persons, more time may also be necessary.

Other factors to take into consideration when obtaining informed consent from participants:

DOs:

- Participants should be approached in a conducive environment.
- Participants should be encouraged to discuss their participation with their care-giver(s) and/or family.
- Informed Consent discussion should take place face to face, in person.
- Informed Consent should be obtained before initiation of the study and before any procedures that are being performed solely for the research.
- Informed Consent must be presented in a language that is understandable to the subject.

DON'Ts:

- It would not be appropriate to approach a subject immediately before a procedure or surgery, while in labor, while under sedation or in any other situation where a participant might feel coerced.

- Avoid giving the appearance of being hurried and short-tempered during the consenting process as this may confuse and intimidate potential participants.
- The investigator should not mail the consent documents to participants with instructions to call back with questions, sign and mail back the informed consent document.
- Finally, consent to participation must be obtained from the participant. However, in cases where the legally acceptable representative is required to consent on behalf of the subject, approval needs to be sought from the ethics board who will assess the request based on the subject population being studied or any other special circumstances.

References:

Good Clinical Practice: A Question & Answer Reference Guide May 2011

SGGCP 4.8 Informed Consent of a Trial Subject

NHG PCR SOP 501-C01 - Informed Consent Document and Process

NHG RDO OHRPP UPDATES
NEW MINIMUM TRAINING REQUIREMENT FOR PRINCIPAL INVESTIGATOR

Minimum Training Requirements: Completion of the Singapore Guideline for Good Clinical Practice (SGGCP) course in addition to the Collaborative Institutional Training Initiative (CITI) program for Principal Investigators who are conducting Clinical Trials.

With effect from 1 August 2014, Principal Investigators (PI) who are submitting a new study application to conduct Clinical Trials will have to complete both the SGGCP course and the CITI Program. The purpose of this new training requirement is to ensure that the PI receives the minimum training required for good clinical practices prior to the initiation of the trial. This is needful as each PI is responsible for ensuring proper conduct of clinical trials and safety of the subjects by adhering to the relevant local regulations and guidelines.

PIs submitting a new study application will be required to produce proof of attendance or completion to the DSRB. Experienced researchers who had assumed the roles and responsibilities of PI for multiple clinical trials may apply for a waiver of this additional requirement. A request form for this waiver may be downloaded from the NHG Research Website.

B. POPULATION HEALTH RESEARCH

Minimum Training Requirements: Completion of at least 5 Social and Behavioural Research (SBR) elective modules in the CITI program for PI and Co-Investigators (Co-I) who are conducting population health research.

Elective modules in the CITI program are differentiated into biomedical research or SBR-focused. The ethical issues and principles discussed in the SBR elective modules (study designs involving surveys, interviews, observation and assessment of risks and benefits etc) are more relevant for population health research.

Hence, it will be more meaningful for the PI and Co-I of population health research to complete the SBR elective modules in order to fulfil the minimum ethics training requirement. The PI and Co-I should complete a minimum number of 5 SBR elective modules in the CITI program. The PI or Co-I has to produce proof of completion to the DSRB.

Removal of SGGCP course as a waiver to the Minimum Training Requirement for PI and Co-I who are conducting population health research.

The SGGCP course is intended for researchers conducting Clinical Trials (involving medicinal products or devices) and may not be relevant to researchers of population health studies. Therefore, completion of SGGCP course will not be accepted as completion of the minimum ethics training requirement for PI and Co-I conducting population health research.

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