DEPARTMENT OF HEALTH
Republic of South Africa

SAHPRA
South African Health Products Regulatory Authority

CLINICAL TRIAL PARTICIPANT TIME, INCONVENIENCE AND EXPENSE (TIE) COMPENSATION MODEL

This document has been prepared to serve as a guidance to applicant/sponsors of clinical trials during the use of registered or unregistered medicines in approved clinical trials. It represents the South African Health Products Regulatory's (SAHPRA) current thinking on participant re-imbursement during clinical trial participation and proposes a minimum compensation that can be paid. It is not intended as an exclusive approach and SAHPRA reserves the right to request any additional information and may make amendments in keeping with the knowledge which is current at the time.

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1 BACKGROUND

As per the published National Health Research Ethics Council (NHREC) guidelines (2012) titled "Payment of trial participants in South Africa: Ethical considerations for Research Ethics Committees (RECs)" Sections 4.1, 4.2 and 4.3, state that trial participants should be compensated appropriately for their time (T), inconvenience (I) and expenses (E). In addition, Council for International Organisations of Medical Sciences (CIOMS) Guideline states that participants may be compensated for inconvenience and time (CIOMS, 2002). United Nations Programme on HIV/AIDS (UNAIDS)(2012) notes that participants should be compensated for expenses related to participation, time, and inconvenience.

The South African Health Products Regulatory Authority (SAHPRA) has considered the above and proposes the following model for TIE compensation of clinical study participants in South Africa.

2 PROPOSED MODEL FOR COMPENSATION FOR ALL CLINICAL STUDY-RELATED VISITS

2.1 **Time spent**: Current minimum wages in South Africa for unskilled labour starts from approximately R20 per hour. Factoring in the inconvenience aspect, R33 per hour is recommended.

Note:

2.1.1 Amounts within a few rands of more cash-manageable numbers may be rounded up, e.g. R99 to R100. This is in order to ease the burden of unnecessary calculation and difficulty in petty-cash flow at sites.

2.1.2 In general, a standard scheduled visit should not take longer than 3 hours. More intensive visits may, however, require additional time at site. This would necessitate a higher "compensation" as the participant is now spending an extensive period of time away, and resulting in them missing the majority of their work/school day as opposed to a portion of it. In such case, this amount should be increased to R50 per hour.

2.2 **Inconvenience (considered in the light of travel/distance from home to a site)**: e.g. Stellenbosch University recommends R3 per km travelled. The travel cost is broken down into 3 categories (0-25, 26-50, >50 km). E.g. a participant falling in the first category will receive R150 travel compensation (R3 x 25 km x 2 [return trip]).

Note:

2.2.1 It would be ideal for each site Principal Investigator to make a decision on the radius around the trial site that maximum recruitment efforts would be focussed on. This would allow for a standardised approach to be adopted per site and per study leading to less per participant variability of travel related costs. When participants are identified beyond the catchment area identified or move beyond the predefined catchment, additional compensation could be explored on a case by case basis.

2.3 **Additional inconvenience**: Some studies call for more invasive procedures (e.g. PK sampling) or strenuous procedures (e.g. Stress ECGs) which are over and above the standard inconveniences of a study visit. Therefore a case can be made for additional compensation.

2.4 **Expenses**: It is recommended that all participants be offered a meal to the value of R50. Should the participant be at site for longer than 3 hours, an additional meal or money should be made available to them.

2.5 **Parent/Legal guardian/caregiver:** In studies where the participant requires a parent/legal guardian present, the same remuneration scheme applies.

2.6 **In-patients:** In-patients recruited to the trial need not be compensated for distance travelled, but the inconvenience, expense and time beyond in-patient stay need to be taken into consideration.

Table 1: Compensation Model

TIME DISTANCE	Standard visit 2-3 hours	Extended visit >3 hours
0-25 km	Travel = R150 (R3 x 25 km x 2[return]) Inconvenience = R100 (R33 x 3h [rounded up]) Expenses = R50 (Meal & refreshment)	T = R150 I = R100 + R50 x h (over & above 3h) E = R100 (2 x meals & refreshment)
	Total = R300	Total = R350 + R50 per h
26-50 km	T = R300 (R3 x 50 km x 2[return]) I = R100 E = R50	T = R300 I = R100 + R50 x h E = R100
	Total = R450	Total = R500 + R50 per h
>50 km	T = R300 + R3 x km (over & above 50 km) I = R100 E = R50	T = R300 + R3 x km I = R100 + R50 x h E = R100
	Total = R450 + R3 per km (over & above 50 km)	Total = R500 + R50 per h + R3 per km

Note: SAHPRA is of the view that in 2018 a minimum of R300 would be the most appropriate compensation level for a standard participants visit. SAHPRA will review this model as in when necessary.

This guideline is not applicable to phase I. Phase I studies include a higher risk for participants, hence should be compensated on a different scale.

3 REFERENCES

Council for International Organizations of Medical Sciences (CIOMS). 2002. International Ethical Guideline for Biomedical Research Involving Human Subjects.

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4 UPDATE HISTORY

Date	Reason for Update	Version & Publication
May 2018	First version published for implementation	v1, June 2018