurate to the risk-benefit balance of the proposed study. This shall involve third parties who are not part of, or related to the research team, staff of the sponsoring institution or their relatives, or the participant's relatives.

3.6 Substituted decision making by appointed surrogates must reflect preferences indicated by the participant while still cognitively capable otherwise surrogates can decide based on perceived best interests of the participant.

3.7 Surrogates may authorize withdrawal of the participant from research.

3.8 When a participant lacks cognitive capacity and demonstrates vigorous refusal to comply with any aspect of the research, this may be construed as refusal to continue participation. This should be reported to the HREC for advice and possible discontinuation of research participation.

3.9 Protocols for community-based cognitive impairment research must include mechanisms for assessments of cognitive capacity that respect prevailing norms and values of communities and demonstrates contextual adaptation of well-referenced prevailing international best practice(s).

4. Advance research directives

4.1 Individuals at risk of cognitive impairment may indicate a choice for research participation in advance of loss of cognitive function in an advance research directive (ARD) document.

4.2 The ARD document must be legally acceptable.

4.3 The ARD document may specify the authority of the surrogate to take decisions only on specific research studies.

Supporting Documentation: This document is to be used in conjunction with the National Code for Health Research Ethics, 2007.