during the meeting. To support research coordinators and ensure that they are given adequate support for their work, a monthly research coordinator's meeting is also held. During these meetings, useful lectures are given on relevant topics such as consent taking, eligibility, hand washing, *Methicillin-Resistant Staphylococcus Aureus* (MRSA) precautions, chemotherapy, targeted therapy, common side-effects, etc.

Best Practice 6 - Training to Equip and Empower the Research Team

Adequate and proper training is imperative to each and every personnel involved in the research team. Aside from the usual Collaborative Institutional Training Initiative (CITI) and Singapore Guideline for Good Clinical Practice (SGGCP) training, research coordinators also attend extra training for self-development such as Proactive Time and Stress Management and 7 Habits of Highly Effective People. Senior research coordinators may also apply for the International Certification offered by the Society of Clinical Research Associates (SoCRA).

PROTOCOL NON-COMPLIANCE

CONTINUOUS OVER-RECRUITMENT OF RESEARCH SUBJECTS

Background

A multicenter clinical trial had exceeded the approved maximum recruitment target due to an oversight by the Principal Investigator (PI) and his study team. The PI reported the over recruitment to the DSRB in a non-compliance report and informed that additional effort would be made to check on the recruitment status before enrolling new subjects in future.

However, the PI continued to over-recruit subjects. This over-recruitment was detected by the DSRB during the study's annual continuing review submission.

Findings & Implications

Because the PI had continued with an over recruitment of research subjects despite the initial reporting, DSRB deems this as a case of continuous non-compliance. As a result, a DSRB warning letter was issued to the PI. A temporary renewal was also issued under the condition that no subjects should be enrolled until the PI could provide a satisfactory response on the situation. Subjects who were recruited above the target number should also be re-consented.

Tips and Recommendations

a. If the Principal Investigator anticipates subject recruitment beyond the approved target, he/she should submit an amendment to the target number and must ensure that recruitment does not exceed the approved target until an approval is received from the DSRB.

b. It is the responsibility of the PI to ensure that communication is kept tight within the study team and that the study team is updated on the study status promptly. Team communications should include the recruitment strategy, recruitment timelines and plans to manage the study.

References from Singapore Guideline for Good Clinical Practice (SG GCP) and NHG – Proper Conduct of Research SOPs (PCR-SOPs):

[SGGCP 4.5.2] The investigator should not implement any deviation from, or changes of the protocol without agreement by the sponsor and prior review and documented approval/favourable opinion from the IRB/IEC of an amendment, except where necessary to eliminate an immediate hazard(s) to trial subjects, or when the change(s) involves only logistical or administrative aspects of the trial (e.g., change in monitor(s), change of telephone number(s)).

[PCR 501-B03 - Study Initiation] 9. Principal Investigator and the study team should discuss the recruitment strategy and recruitment timelines and plan to manage the study accordingly.

The NHG Proper Conduct of Research Standard Operating Procedures may be referenced at the following portal:

http://www.research.nhg.com.sg/wps/wcm/connect/romp/nhgromp/resources/research+sops

GCP TOPIC

INFORMED CONSENT

Informed consent is the process by which a subject voluntarily confirms his or her willingness to participate in a particular research project after being informed of all aspects of the research study that are relevant to the subject's decision to participate.

Informed consent needs to be documented by means of a written, signed, and dated informed consent document. This process is necessary to ensure that subjects are fully informed before deciding to volunteer as research subjects in research projects of any type. It is a good practice and responsible conduct of the researcher to apply the "reasonable man" criterion. The term "reasonable man" criterion includes the following:

- Sufficient time for a person at the appropriate literacy level to read and digest the consent,
- Sufficient time for the individual to ask the study staff questions and consult with a relative or friend,
- Sufficient time, if requested, to review and research some of the provisions in the informed consent form (i.e. alternative therapies), or
- Sufficient time to reflect on the decision.

As a general rule of thumb, if the proposed study, protocol, consent form and decision making process are complicated, a reasonable person would require additional time to think through the decision. For older adults, children, and cognitively impaired

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.

Article and photos contributed by Haematology-Oncology Research Group, NUHS
Edited by NHG Research Quality Management