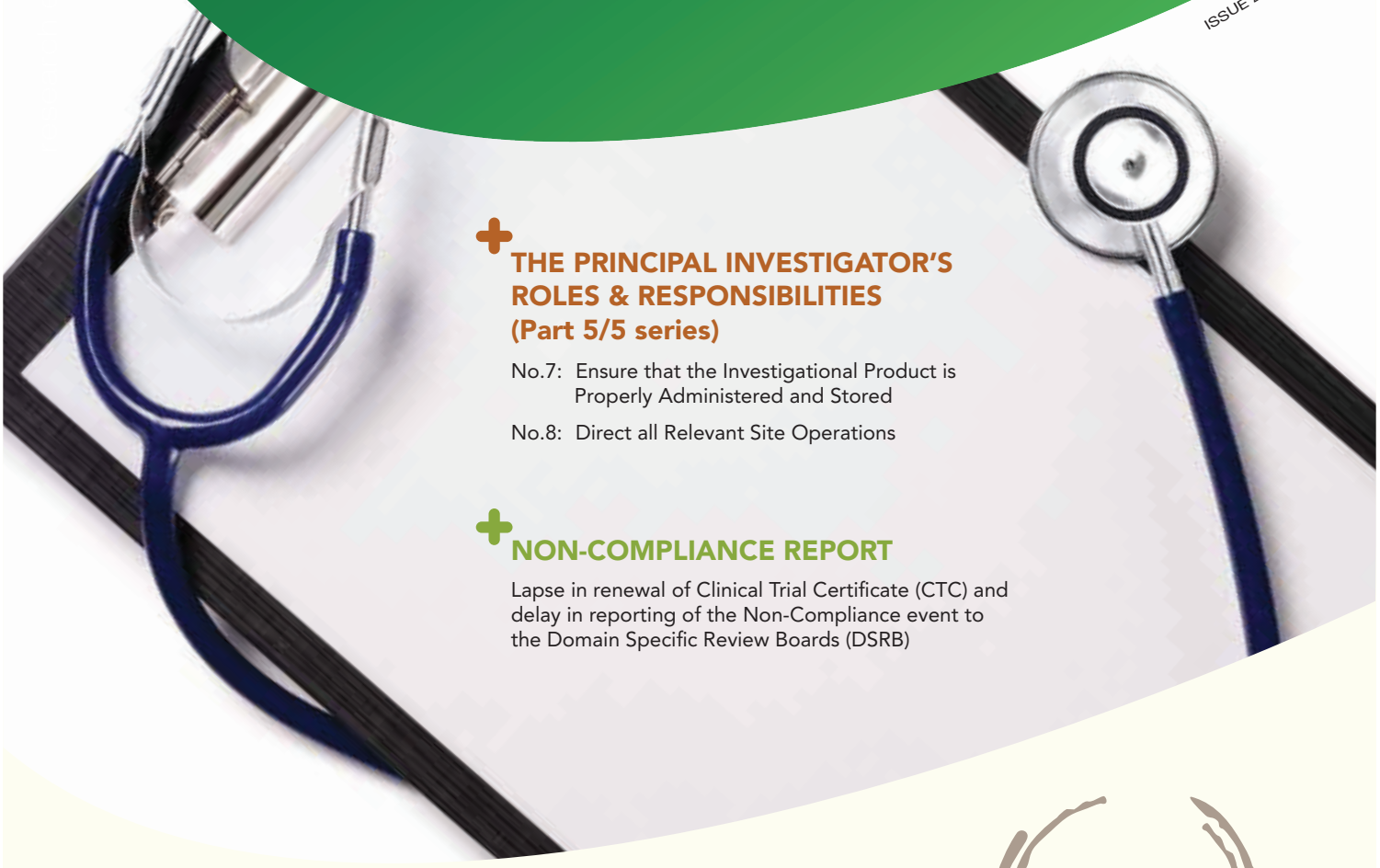
NHG RESEARCH QUALITY MANAGEMENT PROGRAM

QUALITÉ

THE PROGRAM WITH A MISSION TO ENSURE AND ENFORCE THE RESPONSIBLE CONDUCT OF RESEARCH MEETING HIGH ETHICAL STANDARDS

ISSUE 2011/12



THE PRINCIPAL INVESTIGATOR'S ROLES & RESPONSIBILITIES (Part 5/5 series)

No.7: Ensure that the Investigational Product is Properly Administered and Stored

No.8: Direct all Relevant Site Operations

NON-COMPLIANCE REPORT

Lapse in renewal of Clinical Trial Certificate (CTC) and delay in reporting of the Non-Compliance event to the Domain Specific Review Boards (DSRB)

THE PRINCIPAL INVESTIGATOR'S ROLES & RESPONSIBILITIES

The Principal Investigator (PI) is responsible for the Investigational Product (IP) accountability at the trial site. This includes ensuring proper usage and storage of the IP. The investigator can familiarise himself or herself with the use of the IP through reading the product information leaflet or the Investigator's Brochure.

