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:

<table>
<thead>
<tr>
<th>Required by the South-African Medicines Control Council (MCC)</th>
<th>Voluntary</th>
<th>Required by the sponsoring company</th>
<th>Required by South-African government</th>
</tr>
</thead>
<tbody>
<tr>
<td>□</td>
<td>□</td>
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<td>□</td>
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</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Partial compensation</th>
<th>All compensation</th>
<th>Follow-up care/visits</th>
<th>None</th>
</tr>
</thead>
<tbody>
<tr>
<td>□</td>
<td>□</td>
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</tr>
</tbody>
</table>

3. The purpose of this trial is to establish:

<table>
<thead>
<tr>
<th>The difference between 3 Efavirenz capsule products</th>
<th>If the product to be tested (Efavirenz) is not safe</th>
<th>To prove that Efavirenz is the best</th>
<th>To prove that Efavirenz needs to be used in conjunction with Neurontin</th>
</tr>
</thead>
<tbody>
<tr>
<td>□</td>
<td>□</td>
<td>□</td>
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</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Clinic staff only</th>
<th>Laboratory staff only</th>
<th>Both clinic staff and Laboratory staff</th>
<th>Nobody</th>
</tr>
</thead>
<tbody>
<tr>
<td>□</td>
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</tbody>
</table>

5. What is the duration of this study?

<table>
<thead>
<tr>
<th>19 days</th>
<th>135 days</th>
<th>26 days</th>
<th>53 days</th>
</tr>
</thead>
<tbody>
<tr>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
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</tbody>
</table>

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

<table>
<thead>
<tr>
<th>R6570.00</th>
<th>R6570.00 and petrol money</th>
<th>Food, drink and accommodation</th>
<th>None, participation is voluntary</th>
</tr>
</thead>
<tbody>
<tr>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
</tbody>
</table>

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7. **After the trial:**

<table>
<thead>
<tr>
<th>You will have to read the newspaper to get the results</th>
<th>The results will be broadcasted on T.V.</th>
<th>You will be informed of all findings related to your individual case</th>
<th>You will be informed in writing about the results of the trial</th>
</tr>
</thead>
<tbody>
<tr>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
</tbody>
</table>

8. **You are entitled to:**

<table>
<thead>
<tr>
<th>Nothing - you have been paid</th>
<th>The right of access to all the data collected during this trial</th>
<th>The right to all laboratory samples taken for all other volunteers</th>
<th>The right of access to your data</th>
</tr>
</thead>
<tbody>
<tr>
<td>□</td>
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</tbody>
</table>

9. **You may experience:**

<table>
<thead>
<tr>
<th>Bladder infection</th>
<th>High Blood Pressure</th>
<th>Ear Ache</th>
<th>Drowsiness, sleeplessness</th>
</tr>
</thead>
<tbody>
<tr>
<td>□</td>
<td>□</td>
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</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Receive the newest care available</th>
<th>Not have access to a Doctor</th>
<th>Have a complete medical evaluation</th>
<th>Become famous</th>
</tr>
</thead>
<tbody>
<tr>
<td>□</td>
<td>□</td>
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</tbody>
</table>

11. **As a result of this study:**

<table>
<thead>
<tr>
<th>You might contract HIV</th>
<th>The treatment of HIV will be improved</th>
<th>You will never contract HIV</th>
<th>People in Africa will gain access to medicines which prevents HIV</th>
</tr>
</thead>
<tbody>
<tr>
<td>□</td>
<td>□</td>
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<td>□</td>
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</tbody>
</table>

12. **After the study you will**

<table>
<thead>
<tr>
<th>Receive medication free of charge for 3 years</th>
<th>Be phoned to participate in a follow-up study</th>
<th>Follow-up investigations will be conducted within 72 hours</th>
<th>Never have HIV</th>
</tr>
</thead>
<tbody>
<tr>
<td>□</td>
<td>□</td>
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</tbody>
</table>
13. Currently, the following alternative treatment is available for HIV:

- Hypnosis  
- Acupuncture  
- Efavirenz 600mg once daily  
- 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  
- Adcock Ingram Ltd.  
- 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 only
- The study doctor only
- The study doctor and your physician
- None

21. It is the Study doctor'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 Adcock Ingram 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 Free State and the South-African Medicines Control Council:

<table>
<thead>
<tr>
<th>True</th>
<th>False</th>
</tr>
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<tbody>
<tr>
<td>☐</td>
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</table>