UNIVERSITY OF NAIROBI (UoN)
COLLEGE OF HEALTH SCIENCES
P O BOX 19676 Code 00202
Telegrams: varsity
(254-020) 2726300 Ext 44355

KNH-UoN ERC
Email: uonknh_erc@uonbi.ac.ke
Website: http://www.erc.uonbi.ac.ke
Facebook: ttps://www.facebook.com/uonknh.erc
Twitter: @UONKNH_ERC ttps://twitter.com/UONKNH_ERC

KENYATTA NATIONAL HOSPITAL (KNH)
P O BOX 20723 Code 00202
Tel: 726300-9
Fax: 725272
Telegrams: MEDSUP, Nairobi

KNH-UoN ERC COMPENSATION / REIMBURSEMENT GUIDELINES

Purpose / Objective: These guidelines describe the KNH-UoN ERC standards for the fair compensation of human research participants (including both patients and healthy volunteers) during the conduct of research including clinical studies.

1. All proposals should have a description of any benefits/ risks and harms to the participants or to others which may be reasonably expected from the research.
2. Proposal submitted to the KNH-UoN ERC should describe rationale for payment, how amount was calculated, and how and when payment will be made.
3. The nature and amount of compensation to research participants shall be disclosed in the documentation of the voluntary informed consent.
4. Participants should be reimbursed for effort, inconvenience, time spent, expenses incurred like bus fare to and from home to research clinic or for any unfavourable procedures connected with their participation in research so that qualified participants may enroll without incurring personal financial expenses to participate.
5. All reimbursements for participation should be revenue neutral and just enough to cover reimbursement of out-of-pocket expenses or be based on the participants'' anticipated expenses incurred during participation in a clinical study (e.g. meals, travel).
6. Reimbursement amount, the method and timing of disbursement must be consistent with the local societal and cultural norms clearly reflecting the local financial conditions in which the study is being conducted.
7. Reimbursement may come in several forms: including money, gifts, free medical care, travel vouchers, gift vouchers or standardized wage-like payments. However, the payments should not be so large or the medical services so extensive as to induce prospective subjects to consent to participate in the research against their better judgment ("undue inducement or coercion").
8. It is acknowledged that small amounts of money given to participants may facilitate recruitment. However, all payment amounts should minimize the possibility of coercion or undue influence or skewed sample. An inducement is undue if it is "…so attractive[that it] can blind prospective subjects to potential risks or impair their ability to exercise proper judgment"[or] "prompt them to lie or conceal information that would disqualify them from enrolling-or continuing-in research". An excessively attractive offer leads people to

exercise poor judgment about research participation that involves a risk of serious harm or may cause them to undertake risks or discomforts that they otherwise would not assume.

9. Reimbursements of minor participants in clinical studies should be given keen consideration. Parents or guardians who incur expenses e.g for travel, childcare for siblings may receive compensation for those expenses. However, such compensation must not become an improper incentive to enroll the minor i.e the amount should not sway parental decision making. For older children any further compensation for the contribution should go to the child.
10. All reimbursements must be prorated (e.g., per visit) and not contingent on completion of the study by the research participant. Participants must be free to withdraw from a study at any time without penalty or loss of benefits to which they are otherwise entitled.
11. Where applicable, the sponsor generally should cover the cost of protocol-required treatments and procedures supplied during the sponsored clinical studies and should arrange for medical care for any study related physical injury or illness and even death that occurs as a direct result of taking part in a sponsored clinical study. The sponsor may reimburse the medical care at no expense to the participant. Medical insurance policy and certificate should be included in the research protocol.
12. Where any post-study care is necessary or required, which includes treatment or other benefits of tangible value provided to a participant, this must clearly be outlined in the protocol.
13. Justification of compensation for trial related injuries; factors determining the compensation amount and the body deciding collectively the compensation (preferably multiple stakeholders) must clearly be provided.
14. The compensation need be given only if there's proof that the death or injury was caused by the trial. The amount should not act as an inducement for trial participation such that relatives would end up taking advantage for seriously ill patients (e.g. oncology studies).
15. The period of free medical management in the case of an injury occurring to the clinical trial participant should be provided. Medical management should be provided in case the injury is due to clinical trial related activities only, as the free medical management may create undue influence for patient to enroll in a clinical trial". Only cases where a direct connection between the injury or death and the trial is established should be considered.
16. The clinical lead is responsible for assessing whether compensation to participants is appropriate for studies that they sponsor or conduct.
17. Final approval of compensation and any changes to compensation of participants is up to the KNH-UoN ERC overseeing the study and offered for participants in a cohort (i.e not specific to an individual).
18. KNH-UoN ERC shall not consider payment a benefit to offset research risks when deciding whether to approve a study.