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Informed consent methods: an analysis of volunteer understanding

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Informed Consent Questionnaire

Instructions:

- *This questionnaire is intended to establish your understanding of the clinical trial that you are enrolling in. It will NOT affect your eligibility to enroll into the study.*
- *The questionnaire is anonymous- please DO NOT write your name (or any part of it) on the questionnaire*
- *Please tick the correct answer with a "x"*
- *Note that there may be more than one correct answer*
- *Thank you for completing the questionnaire*

ARM

☐ ICD Only

☐ ICD & QA

☐ ICD & Presentation

☐ Presentation & QA

☐ ICD, Presentation & QA

1 Questionnaire Number:

2 Highest level of Education:

Primary school	High school	Tertiary education	Illiterate
☐	☐	☐	☐

3 Race:

Black	White	Coloured	Asian
☐	☐	☐	☐

4 Date of Birth:

Day (dd)	Month (mm)	Year (yy)

5 Gender:

Male	Female
☐	☐

1. Participation in this clinical trial is:

Required by the South-African Medicines Control Council (MCC)	Voluntary	Required by the sponsoring company	Required by South-African government
☐	☐	☐	☐

2. If you withdraw from the clinical trial you will lose the following benefits you would otherwise be entitled to:

Partial compensation	All compensation	Follow-up care/visits	None
☐	☐	☐	☐

3. The purpose of this trial is to establish:

The difference between 2 Theophylline prolonged-release (PR) tablet products	If the product to be tested (Theophylline) is not safe	To prove that Theophylline is the best	To prove that Theophylline needs to be used in conjunction with Neurontin
☐	☐	☐	☐

4. The following staff will know which volunteers has received which Theophylline product:

Clinic staff only	Laboratory staff only	Both clinic staff and Laboratory staff	Nobody
☐	☐	☐	☐

5. What is the duration of this study?

19 days	34 days	26 days	53 days
☐	☐	☐	☐

6. You will be compensated for your participation in the following way:

R1860.00	R1860.00 and petrol money	Food, drink and accommodation	None, participation is voluntary
☐	☐	☐	☐

7. After the trial:

You will have to read the newspaper to get the results	The results will be broadcasted on T.V.	You will be informed of all findings related to your individual case	You will be informed in writing about the results of the trial.
☐	☐	☐	☐

8. You are entitled to:

Nothing- you have been paid	The right of access to all the data collected during this trial	The right to all laboratory samples taken for all other volunteers	The right of access to your data
☐	☐	☐	☐

9. You may experience:

Bladder infection	High Blood Pressure	Ear Ache	Nausea, vomiting
☐	☐	☐	☐

10. As a result of your participation, you will:

Receive the newest care available	Not have access to a Doctor	Have a complete medical evaluation	Become famous
☐	☐	☐	☐

11. As a result of this study:

You might experience shortness of breath	The treatment of breathing difficulties will be improved	You will never have any shortness of breath	People in Africa will gain access to medicines which prevents asthma
☐	☐	☐	☐

12. After the study you will

Receive medication free of charge for 3 years	Be phoned to participate in a follow-up study	Follow-up investigations will be conducted within 72 hours	Never have any seizures
☐	☐	☐	☐

13. Currently, the following alternative treatment is available for wheezing or shortness of breath:

Exercise	Physiotherapy	Theo-dur 5mg	No alternative treatment is available
☐	☐	☐	☐

14. Your privacy will be protected in the following way:

Your telephone number will not be recorded anywhere at all	Only your participant number will be used during analysis	Staff will have access to your personal details	By confirming your details with your next of kin
☐	☐	☐	☐

15. Any personal results from this study

Will not be communicated to anybody without your permission	Will be communicated to your next of kin only	Will be communicated to your insurance company	Will be communicated to anybody who needs to know
☐	☐	☐	☐

16. This study is sponsored by:

GSK	Novartis CH	Valpharma International	South-African Government
☐	☐	☐	☐

17. Any records/data collected from you during the course of this study will

Be made available for all follow-up studies as well	Not be used for any other purpose other than this study	May be used to develop training material	May be used to collect national statistics
☐	☐	☐	☐

18. After the clinical trial, your biological samples (i.e. blood or urine) will be:

Stored for 10 years	Stored for 15 years	Stored for 5 years	Destroyed
☐	☐	☐	☐

19. A commercial product will be developed from your biological sample:

True	False
☐	☐

20. The doctor involved in the study will be acting as:

Your physician	The Investigator	The Investigator and your physician	None
☐	☐	☐	☐

21. It is the investigator's responsibility to

Provide only seizure related care	Protect life and health	Protect, life, health and privacy	Protect, life, health, dignity and privacy
☐	☐	☐	☐

22. Should you experience any adverse effects due to your participation to this study, you will:

Receive medical care free of charge until you are healthy again	Have to pay for 10% of your medical care	Your medical aid will have to pay for your medical care	Receive nothing
☐	☐	☐	☐

23. Should you die or be disabled as a result of your participation in this study, you or your family or dependants will receive:

R100 000 from the Medicines Control Council (MCC)	No compensation	R100 000 from Rivopharm SA	Insurance coverage from Santam to indemnify you of any costs
☐	☐	☐	☐

24. The right to compensation is legally guaranteed:

True	False
☐	☐

25. The protocol for this study has been approved by the Ethics Committee for Medical Research of the University of the Freestate and the South-African Medicines Control Council:

True	False
☐	☐