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DEFENCE PERSONNEL EXECUTIVE

SG97-6600

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- (5) **PROTOCOL 216/00 – A RANDO MISED, DOUBLE-BLIND, COMPARATIVE STUDY TO EVALUATE THE SAFETY, TOLERABILITY AND EFFECTIVENESS OF TAFENOQUINE AND MEFLOQUINE FOR THE PROPHYLAXIS OF MALARIA IN NON-IMMUNE AUSTRALIAN SOLDIERS DEPLOYED TO EAST TIMOR**

Decision:

ADMEC decided that the consent form required to be reworded to include the usual provision that members can withdraw at any time “without detriment to my career or ongoing medical care.” The correct contact details and address for ADMEC are to be used on the information sheet. Providing these requirements are met Committee agreed to approve the protocol.

For action:

Exec Sec

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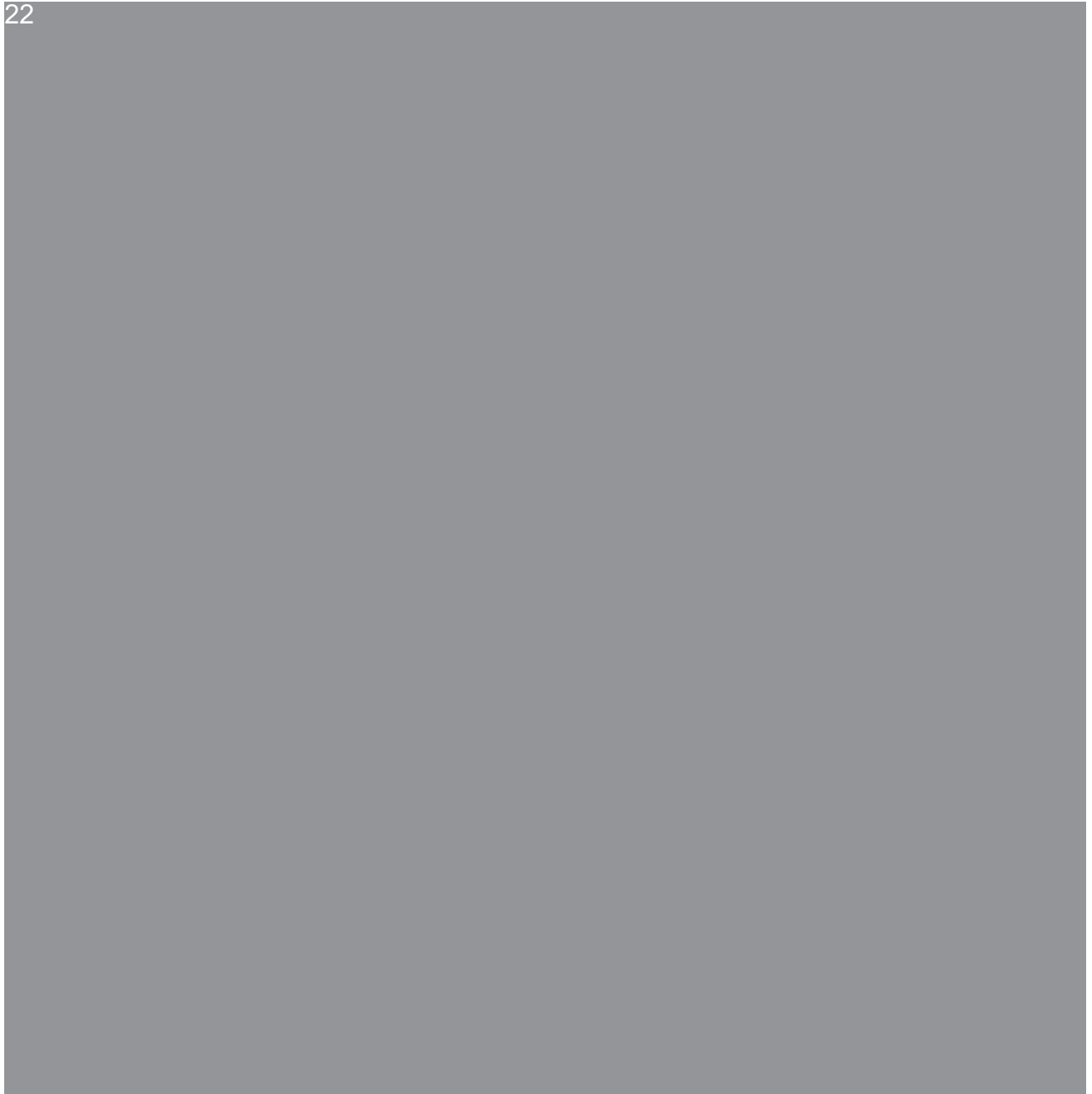
DEFENCE PERSONNEL EXECUTIVE

