

# The Principal Investigator's Roles & Responsibilities

## No. 4 : Managing the Medical Care of Subjects

During a subject's participation in a trial, the investigator (or designated co-investigator) should ensure that **reasonable medical care is provided to the subject for any adverse events**, including clinically significant laboratory values, related to the study participation. Subjects should receive appropriate medical evaluation and treatment until resolution of the emergent condition.

The Investigator should **document in writing the assessment of the adverse event**, in terms of severity, expectedness and relatedness to the research study. Where required, **prompt reporting** should be made to the relevant authorities (sponsor, regulatory, ethics committee).

The Investigator should also **inform a subject when medical care is needed** for conditions or illnesses unrelated to the study intervention or the condition under study when such condition or illness is

readily apparent or identified through screening procedures and eligibility criteria for the study. The subject should also be advised to seek appropriate care from the physician who was treating the illness prior to the study.

Investigators should be **available to subjects during the study**. Availability is particularly important when subjects are receiving a drug that has significant toxicity or potential for abuse.

Prior to conducting a research study, the investigator should also consider whether they can be available to the extent needed given the nature of the study.

**During any period of unavailability, the investigator should delegate responsibility** of medical care to a specified qualified physician who will be readily available to subjects during that time.

### References

- 1) FDA Guidance for Industry : Investigator Responsibilities – Protecting the Rights, Safety and Welfare of Study Subjects.

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM187772.pdf>

- 2) NHG PCR SOP 501-A02 Responsibilities of the Research Team

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

