

APPENDIX A

INFORMED CONSENT

Informed consent Simhealth 02 07 01: **Background information and request for consent of workers asked to participate**

This form is to be administered to selected workers before their participation in audiometric and ASSR testing by the audiologists.

Read the following to each prospective subject, pausing to answer any questions:

This mine has agreed to help the SIMRAC research team investigate how certain hearing tests might be helpful in identifying noise-induced hearing loss. Information from the study will be used to decide if changes can be made to normal testing procedures that will allow better identification of hearing losses caused by noise, in order to improve workers' health and safety. The study has been approved by the Union, because all of the workers who agree to participate will remain unanimous, and the results will be used to help protect workers from noise.

If you agree to participate, we will ask you some questions about you, any problems that you might have experienced with your hearing, your job and the noise in places on the mine where you work.

Your hearing will then be tested in the normal way, after which some special tests will be used to check your hearing. Comparisons will be made between results from the normal tests and from the special tests, to find out if the special tests would be better for identifying and describing hearing loss caused by noise.

The experiment is not meant to check your hearing, but to find out the best way of testing ears. Accordingly, the tests and the results will have no effect on your job, and will have nothing to do with compensation. Your test results will be kept confidential, and only you and the research team will be able to look at them. The results will be used to find out if the new tests are helpful in the correct description and identification of noise-induced hearing loss.

We will explain to you the way each test is done, we will show you the results and we will explain what they mean. Some of the tests will be done more than once, to double-check on the results.

We will keep your name and any information you tell us in strict confidence, and not tell the mine or the managers anything about you or your test results.

Your participation in the study is voluntary. If you do not want to take part, it will not affect your job in any way. If you do decide to take part, this will also not affect your job in any way, but will be helpful to all workers who are working in the noise. We ask that you decide for yourself whether you want to participate, and if you have some questions that need to be answered before you decide, please ask them.

Will you help us with this research? (YES or NO)

If NO, ask the next worker. If YES, ask worker to sign or make a mark in the space below to indicate that he has been given the information and understands it. Then record the other details.

.....

I have been told about the study and have been given the chance to ask questions about it and about my participation. I also understand that if I have any questions at any time, they will be answered, and that if I am not satisfied with the answers I can withdraw from the study.

Name:..... Company number:

Date:.....

APPENDIX B

CONSENT-VALIUM

Informed consent Simhealth 02 07 01: **Background information and request for consent of workers asked to participate.**

This form is to be administered to selected workers before their participation in audiometric and ASSR testing by the audiologists.

Read the following to each prospective subject, pausing to answer any questions:

This mine has agreed to help the SIMRAC research team investigate how certain hearing tests might be helpful in identifying noise-induced hearing loss. Information from the study will be used to decide if changes can be made to normal testing procedures that will allow better identification of hearing losses caused by noise, in order to improve workers' health and safety. The study has been approved by the Union, because all of the workers who agree to participate will remain unanimous, and the results will be used to help protect workers from noise.

If you agree to participate, we will ask you some questions about you, any problems that you might have experienced with your hearing, your job and the noise in places on the mine where you work.

Your hearing will then be tested in the normal way, after which some special tests will be used to check your hearing. Comparisons will be made between results from the normal tests and from the special tests, to find out if the special tests would be better for identifying and describing hearing loss caused by noise.

The experiment is not meant to check your hearing, but to find out the best way of testing ears. Accordingly, the tests and the results will have no effect on your job, and will have nothing to do with compensation. Your test results will be kept confidential, and only you and the research team will be able to look at them. The results will be used to find out if the new tests are helpful in the correct description and identification of noise-induced hearing loss.

We will explain to you the way each test is done, we will show you the results and we will explain what they mean. Some of the tests will be done more than once, to double-check on the results.

We will keep your name and any information you tell us in strict confidence, and not tell the mine or the managers anything about you or your test results.

Your participation in the study is voluntary. If you do not want to take part, it will not affect your job in any way. If you do decide to take part, this will also not affect your job in any way, but will be helpful to all workers who are working in the noise. We ask that you decide for yourself whether you want to participate, and if you have some questions that need to be answered before you decide, please ask them.

I agree to taking medicine (10mg of Valium) to help me relax during the test

Will you help us with this research? (YES or NO)

If NO, ask the next worker. If YES, ask worker to sign or make a mark in the space below to indicate that he has been given the information and understands it. Then record the other details.

.....

I have been told about the study and have been given the chance to ask questions about it and about my participation. I also understand that if I have any questions at any time, they will be answered, and that if I am not satisfied with the answers I can withdraw from the study.

Name:..... Company number:

Date:.....

