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01 July 2022

GUIDELINE FOR 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.

Document History

Final Version	Reason for Amendment	Effective Date
1	First version published for implementation	June 2018
2	– Section 2, reimbursement revised – Change of document number from 2.51 to SAHPGL-CEM-CT-02	01 August 2022

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Glossary

Abbreviation/ Term	Meaning
CIOMS	Council for International Organizations of Medical Sciences
eCOA	Electronic Clinical Outcome Assessment
NHREC	National Health Research Ethics Council
REC	Research Ethics Committees
SAHPRA	South African Health Products Regulatory Authority
TIE	Time, Inconvenience and Expenses
UNAIDS	United Nations Programme on HIV/AIDS

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)[1]. In addition, Council for International Organisations of Medical Sciences (CIOMS) Guideline states that participants may be compensated for inconvenience and time (CIOMS, 2002)[2]. United Nations Programme on HIV/AIDS (UNAIDS)(2012) notes that participants should be compensated for expenses related to participation, time, and inconvenience[3].

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

2. MODEL FOR COMPENSATION FOR CLINICAL STUDY-RELATED VISITS

2.1 Time spent:

Current minimum wages in South Africa for unskilled labour starts from approximately R25 per hour[3.4]. Factoring in the inconvenience aspect, R50 per hour is recommended[4].

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 extended 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):

Based on rates prescribed by AA South Africa[5] and Stellenbosch University[6], it is recommended that R4 per km travelled is paid. 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 R200 travel compensation (R4 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 / care giver 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. A minimum of R50 to R200 per visit is recommended depending on whether informed consent or other investigations and/or patient-reported outcome questionnaires are being done.

2.7 Patient diary completion:

The completion of paper and/or electronic diaries between visits are increasingly being incorporated into clinical trials. This amounts to an additional trial-related activity and can be inconvenient and burdensome for trial participants to complete these diaries. The participant should thus be remunerated for this task. In addition, when using electronic diaries, the majority of people in South Africa do not have access to free wi-fi. Free wi-fi and/or sufficient airtime should be made available to all participants to complete the necessary trial related activities. Alternatively, Sponsors can provide devices that have data pre-loaded.

2.8 Electronic Clinical Outcome Assessment (eCOA)s including the use of tablets, smartphones, wearables and other such devices:

As for 2.7 above, participants need to be remunerated appropriately for this task. In addition, sufficient airtime needs to be made available to all participants and/or a device with pre-loaded data needs to be provided by the Sponsor.

2.9 Home based/ virtual consultation visits:

Participants need to be remunerated for time and inconvenience. A minimum of R150 per visit is recommended; this could be increased depending on the time and complexity of the visit.

Table 1: Compensation Model

TIME DISTANCE	Standard visit 2-3 hours	Extended visit >3 hours
0-25 km	Travel = R200 (R4 x 25 km x 2[return]) Inconvenience = R150 (R50 x 3h [rounded up]) Expenses = R50 (Meal & refreshment)	T = R200 I = R150 + R50 x h (over & above 3h) E = R100 (2 x meals & refreshment)
	Total = R400	Total = R450 + R50 per h
26-50 km	T = R400 (R4 x 50 km x 2[return]) I = R150	T = R400 I = R150 + R50 x h

	E = R50	E = R100
	Total = R600	Total = R650 + R50 per h
>50 km	T = R400 + R4 x km (over & above 50 km) I = R150 E = R50	T = R400 + R4 x km I = R150 + R50 x h E = R100
	Total = R600 + R4 per km (over & above 50 km)	Total = R650 + R50 per h + R4 per km

Note: SAHPRA is of the view that in 2022 a minimum of R400 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

The following related documents are referenced:

1. National Department of Health. 2012. Guideline for payment of trial participants in South Africa. South Africa.
2. Council for International Organizations of Medical Sciences (CIOMS). 2002. International Ethical Guideline for Biomedical Research Involving Human Subjects.
3. United Nations Programme on HIV/AIDS (UNAIDS). 2012. Ethical considerations in Biomedical HIV prevention trials.
4. New minimum wage announced for South Africa. https://businesstech.co.za/news/finance/556460/new-minimum-wage-announced-for-south-africa/#:~:text=In%20a%20gazette%20published%20on,minimum%20wage%20set%20in%202021. Accessed 15 February 2022
5. Prescribed rate per kilometer: The prescribed rate per kilometer used for reimbursive travel allowance for 2021/2022 will decreased from R3.98 to R3.82.

   https://www.sagecity.com/za/sage-vip-payroll-hr-south-africa/f/sage-200c-south-africa-general-discussion/166061/prescribed-rate-per-kilometer-the-prescribed-rate-per-kilometer-used-for-reimbursive-travel-allowance-for-2021-2022-will-decreased-from-r3-98-to-r3-82#:~:text=click%20to%20join-Prescribed%20rate%20per%20kilometer%3A%20The%20prescribed%20rate%20per%20kilometer%20used,82.

   Accessed 15 February 2022.
6. Vehicle Services. 2022. https://www0.sun.ac.za/voertuigvloot/media/pdfs-docs/2022/VEHICLE%20POOL%20KM%20and%20DAY%20tariffs%20since%201%20Jan%202022.pdf. Accessed on 15 February 2022.

4. VALIDITY

This guideline is valid for a period of 5 years from the effective date of revision and replaces Guideline for Clinical Trial Participant Time, Inconvenience and Expense (TIE) Compensation Model, old document number 2.51. It will be reviewed on this timeframe or as and when required.