



*Australian Defence*

*Medical Ethics*

*Committee*



*Annual Report 1999*



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# Foreword

As the Human Research Ethics Committee for Defence, the Australian Defence Medical Ethics Committee (ADMEC) is committed to the creation and maintenance of an environment in which research on humans undertaken on Australian Defence Force (ADF) personnel, by ADF personnel, or on Defence property is conducted both professionally and ethically.

ADMEC's mission is to promote and encourage health research in the military context. Clearly, such research needs to be of the highest ethical standard, as the best research has as its essential ingredient, best ethical practice.

The ethical principles of autonomy, beneficence, non-malevolence and justice are used to ensure the protection of the welfare and rights of research participants. Research on humans which involves Servicemen and women is, in many ways, unique. As a research population, the ADF is especially attractive. It is a large population, enjoying both a high level of physical fitness and readily available expert medical care, but it is also a captive population, whose working lives are regimented in a way that civilian personnel rarely experience. ADF personnel are subject to order in a way that civilian personnel are not, and for them, therefore, the issue of voluntary consent is a particularly important and sensitive one. ADMEC exists to safeguard the rights of these men and women, the same rights that the civilian population expects to enjoy.

An overview of 1999 demonstrates how productive the past year has been for the Committee:

- *33 new research protocols were considered;* Although the number of research protocols submitted in 1999 is slightly down on 1998 figures, this figure still represents a positive trend.
- *Publication of the National Health and Medical Research Council's (NHMRC) National Statement on Ethical Conduct of Research Involving Humans;* The NHMRC's new National Statement is the most comprehensive statement on the ethical principles of research to be produced in Australia. We have appointed a new committee member in line with the new membership requirements of the National Statement.
- *The evolution of an inclusive Committee;* The Committee has always enjoyed an element of external involvement at meetings. This year, this participatory style has firmly taken root, with invitations issued to the three Assistant Surgeons General, as well as to other visitors. We have also enjoyed presentations from some of our more prolific researchers, who informed us of the progress of some of their more important projects. We expect this to continue as an important and valuable means by which the Committee can fulfil its mission and maintain open communication with researchers and other elements of Defence.

**Major General John H. Pearn AM, RFD  
Surgeon General Australian Defence Force  
Chair - Australian Defence Medical Ethics  
Committee – 7 December 1999**

Foreword

# Australian Defence Medical Ethics Committee



*Major General J.H. Pearn, AM  
RFD Chair*

Major General Pearn is the Surgeon General Australian Defence Force. He has been a member of the Australian Defence Medical Ethics Committee since 1990, and its Chair from 1998. During his service career, Major General Pearn has served in a number of Medical Officer, command and non-regimental positions in Australia, the United Kingdom and Papua New Guinea. He has published extensively in the area of military medicine and military history. In his civilian life, Major General Pearn is the Professor of Paediatrics and Child Health (University of Queensland) and the Deputy Head of the Graduate Medical School within the University of Queensland. He is a Senior Paediatric Consultant at the Royal Children's and Mater Children's Hospitals in Brisbane and Honorary Consultant in Paediatrics and Genetics to the Royal Women's Hospital, also in Brisbane. He is an Honorary Life Member of the Human Genetics Society of Australasia of which he is a past president. He is the author of some 300 papers on clinical medicine and medical research in the international refereed literature, the author of 12 books and of some 60 chapters in medical textbooks in the international medical literature. He has a special interest in medical ethics and for his work in this field was created a Fellow of Green College, the University of Oxford.

*Member*

## *Colonel Peter G. Warfe, CSC*



Colonel Peter Warfe is a military physician specialising in Tropical and Preventive Medicine. He has served in Papua New Guinea, Northwest Europe with NATO forces and in the United States of America. He is a graduate of the Australian Army's Command and Staff College and has held six command appointments during his 27 years of regular service. In January 2000, Colonel Warfe transferred to the Reserve force serving as the Chair of Defence Health Research Consultancy Group in Australian Defence Headquarters. Colonel Warfe has conducted research on the seroprevalence of infectious disease and is the author of numerous papers on Military Medicine topics including Stress and Peacekeeping. He has also conducted and published ADMEC cleared research on mortality in the Australian Army. Colonel Warfe is now a private consultant in public health and is also a member of a number of advisory boards and committees. These include: the Australian Agency for International Development Board on International Health, the Board of Censors for the Faculty of Public Health Medicine in the Royal Australasian College of Physicians, Diabetes Australia, the United Nations Advisory Committee on Traumatic Stress Syndromes and the Department of Veteran's Affairs Mental Health Strategy Working Group. In addition, Colonel Warfe is the Deputy Director of Training for Saint John Ambulance Australia. In 1995 Colonel Warfe acted as the Force Medical Officer and commanded the Australian Contingent to the United Nations Assistance Mission in Rwanda. For outstanding achievement as the Contingent Commander to Rwanda he was awarded the Conspicuous Service Cross. Married with four children, he enjoys golf, fishing and military history. Colonel Warfe was appointed to ADMEC in 1998.