SG97-6600

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**MINUTES OF THE THIRTY-NINTH MEETING OF THE AUSTRALIAN DEFENCE
MEDICAL ETHICS COMMITTEE,
HELD AT CAMPBELL PARK OFFICES (CP2-5-04) CANBERRA ACT 2600 ON
MONDAY 21 AUGUST 2000 AT 1630 HOURS**


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(2) **Protocol 216/00 – A Randomised, Double-Blind, Comparative Study To Evaluate The Safety, Tolerability And Effectiveness Of Tafenoquine And Mefloquine For The Prophylaxis Of Malaria In Non-Immune Australian Soldiers Deployed To East Timor.**

22. The Committee requests that in future if amendments are extensive, changes be displayed using strikethrough, to clarify their context. Exec Sec is also to clarify with ^{47F}  that the nominal rolls of participants ADMEC requires for clinical trials is essentially the same as the American requirement, using the ADF service number as the identifier. Data is to be retained in accordance with privacy provisions for five years for non-intervention studies and fifteen years in the case of clinical studies

Decision:

Committee agreed to approve the protocol providing the above requirements are met.

For action:

Exec Sec

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DEFENCE PERSONNEL EXECUTIVE

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**MINUTES OF THE FORTIETH MEETING OF THE AUSTRALIAN DEFENCE
MEDICAL ETHICS COMMITTEE,
HELD AT CAMPBELL PARK OFFICES (CP2-5-04) CANBERRA ACT 2600 ON
MONDAY 27 NOVEMBER 2000 AT 1530 HOURS**

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b. **Protocol 216/00 – A randomised, double-blind, comparative study to evaluate the safety, tolerability and effectiveness of Tafenoquine and Mefloquine for the prophylaxis of malaria in non-immune Australian soldiers deployed to East Timor**

- (1) After inviting ^{47F} [REDACTED] to address the meeting again, Amendment 3 and Amendment 4 to the above protocol were discussed.

Decision

ADMEC agreed to accept the amendments.

For action:

Exec Sec

- (2) ^{47F} [REDACTED] reported that of 13 serious adverse events reported from the study of 670 participants, only two gastro intestinal events could possibly relate to the administration of Tafenoquine.

Decision

ADMEC agreed to accept the report.

For action:

Exec Sec

22



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**MINUTES OF THE FORTY FIRST MEETING OF THE AUSTRALIAN DEFENCE
MEDICAL ETHICS COMMITTEE,
HELD AT CAMPBELL PARK OFFICES (CP2-5-04) CANBERRA ACT 2600 ON
MONDAY 26 FEBRUARY AT 1630 HOURS**

22





b. **Protocol 249/01 – Evaluation of Mefloquine for the Prophylaxis of Malaria in Non-Immune Australian Subjects**

- (1) This protocol caused considerable debate when it became apparent that Mefloquine had potentially serious side effects of which ADMEC had been previously unaware. In particular, CNS side effects of depression and psychosis caused considerable concern to Committee, especially were they to occur in deployed troops. [REDACTED] emphasised that this prospective study was scientifically [REDACTED] necessary in order to accurately

categorise the side effect profile of the drug, which is currently the second line treatment of choice for malaria. He also explained that by far the majority of side effects manifest within the first four doses of the drug, which will be administered within Australia. 47F

A revised consent and information sheet

Decision

ADMEC agreed to accept the protocol on the following conditions:

- a. The information and consent sheet are to be amended to clearly outline in quantitative terms the side effects of the medication, including CNS and cardiovascular side effects, and are to include rare events as well as common.
- b. The study should be retitled "Evaluation of Safety and Adverse Effects of Mefloquine in the Prophylaxis of Malaria In Non-Immune Australian Soldiers" to more accurately reflect the intent of the study.
- c. Six doses of the medication are to be given in Australia prior to deployment.

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- h. **Protocol 216/00 - A Randomised, Double-Blind, Comparative Study To Evaluate The Safety, Tolerability And Effectiveness Of Tafenoquine And Mefloquine For The Prophylaxis Of Malaria In Non-Immune Australian Soldiers Deployed To East Timor**

Decision

ADMEC agreed to accept the modification to the protocol. In addition, ADMEC decided to develop its own Serious Adverse Events form for use in the event that one was not otherwise provided by the researcher.

For action:

Exec Sec

22



13. ADMEC then considered and noted the following Progress reports:

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- f. **Protocol 216/00 - A Randomised, Double-Blind, Comparative Study To Evaluate The Safety, Tolerability And Effectiveness Of Tafenoquine And Mefloquine For The Prophylaxis Of Malaria In Non-Immune Australian Soldiers Deployed To East Timor;**

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**MINUTES OF THE FORTY SECOND MEETING OF THE AUSTRALIAN DEFENCE
MEDICAL ETHICS COMMITTEE,
HELD AT CAMPBELL PARK OFFICES (CP2-5-04) CANBERRA ACT 2600 ON
MONDAY 23 APRIL AT 1630 HOURS**

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- b. **Protocol 249/01 – Evaluation of Mefloquine for the Prophylaxis of Malaria in Non-Immune Australian Soldiers.**

Decision

ADMEC approved the modifications as detailed.