Protect the Rights and Welfare of Research Participants

Approval for Conduct of Research

The Principal Investigator (PI) has the responsibility of protecting the rights and welfare of the research participants throughout their involvement in a research study.

Prior to the commencement of any research study involving human subjects or use of human data, it is always necessary to ensure that approval from the Domain Specific Review Board (DSRB) is obtained. For research studies involving medical drugs and devices, approval from the Health Sciences Authority (HSA) is required.

Informed Consent from Participants

Before a research participant can be enrolled into the study, informed consent must be obtained from him/ her. The informed consent document should contain the elements required by the DSRB, and these elements are outlined in the DSRB Investigators' Manual Chapter 8.1-Informed Consent. When conducting the informed consent process, it is imperative that the language used is one that is understood by the participant. Study-related procedures, including screening tests, can only be carried out after informed consent has been obtained from the participant.

After sufficient time and opportunity have been given to discuss the research study and to address the concerns of the participant, the informed consent document shall be personally signed and dated by the research participant and by the person obtaining the consent. In most cases, the informed consent is obtained by the PI or by a Co-Investigator (Co-I) authorised by the PI to do so. Thereafter, a copy of the signed and dated informed consent document (information sheet and consent form) shall be provided to the participant. It is important to note that only the person conducting the informed consent can sign on the consent form.

If new information becomes available during the course of the research study that may be relevant to the participant's willingness to continue participation in the study, the participant should be informed in a timely manner. An example of such information would be new side-effects associated with the use of an investigational product.

Participants who are unable to read

In situations where the participant is unable to read, the PI has to secure an impartial witness for the entire conduct of the informed consent process and to ensure that the participant is properly informed of all aspects of the research study. An impartial witness is a person who is independent of the research study, who cannot be unfairly influenced by people involved with the study, who attends the informed consent process if the participant cannot read, and who reads the informed consent document and any other written information supplied to the participant.

Legally Acceptable Representative

A Legally Acceptable Representative (LAR) may give consent on behalf of an individual for participation in a research only when the individual is not capable of giving legally effective informed consent, such as in the case of a child, an individual who is cognitively impaired, or an individual who is unconscious. A LAR may be the spouse, parent, guardian (if there is no parent), person having charge of the individual, or person authorised by state law to consent on behalf of the individual. When consent is obtained from the LAR, the above-mentioned requirements must continue to be observed.

Research Involving Children

For research involving children (below 21 years), the person conducting the consent discussion should ask the child whether or not he or she wishes to participate in the research. This is out of respect for children as developing persons. In general, the DSRB requires that assent be obtained from children who are six years and above. The assent document should be submitted for DSRB's approval prior to being used.

Participant's Privacy and Confidentiality

As research studies may involve the collection of confidential and sensitive patient information, care must be taken to ensure that the participant's privacy and confidentiality are protected. A common practice amongst researchers is to use subject identification codes on data collection forms instead of using participants' actual names. A subject identification log may be used to document the link between the codes and the participants' identifiable information, and the log should be kept separate from the data collection forms and stored in a secure location.

Reporting Adverse Events

During the course of the research, adverse events may arise. When unanticipated and related adverse events or problems are discovered, they shall be promptly reported to the DSRB and the HSA (if applicable). Unexpected Serious Adverse Events (SAE) that are life-threatening or results in death shall be reported immediately to the DSRB, the HSA and the sponsor. Reporting timelines for adverse events may be found in the DSRB Investigators' Manual Chapter 4.4-UPIRTSO and on the HSA website.

References:

- *Singapore Guideline for Good Clinical Practice (SG-GCP)*
- *NHG Proper Conduct of Research SOP 501-A02 Responsibilities of the Research Team*
- *NHG Proper Conduct of Research SOP 501-C01 Informed Consent Document and Process*
- *NHG Proper Conduct of Research SOP 501-C01 Unanticipated Problems Involving Risks to Subjects and Others*