CHICKEN SOUP FOR THE BUSY COORDINATOR

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Responsible Conduct of Research (RCR) – Protection of Human Subjects

Under the Office of Human Research Protection Programme (OHRPP), the RCR Unit aims to equip researchers with knowledge of best practices to guide them in making the right decisions especially in instances when individual values and integrity may be challenged. The RCR consists of 8 components; and they are summarized in fig 1.

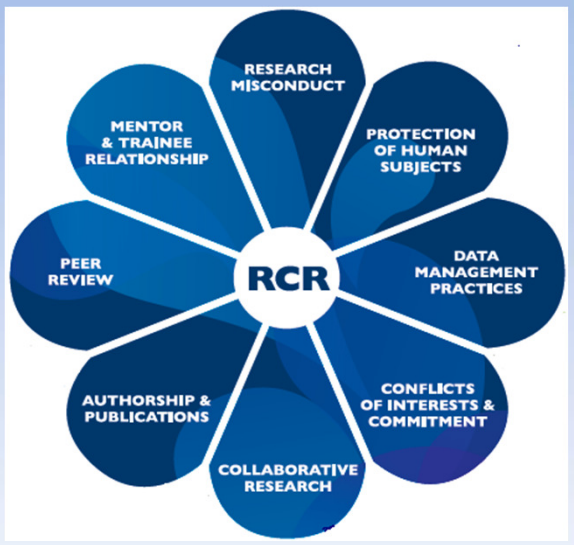

Fig. 1 Core Components of RCR

Scenario on the Protection of Human Subjects:

During his routine medical visit, Mr Lee was asked by his attending physician to participate in a clinical trial investigating a new hypertensive drug. Dr King, who was the principal investigator (PI) of the trial, briefed Mr Lee about the potential risks and benefits of participation. He was informed that as this was a randomised placebo-controlled trial, there would be a 50% chance of being randomised into either the placebo arm or active treatment arm.

Mr Lee was assured that regardless of the treatment arm allocation, appropriate medical care would be given throughout all follow-up visits. In addition, Dr King further assured him that medical care would still be provided even if he decided against participation or withdrew anytime during the study.

Mr Lee requested to be given time to read through the informed consent form and discuss with his family members regarding study participation. On his next visit 2 months later, Mr Lee agreed to participate and signed the consent form.

How was Mr Lee protected as a resarch subject?

From the scenario above, Dr King briefed Mr Lee on the potential risks and benefits of participating in the clinical trial. He was also assured that regardless of the treatment allocation, appropriate medical care would be given throughout all follow-up visits and even upon study withdrawal. Mr Lee was also given ample time to read through the informed consent form and discuss his participation with his family members.

Protection of Human Subjects – A Shared Responsibility

As the PI of the trial, Dr King is responsible for ensuring that informed consent is taken prior to subjects' participation, as well as ensuring their appropriate medical care throughout the trial. In addition, the ethics committee and regulatory authority play an important role in reviewing the study protocol, in order to ensure that the trial is safe to conduct in human subjects and meets the applicable ethical and regulatory standards.

To find out more about the RCR components, please visit:
https://www.research.nhg.com.sg/wps/wcm/connect/romp/nhgromp/hspp/responsibleconductofresearch/corecomponentsofrcr

References:
NHG Responsible Conduct of Research Manual Chapter 3 – Protection of Human Subjects
NHG Proper Conduct of Research SOP 501-A02 – Responsibilities of the Research Team
Singapore Good Clinical Practice 4.3 – Medical Care of trial patients
Singapore Good Clinical Practice 4.8 – Informed consent of trial subjects
NHG Investigator's Manual (2nd Edition) Chapter 2.0 – Principles of Research Ethics

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