For action:

Exec Sec

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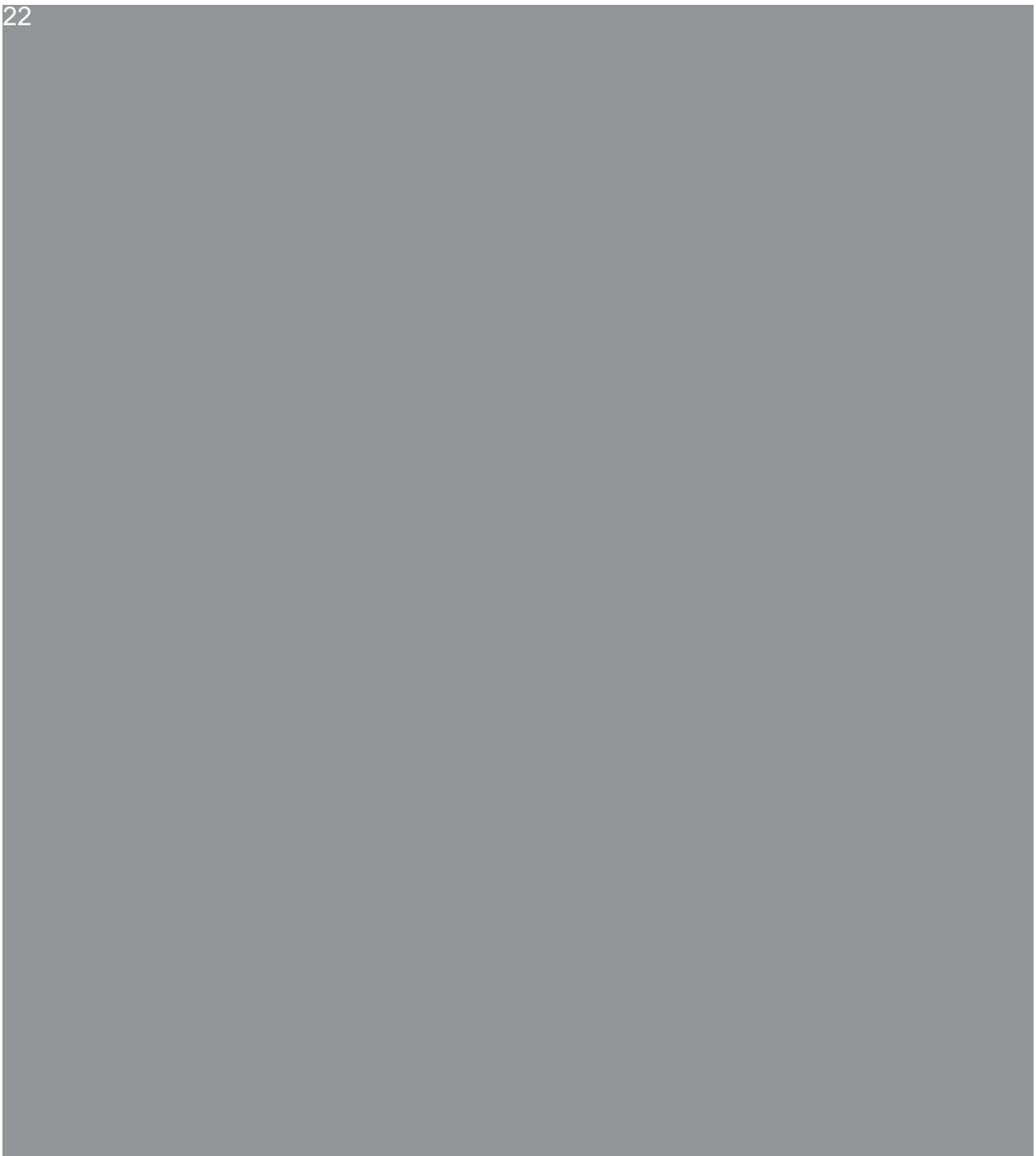
DEFENCE PERSONNEL EXECUTIVE

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**MINUTES OF THE FORTY THIRD MEETING OF THE AUSTRALIAN DEFENCE
HUMAN RESEARCH ETHICS COMMITTEE,
HELD AT CAMPBELL PARK OFFICES (CP2-5-04) CANBERRA ACT 2600 ON
MONDAY 18 JUNE AT 1630 HOURS**

22





- (1) Serious Adverse Events (SAE) from the use of Tafenoquine in Protocol 216/00 – A Randomised Double Blind Comparative Study to Evaluate the Safety, Tolerability, and Effectiveness of Tafenoquine and Mefloquine for the Prophylaxis of Malaria in Non-Immune Australian Soldiers Deployed to East Timor

6. [47F] addressed ADHREC at length with regard to the SAEs observed in the above study. He referred in particular to the keratopathy resulting in whorls in front of the cornea which have been observed following ophthalmological examination of study subjects. These effects have been found in approximately 75% of the 97 subjects randomly selected for detailed examination. [47F] was unable to confirm whether this proportion related to the 75% of subjects receiving Tafenoquine, as the researchers are blinded to which subjects are receiving Tafenoquine, and which Mefloquine.

