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RJM Office
Faculty of Medicine, University of Ruhuna
Galle
SRI LANKA

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Tel/Fax: +94 91 2234801
E-mail: rjm@med.ruh.ac.lk
Web Site: <http://www.medi.ruh.ac.lk/>
Internet Home Page:
<http://www.medi.ruh.ac.lk/research-and-collaboration/>

EDITORIAL**Informed Consent in Clinical Research**

Informed consent is one of the most important aspects of research ethics. Recognition of the moral right of research subjects to self-determine participation in research has been one of the most important developments in the field of ethics related to biomedical research involving human subjects. Regulations requiring informed consent are to protect the human participants in clinical research. Informed consent is based on three critical and essential elements: voluntarism, information disclosure, and decision-making capacity. These three elements are essential for informed consent to be ethically valid.

Voluntarism. Voluntarism will depend on the research participant's intellectual and emotional maturity to make complex decisions, illness-related considerations, religious and cultural values, economic burden and undue influence on research participation. The voluntarism of vulnerable subjects is usually compromised; therefore, while inviting such participants for research and obtaining their consent, special precautions are required to be implemented in obtaining consent.

Information disclosure. The information disclosure is aimed at enabling the potential participant to make an informed, rational, and logical decision in the light of their cultural, psychological, and social values and beliefs. The information disclosure is by way of an information sheet which invites research participation and should be in simple language which the participant could easily comprehend and include, but not limited to, the nature and purpose of the study, obligations and consequences of research participation, health condition for which the research is proposed, study treatment or intervention and experimental procedures, probable risks and benefits associated with research participation, nature of illness and the possible outcome if the condition is left untreated, availability, risks and benefits of alternative treatments, right to withdraw at any time, any compensation that would be provided and any other information seems necessary for an informed decision to be taken by the potential participant.

Therefore, researchers are recommended to provide the study-related information adequately, judiciously, and truly maintaining an ethical balance between the expected risks and benefits of the intervention under investigation.

Decision-making capacity. The decision-making capacity of a participant depends on the cognitive ability of the participant. Decisional capacity comprises of four abilities, understanding the information, appreciation of the situation, rational manipulation of the information and communicating a choice. Researchers are advised to ensure that the

patient has, at least, understood the purpose of the research, risks associated with the research intervention, obligations and consequences of research participation, and the right to withdraw consent at any time during the study.

Ajith de Silva Nagahawatte

Editor-in-Chief – Ruhuna J. Med.

Professor of Microbiology,

Former Chairperson Ethical Review Committee,

Faculty of Medicine,

University of Ruhuna, Galle,

Sri Lanka.

ajith@med.ruh.ac.lk