CHICKEN SOUP FOR THE BUSY COORDINATOR

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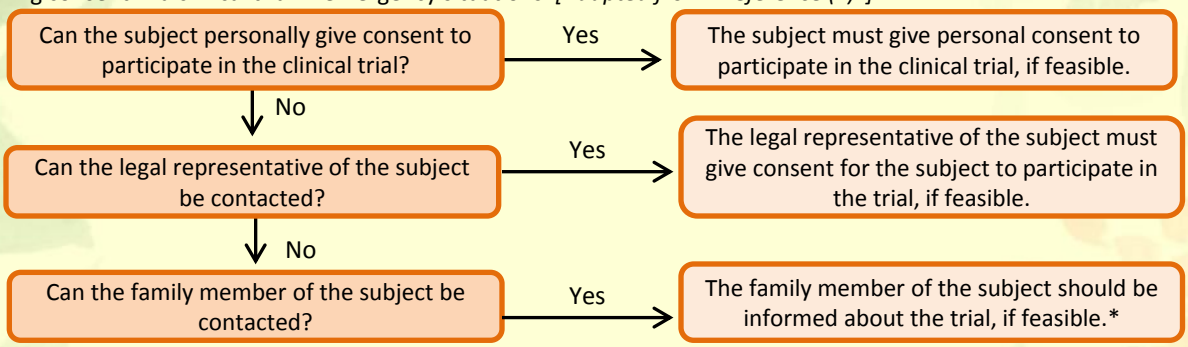
PROCESSES FOR CONSENTING A SUBJECT INTO A CLINICAL TRIAL IN AN EMERGENCY SITUATION

Scenario

Site ABC is conducting a clinical trial on thrombolytic therapy for patients with acute myocardial infarction in the Emergency Department. The study was monitored internally. Below were the 2 findings involving the informed consent process for subjects enrolled into the emergency trial (clinical trial).

1) Consent of subject TT01: The Principal Investigator missed obtaining consent from the subject's legal representative who was present in the emergency room during the occurrence of event.
2) Consent of subject TT03: The consent from subject was not obtainable. In addition, the subject's legal representative and family members were not contactable to determine if they had any objections to the subject being enrolled in the clinical trial. Only the co-investigator (who was a specialist) was present to enroll the subject into the clinical trial. There was no independent specialist to certify in writing that subject fulfilled the conditions required prior to the enrollment into a trial in an emergency situation.

What should have been done as part of the Corrective Action and Preventive Action Plan (CAPA)?
The clinical research coordinator created a flow chart below (as a guide for study team members) on the processes for obtaining consent in a clinical trial in emergency situations. *[Adapted from "Reference (ii)"]*



***Conditions to be fulfilled prior to the enrollment of a subject into a clinical trial in an emergency situation.**

If consent cannot be obtained from the prospective subject or prospective subject's legal representative, and no family member has objected to the prospective subject's trial participation (if feasible), the prospective subject may be enrolled in the clinical trial if the investigator of the trial who is a specialist and one specialist who is not conducting the trial must certify in writing that:

a) the person is facing a life-threatening situation which necessitates intervention
b) the person is unable to consent as a result of the person's medical condition
c) it is not feasible to obtain consent from the legal representative of the person within the window period
d) neither the person nor the legal representative of the person nor any member of the person's family has informed the principal investigator of any objection to the person being a subject in the clinical trial. The certification should either be documented in the subject's medical records or source document.

Please refer to the "Guidance on Safeguards and Consent Requirements in Vulnerable Subject" for the full requirement on the consent process requirements for emergency trials.

Reference:
i. NHG Investigator's Manual 3rd Edition, Chapter 5.8.2: Clinical Trials Conducted in Emergency Situations
ii. Health Sciences Authority, Health Products Regulation, Clinical Trial, Regulatory Guidance: *Guidance on Safeguards and Consent Requirements in Vulnerable Subject*
http://www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/Clinical_Trials/Overview/Regulatory_Guidelines.html

Article Contributed By: Ms. Pang Mei Yan Sr. Clinical Research Coordinator, HORG, NCIS, NUHS
Edited By: NHG-RDO

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(researchcoord@nhg.com.sg)