7. [47F] in particular questioned [47F] as to whether he had any knowledge of the keratopathy having long term manifestations, or whether the keratopathy had ever recurred at a later date, for example years later, following cessation of administration

of related drugs. 47F [redacted] assured ADHREC that in his extensive research into these questions he had not discovered that either situation had ever arisen.

8. The Chair then asked 47F [redacted] be excused. Lengthy discussion took place regarding the SAEs above, and the implications for any further use of the drug in the future. The Chair explained to ADHREC that this type of side effect is well known in other drugs of similar type, known as cationic amphiphilic compounds, notably amiodarone, which is used in the treatment of cardiac dysrhythmia. Keratopathy in this case is not regarded as an indication for cessation of treatment, but rather a sign that the patient is taking their medication. Changes are well known to be reversible on cessation of the medication.

9. 47F [redacted] suggested to ADHREC that an opinion from an independent ophthalmologist be sought to advise Committee of the likely significance of the above findings. In addition, discussion took place as to how long a time period to full or partial resolution of the effects was reasonable. Discussion also took place to the effect that any commencement of further trials involving Tafenoquine could occur until these matters were resolved.

Recommendation:

The meeting resolved to request an independent ophthalmological assessment of the likely effects of keratopathy from the specialist Reserve ophthalmology consultant to the Defence Health Service. ADHREC maintained its position that no further administration of Tafenoquine is to take place in any AMI trials until formal ophthalmological review has shown that keratopathy has completely resolved, or that specialist advice is that it will resolve in the near future. An appropriate time frame for this resolution is to be indicated. This opinion is to be furnished in writing to ADHREC. Formal clearance in writing to AMI to proceed with any use of Tafenoquine will only be given when ADHREC has had the above matters addressed to its satisfaction.

For action:

Chair
Exec Sec

47F [redacted]

- (2) Protocol 249/01 – Evaluation of Mefloquine for the Prophylaxis of Malaria in Non-Immune Australian Soldiers

11. 47F [redacted] addressed ADHREC on the above protocol.

Recommendation:

The meeting resolved to approve 47F [redacted] request to extend the research sample size. The name of the protocol is to be changed to read: ‘Evaluation of Tolerability of Mefloquine in the Prophylaxis of Malaria in Non-Immune Australian Soldiers’

For action:

Exec Sec

22 [redacted]



DEFENCE PERSONNEL EXECUTIVE

SG97-6600

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e. Protocol Audit Reports

- (1) Protocol 216/00 – A Random ized, Double-Blind, Comparative Study to Evaluate the Safety, Tolerability and Effectivene ss of Tafenoquine and Mefloquine for the Prophylaxis of Malaria in Non-Im mune Australian Soldiers Deployed to East Timor.

19. 47F [REDACTED] visited the Army Malaria Institute in Brisbane to conduct an audit on the above protocol. 47F [REDACTED]

47F [REDACTED] 47F [REDACTED] informed the com mittee that the ADHREC audit team was very well received by the unit, a nd that the level of record keeping was of a high standard.

20. During the course of the audit, it was f ound that there was one consent form missing. The unit has undertaken to inform ADHREC when this form is located.



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**MINUTES OF THE FORTY SIXTH MEETING OF THE AUSTRALIAN DEFENCE
HUMAN RESEARCH ETHICS COMMITTEE,
HELD AT CAMPBELL PARK OFFICES (CP2-5-04) CANBERRA ACT 2600 ON
MONDAY 25 FEBRUARY 2002 AT 1630 HOURS**

22



e. Protocol 216/00 – A Randomized, Double-Blind, Comparative Study to Evaluate the Safety, Tolerability and Effectiveness of Tafenoquine and Mefloquine for the Prophylaxis of Malaria in Non-Immune Australian Soldiers Deployed to East Timor.

(1) Safety Update.

13. 47F [REDACTED] whilst the information provided in this safety report was reassuring, it would be preferable to have all information conveyed openly and honestly to every member involved in current and previous Tafenoquine trials. This will markedly reduce the risk of a perceived cover up.

Decision

The Principal Investigator is to provide a copy to ADHREC for review of the draft letter from Glaxo SmithKline that is proposed to be distributed to subjects.

For Action:

Exec Sec

(2) Progress Report.

Decision

The Progress Report was noted by ADHREC.

(3) Corrective Action Request – AMI Response.

14. The missing consent form has not yet been located. AMI will notify ADHREC when they find it.

Decision

Exec Sec and Assistant Exec Sec to monitor this situation and report back to ADHREC when the missing form is found.