Patient information sheet

ASSR tests: VALIUM

- 1. Thank you for agreeing to participate in this study.**
- 2. The medicine that you have agreed to take will make you feel sleepy/drowsy. There is a bed available where you can lie down.**
- 3. During the test you will also lie down and be able to sleep/rest. The test will take an hour.**
- 4. After completion of the test you will be transported back to your hostel**
- 5. Please refrain from driving a car. Remain at the hostel for the duration of today. Do sleep or rest.**
- 6. You are not required to work today and will receive a shift.**



GOLD FIELDS

12 August.2002

Elize de Koker
PO Box 3397
Kenmare
1745

OCCUPATIONAL MEDICINE

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South Africa

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Cell +27 83 407 4624
stuart.shearer@goldfields.co.za

Dear Elize

Re: An assessment of the clinical value of auditory steady state responses in the audiological evaluation of noise-induced hearing loss in the South African mining industry

This is to confirm that you have my consent to conduct this SIMRAC study (SIM 020701) at Driefontein Occupational Health Centre conditional on your receiving Ethical Committee approval from a recognised authority.

Permission is granted to examine the medical surveillance records of the study subjects conditional on written consent being obtained from each subject.

I should be grateful if you would provide me with copies of the ethical approval and the consent form prior to embarking on the study.

With kind regards

Yours sincerely

Dr Stuart Shearer
Senior Consultant: Occupational Medicine

PHUMLANI OCCUPATIONAL HEALTH CENTRE
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HARMONY
GOLD MINING CO.
Company Registration Number:
05/38232/06

12 August, 2002

Elize de Koker
PO Box 3397
Kenmare
1745

Dear Elize

Re An assessment of the clinical value of auditory steady state responses in the audiological evaluation of noise induced hearing loss in the South African mining industry

This is to confirm that you have my consent to conduct this SIMRAC study (SIM 020701) at Phumlani Occupational Health centre conditional on your receiving Ethical Committee approval from a recognised authority.

Permission is granted to examine the medical surveillance records of the study subjects, conditional on written informed consent being obtained from each subject.

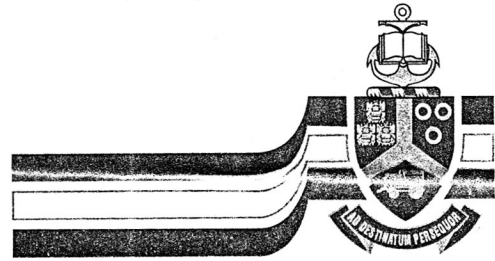
I should be grateful if you would provide me with copies of the Ethical approval and the consent form prior to embarking on the study.

With kind regards

Yours sincerely

Dr J Geysers

Manager Occupational health



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Department of Communication Pathology
Speech, Voice and Hearing Clinic

29 August, 2002

Ms E de Koker
P.O. Box 3397
Kenmare
KRUGERSDORP
1745

Dear Ms De Koker

APPLICATION: CLEARANCE ETHICS COMMITTEE

Your application to the Research Ethics Committee of the Faculty of Humanities regarding ethical procedures for your PhD (Communication Pathology) was reviewed in August, 2002.

We have the pleasure of informing you that your application with the title "***Dichotic Multiple Frequency Steady State Response Audiometry: a diagnostic tool within the mining environment***" has been approved.

We wish you every success in conducting your research.

Sincerely

Handwritten signature of Prof. B Louw.

Prof. B Louw
CHAIR: RESEARCH ETHICS COMMITTEE
FACULTY OF HUMANITIES

cc. Prof. René Hugo
Department Communication Pathology



Safety In Mines Research Advisory Committee

Facilitating safety and health research in the South African mining industry

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2 May 2001

Healing Centre
Ms E de Koker
Gehoorcentrum@icon.co.za

Dear Sir

Award of SIMRAC Project

I am pleased to inform you that your **Proposal** on the **Project** "Feasibility of using oto-acoustic emission (OAE) methods for screening early hearing impairment in South African mineworkers" Ref No. HEALTH 802 dated 5 October 2000, to the amount of R1 160 400 has been accepted by the **Chief Inspector**, as indicated in the attached **Memorandum of Agreement**. The **Memorandum** and **Approved Proposal** constitute the Contract in terms of which the Project shall be conducted.

The **Contract** will come into effect on the date of the signing of the **Memorandum** by an authorised person on behalf of the **Proposer**.

Please return the signed (and page initialed) **Contract together with your original signed proposal** to the Research Manager at 2nd Floor, Braamfontein Centre, 23 Jorrisen Street, Braamfontein (Private Bag X63, Braamfontein 2017), as well as an electronic copy of the Research Proposal in the prescribed format, attached hereto, as soon as possible.

In all communications regarding the **Project**, the **Project** title and reference number must be clearly stated.

NB : To expedite payment all invoices are to be made out to "Mine Safety Research" and are only to be forwarded to this office on receipt of an "Order for Invoice"

Yours faithfully,

Ms M Hermanus
Chief Inspector of Mines