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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 4 Acamprosate calcium capsule products | If the product to be tested (Acamprosate calcium) is not safe | To prove that Acamprosate calcium is the best | To prove that Acamprosate needs to be used in conjunction with Besobrial |
|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ |

**4. The following staff will know which volunteers has received which Acamprosate** calcium **product:**

| All staff | Laboratory staff only | Both clinic staff and Laboratory staff | Nobody |
|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ |

**5. What is the duration of this study?**

| 19 weeks | 9-12 weeks | 6 weeks | 15 weeks |
|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ |

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

| R9 400.00 | R9 400.00 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:**

| | | | |
|---|---|---|---|
| Asthma | High Blood Pressure | Ear Ache | Diarrhea, flatulence |
| ☐ | ☐ | ☐ | ☐ |

**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 become addicted to alcohol | The treatment of people with alcohol addictions will be improved | You will never be addicted to alcohol | People in Africa will gain access to medicines which prevents alcohol addictions |
| ☐ | ☐ | ☐ | ☐ |

**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 be addicted to alcohol |
| ☐ | ☐ | ☐ | ☐ |

**13. Currently, the following alternative treatment is available for alcohol addiction:**

| Hypnosis | Acupuncture | Besobrial 666mg | 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 | Somaxon Pharmaceuticals, Inc | 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 alcohol 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 Freestate and the South-African Medicines Control Council:**

| True | False |
| --- | --- |
| ☐ | ☐ |