For Action:

Exec Sec

Assistant Exec Sec

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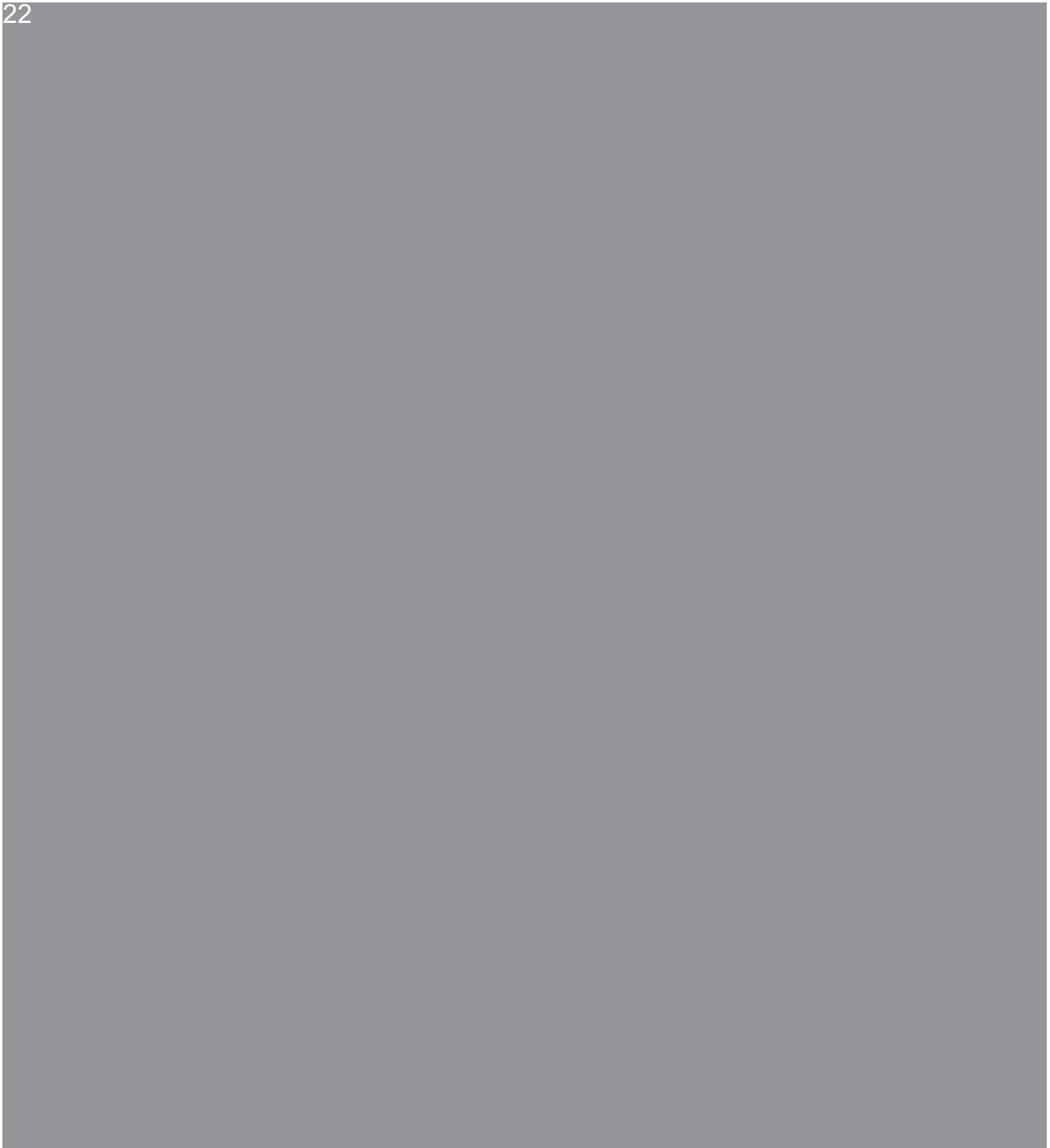
DEFENCE PERSONNEL EXECUTIVE

SG97-6600

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**MINUTES OF THE FORTY EIGHTH MEETING OF THE AUSTRALIAN DEFENCE
HUMAN RESEARCH ETHICS COMMITTEE,
HELD AT CAMPBELL PARK OFFICES (CP2-5-04) CANBERRA ACT 2600 ON
MONDAY 17 JUNE 2002 AT 1630 HOURS**

22



c. 47F
47F **Protocols 216/00 – A Randomised, Double-Blind, Comparative Study to Evaluate the Safety, Tolerability and Effectiveness of Tafenoquine and Mefloquine for the Prophylaxis of Malaria in Non-Immune Australian Soldiers Deployed to East Timor** 47F
47F

3. The Chair invited 47F 47F to address ADHREC. 47F informed ADHREC that the research relating to Protocol 216/00 is now complete. The eye changes that were previously reported in some patients have now resolved, and there have been no further reports of visual disturbances experienced by any patient.

