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