4. During the course of the analysis of the data collected, it was noted that there were a number of patients whose serum creatinine levels did not return to baseline, although they stayed within the normal range. Amendment 7 was written to address this issue. 47F 47F asked ADHREC to consider whether it would be appropriate for the continued investigation of these patients to be conducted as clinical follow up instead of as a formal amendment to the Protocol. He stated that this would prevent further delay in the assessment of these patients. He also requested that ADHREC consider appointing a renal physician to assist in the assessment of any patients whose serum creatinine is found to be still above baseline at the follow up assessment. He said that this had been a recommendation from Glaxo SmithKline's renal consultative group.

5. 47F stated that, with ADHREC's approval, it was the intention of the researchers to close the study, but to continue to clinically monitor the patients who had been involved in the trial.

6. 47F were then asked to wait outside while the proposals were discussed.

Decision:

It was felt among the members that the researchers were displaying due diligence in following up on results that, even though they were still in the normal range, were not back to pre-trial levels. It was decided that;

- (1) it would be appropriate for the affected patients to be clinically monitored, rather than amend the protocol,
- (2) amendment 7 to Protocol 216/00 would be withdrawn, and
- (3) a renal physician would be appointed to assist with clinical follow up if required.

For action:

Exec Sec
Assistant Exec Sec



DEFENCE PERSONNEL EXECUTIVE

SG97-6600

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**MINUTES OF THE FORTY NINTH MEETING OF THE AUSTRALIAN DEFENCE
HUMAN RESEARCH ETHICS COMMITTEE,
HELD AT CAMPBELL PARK OFFICES (CP2-5-04) CANBERRA ACT 2600 ON
MONDAY 12 AUGUST 2002 AT 1630 HOURS**

22



- (3) Protocol 249/01 – Evaluation of Mefloquine for the Prophylaxis of Malaria in Non-immune Australian Soldiers.

35. The apparent high incidence of adverse events was of concern to the Committee. The Exec Sec asked that the e-mail from 47F be taken away and reviewed by the Committee. She further explained that the AMI position on reporting of adverse events had been discussed with ADHREC previously. Following this discussion, the decision was made that AMI would only report on adverse events that were possibly drug related.

Decision:

ADHREC requires further information on the adverse events recorded in this study. This is to be circulated out of session for discussion at the next meeting.

The reporting of adverse events by researchers is to be tabled as a discussion point for the next meeting.

For action:

Exec Sec

Assistant Exec Sec



DEFENCE PERSONNEL EXECUTIVE

SG97-6600

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**MINUTES OF THE FIFTIETH MEETING OF THE AUSTRALIAN DEFENCE
HUMAN RESEARCH ETHICS COMMITTEE,
HELD AT CAMPBELL PARK OFFICES (CP2-5-04) CANBERRA ACT 2600 ON
MONDAY 25 NOVEMBER 2002 AT 1600 HOURS**

22



d. Protocol 249/01 – Evaluation of Mefloquine for the Prophylaxis of Malaria in Non-Immune Australian Soldiers.

15. There was still a deal of unease among the members with regard to this Protocol. The Chair explained that the psychological evaluation has become an operational requirement. However, there were other problems that the Committee felt needed to be addressed. These included listing 47F [REDACTED] as the Principal Investigator in the Protocol submission, a concern that the protocol presented was different to the research being proposed, and a requirement for a new questionnaire to be produced by the researchers.

Decision:

This Protocol is to be flagged as one to be audited by the Secretariat in the New Year.

For action:

Exec Sec

Assistant Exec Sec

22





Australian Government

Department of Defence

Defence Personnel Executive

DEFENCE PERSONNEL EXECUTIVE

SG97-6600

See distribution

**MINUTES OF THE FIFTY SIXTH MEETING OF THE AUSTRALIAN DEFENCE
HUMAN RESEARCH ETHICS COMMITTEE,
HELD AT CAMPBELL PARK OFFICES (CP2-7-069) CANBERRA ACT 2600 ON
MONDAY 05 JULY 2004 AT 1630 HOURS**

22



ITEM 2. BUSINESS ARISING FROM THE PREVIOUS MEETING

a. Protocol 249/01- Evaluation of Mefloquine for the Prophylaxis of Malaria in non-immune Australian soldiers.

6. At the last meeting ADHREC members requested that all researchers advise ADHREC of all SAE reports. AMI has drafted Standing Operating Procedures (SOPs) for dealing with serious adverse events (SAEs) related to current and future trials. The SGADF approved the draft SOPs out of session.

7. The Draft SOPs were tabled by the Chair for approval by the Committee.

Decision:

The Committee approved the SOPs but highlighted the need for all SAEs to be reported to ADREC.

For action:

Exec Sec
Assistant Exec Sec



Australian Government
Department of Defence
Defence Personnel Executive

**DEFENCE HEALTH
SERVICE**
CP2-7-068
Campbell Park
CANBERRA ACT 2600

2002/1936/3
DHSB 214/05

See distribution

**MINUTES OF THE FIFTY-SEVENTH MEETING OF THE AUSTRALIAN DEFENCE
HUMAN RESEARCH AND ETHICS COMMITTEE
CAMPBELL PARK OFFICES (CP2-7-069) CANBERRA ACT 2600
MONDAY 28 FEBRUARY 2005 AT 1600 HOURS**

22



b. Protocol 249/01: Evaluation of Mefloquine for the prophylaxis of Malaria in non-immune Australian soldiers.

11. The committee noted that the modification details had not been clarified or presented from last meeting. The Executive Secretary explained that the modifications had been discussed with the Commanding Officer of AMI. He would clarify that the modifications referred to were not to the protocol per se, but to the operational orders of the soldiers representing the protocol participants.

Decision:

The committee requested the clarification of the above modifications, i.e. that they refer to operational modifications, not protocol modifications.

Action:

Exec sec

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Australian Government

Department of Defence

Defence Personnel Executive

**DEFENCE HEALTH
SERVICES**

CP2-7-068

Campbell Park

CANBERRA ACT 2600

2002/1936/3

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**MINUTES OF AUSTRALIAN DEFENCE HUMAN RESEARCH ETHICS
COMMITTEE (ADHREC) FIFTY-NINTH MEETING HELD AT
CAMPBELL PARK OFFICES (CP2-7-069) CANBERRA ACT 2600 ON
MONDAY 4 JULY 2005 - 1630 HOURS**

22



ITEM SEVEN – FINAL REPORTS

a. Protocol 249/01: Evaluation of mefloquine for the prophylaxis of malaria in non-immune Australian soldiers

- a) Article: “Mefloquine and Doxycycline Malaria Prophylaxis in Australian Soldiers in East Timor”, Medical Journal of Australia, Vol 182 Number 4, 21 February 2005.

31. ADHREC noted that this was a very good paper.

32. The committee asked the Secretariat to look at the stated risks for doxycycline from this study and all studies using doxycycline that ADHREC holds.

33. The study contained one participant with undisclosed schizophrenia, one participant had epilepsy and one had depression. These numbers are within standard population rates.

Decision: Secretariat to write a letter of thanks for the report and congratulations on a project well completed. Secretariat to list risks of doxycycline from this and other Australian Malaria Institute (AMI) studies.

Action by: Exec Sec
Assist Exec Sec

- b) Study report: "Evaluation of safety and adverse events of mefloquine in the prophylaxis of malaria in non-immune Australian soldiers", AMI Journal, January 2005.

34. Discussion occurred to the effect that this study is of benefit to the ADF. A query was raised as to whether the participants with pre-existing epilepsy were in the Reserve or Full time service. It was presumed that they were in the Full time service, since participants were all from a regular Army Infantry Battalion.

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ITEM ELEVEN- NEW BUSINESS

a. Complaint/query

55. ADHREC received a complaint/query from a member of the ADF, regarding *Protocol 249/01: Evaluation of Mefloquine for the prophylaxis of Malaria in non-immune Australian soldiers*. The member considered headaches suffered from about the time of taking mefloquine as a Serious Adverse Reaction and was not satisfied that the members' medical records were reflected in the final published report. Exec Sec has spoken at length with the complainant and 47F on this issue. Responses from 47F have been forwarded to the member concerned.

56. Exec Sec explained to the committee that the question of severity of symptoms was the issue. 47F clarified with the member what Serious Adverse Reaction denoted, i.e. hospitalisation etc and that the headaches did not fall under this category.

57. The member having been given 47F explanation made correspondence with the Secretariat just prior to the meeting and was satisfied with the explanations and efforts made by 47F and the Executive Secretary and required no further action.

58. 47F



Decision: ADHREC noted the complaint/query.

Action By:

Exec Sec
Assist Exec Sec

22



f. Protocol 216/00: Randomised, double blind, comparative study to evaluate the safety, tolerability and effectiveness of tafenoquine and mefloquine for the prophylaxis of malaria in non-immune Australian soldiers deployed to East Timor- Antibody studies

Researchers requested that samples be re-tested using new technology and equipment. The samples are being tested for Malaria, as per the original consent/information process. The committee noted and ratified the decision.

Decision: ADHREC concurred that the samples can be tested using the new technology. It requested researchers submit a formal request for extension of the protocol.

Action by:

Exec Sec
Assist Exec Sec

22





Australian Government

Department of Defence

Defence Personnel Executive

**DEFENCE HEALTH
SERVICES**

CP2-7-068

Campbell Park

CANBERRA ACT 2600

2002/1936/3

DHSB /05

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**MINUTES OF AUSTRALIAN DEFENCE HUMAN RESEARCH ETHICS
COMMITTEE (ADHREC) SIXTIETH MEETING HELD AT
CAMPBELL PARK OFFICES (CP2-7-069) CANBERRA ACT 2600 ON
MONDAY 29 AUGUST 2005 - 1630 HOURS**

47F



47F



d. Protocol 216/00: A randomized, double-blind, comparative study to evaluate the safety, tolerability and effectiveness of tafenoquine and mefloquine for the prophylaxis of malaria in non-immune Australian soldiers deployed to East Timor – Antibody studies.

70. ADHREC noted that the extension letter and approval out-of-session

Decision: No further action required.



**AUSTRALIAN DEFENCE HUMAN RESEARCH ETHICS COMMITTEE (ADHREC)
SIXTY-SIXTH MEETING
CAMPBELL PARK OFFICES (CP2-7-069) CANBERRA ACT 2600
MONDAY 3 JULY 2006 - 1630 HOURS**

22



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7. Exec Sec was questioned at length as to why the progress report for **Protocol 216/00 A Randomized, Double-Blind, Comparative Study To Evaluate The Safety, Tolerability And Effectiveness Of Tafenoquine And Mefloquine For The Prophylaxis Of Malaria In Non-Immune Australian Soldiers Deployed To East Timor** is still overdue. She stated on a number of occasions that, by her recollection, Army Malaria Institute (AMI) were still waiting for further reports from the overseas sponsors of the study. Despite stating that she would confirm this with AMI, the issue was raised again later in the meeting, but Exec Sec was unable to add anything to her previous response. *Note by Exec Sec: For brevity, the issue is dealt with in full here. The protocol was initially closed on 12 June 2002, but re-opened following a request to do so by AMI on 13 July 2005. ADHREC granted an extension on 1 August 2005 until 31 December 2007, to enable further analysis of samples which have been sent to America. As was recalled by Exec Sec, the final report from GlaxoSmithKline is still being awaited. Exec Sec spoke to Commanding Officer Army Malaria Institute on 4 July 2006. ^{47F} [redacted] will provide a progress report to Exec Sec as a matter of urgency. A package summarising key events to do with Protocol 216/00 is enclosed with these Minutes*

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Australian Government

Department of Defence

Defence Support Group

**DEFENCE HEALTH
SERVICES**

CP2-7-121

Campbell Park

CANBERRA ACT 2600

**AUSTRALIAN DEFENCE HUMAN RESEARCH ETHICS COMMITTEE (ADHREC)
SIXTY-SIXTH MEETING
CAMPBELL PARK OFFICES (CP2-7-069) CANBERRA ACT 2600
MONDAY 28 AUGUST 2006 - 1630 HOURS**

22



ITEM EIGHT – FINAL REPORTS

37. Protocol 216/00: A randomised, double-blind, comparative study to evaluate the safety, tolerability and effectiveness of tafenoquine and mefloquine for the prophylaxis of malaria in non-immune Australian soldiers deployed to East Timor.

23. Discussion occurred as to the apparent efficacy of both agents, with a different side-effect profile being the main differences.

Decision: Letter of thanks to be sent to the researcher.

Action:

Exec Sec

Asst Exec Sec



Australian Government

Department of Defence
Defence Support Group

Defence Health Services
CP2-7-124
Campbell Park
CANBERRA ACT 2600

**AUSTRALIAN DEFENCE HUMAN RESEARCH ETHICS COMMITTEE (ADHREC)
SEVENTY-FIFTH MEETING
CAMPBELL PARK OFFICES (CP2-7-069) CANBERRA ACT 2600
MONDAY 15 OCTOBER 2007 - 1630 HOURS**

22



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ITEM EIGHT – FINAL REPORTS

21. Protocol 216/00: A randomized, double – blind, comparative study to evaluate the safety, tolerability and effectiveness of tafenoquine and mefloquine for the prophylaxis of malaria in non-immune Australian soldiers deployed to East Timor. Support Paper.

30. Letter of thanks to the Researchers.

Decision: Letter of thanks to the Researchers.

Action:

Exec Sec

Asst Exec Sec

22. Protocol 249/01: Evaluation of mefloquine for the prophylaxis of malaria in non-immune Australian soldiers.

31. Letter of thanks to the Researchers.

Decision: Letter of thanks to the Researchers.

Action:

Exec Sec

Asst Exec Sec

22





ADHREC, CP2-7-100, Campbell Park Offices, Campbell ACT 2600

ATTACHMENT A TO
ADHREC/OUT/2010/AF2061797

**AUSTRALIAN DEFENCE HUMAN RESEARCH ETHICS COMMITTEE (ADHREC)
NINETY THIRD MEETING
CAMPBELL PARK OFFICES (CP2-7-069) CANBERRA ACT 2600
MONDAY 12 APRIL 2010 - 1630 HOURS**

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ITEM EIGHT – FINAL REPORTS

34. 216-00 A randomized, double – blind, comparative study to evaluate the safety, tolerability and effectiveness of tafenoquine and mefloquine for the prophylaxis of malaria in non-immune Australian soldiers deployed to East Timor.

42. Scientific article published in “Antimicrobial Agents and Chemotherapy” Feb 2010.

Decision: Noted with thanks.

Action:

Executive

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