*Member*

## *Justice Terence J. Higgins*

Justice Terence Higgins is a resident Judge of the Supreme Court of the Australian Capital Territory and a Judge of the Federal Court of Australia, being appointed on 2 July 1990. He was born in Hobart, Tasmania but was educated at St Augustine's Christian Brothers College in Yarraville, Victoria and later, at St Edmund's College, Canberra and the Australian National University, Canberra. He was admitted as a barrister and solicitor in the ACT in 1967 and served at the bar as Queen's Counsel (ACT, NSW and Victoria) from 1987 to 1990. He was Vice President of the ACT Bar Association from 1988 until his judicial appointment in 1990. Justice Higgins first began practising law with J.J. O'Neill, solicitor in 1967 and remained until 1971 when he became partner in the law firm Higgins, Faulks & Martin (formerly Higgins & Faulks). In 1981 that firm became Higgins Solicitors and he remained a partner until 1984 when he went to the ACT Bar.



Justice Higgins is currently the National President of the Royal Life Saving Society of Australia (appointed 1997), Chairman of the St Edmund's College Board, Chairman of the Open Family Foundation ACT (as well as a National Board member), Chairman of the Australian National University's Legal Workshop Committee and Member of the Australian Academy of Forensic Sciences ACT Chapter. In the past, Justice Higgins has been involved in many varied committees and associations including Chair of the ACT Community Law Reform Committee (1994-96), Senior Member of the ACT Gaming and Liquor Authority (1987-90) and President, Senior Common Room of the John XXIII College ANU (1993-95). Married to Anne with five children and residing in the Australian Capital Territory, Justice Higgins enjoys squash, chess, reading, tennis and bridge. Justice Higgins was appointed to ADMEC in 1993 and has served on the Committee continuously since.

*Member*

## *Mr David Dillon*



Mr Dillon was born in Sydney, and spent most of his childhood in Sydney and the Blue Mountains. Mr Dillon graduated from Wagga Wagga Teachers College and, after completing compulsory National Service in the Army, taught in the Snowy Mountains, Cooma, Mittagong, North West NSW and Tenterfield. After completing a Bachelor's Degree at the University of New England, Mr Dillon spent over 20 years in the ACT Schools Authority, both in Schools and Schools Office positions. During that period Mr Dillon held a number of professional and community positions including President of the ACT Primary Principals' Association and President of the Australian Primary Principals' Association, representing over 7,000 Government and non-Government schools throughout Australia. He also was the foundation President of Belconnen Soccer Club and Canberra City Soccer Club, when the latter club first entered the national Soccer League of Australia. In addition, Mr Dillon held administrative positions with the ACT Soccer Federation, the National Soccer League Executive and the Executive of Australian Soccer Federation. Mr Dillon maintains a long-term affiliation with the Anglican Church, having served in various capacities in parishes for some 30 years, including Lay Reader, Parish Council Chairman and Synod Representative. He retired as Principal of Melba Primary School in 1990, and settled on a small farm on the Far South Coast of NSW, where he still resides. Married with three children, he enjoys life on the farm, entertaining grandchildren, golf, fishing, travel and church activities, where he is still a licensed Lay Minister. Mr Dillon is a foundation member of ADMEC and has served continuously since.

*Member*

## *Elizabeth* Mrs Elizabeth Grant

Mrs Grant is a pharmacist and a company director. She has been a member of ADMEC since its formation in 1988. She was also an inaugural member of the National Health and Medical Research Council (NHMRC) Medical Research Ethics Committee, 1982 - 91, a member of the NHMRC, from 1982, and the Chairman of the Australian Capital Territory Department of Health and Community Care Ethics Committee, from 1997. She has been a member of this committee since 1994. Mrs Grant has also been the Chair of ACT Festivals Incorporated, 1989 - 1998. Her interests include community affairs, sport and the Arts.



*Member*



## Reverend Monsignor Max L. Davis, AM RANR



Monsignor Davis was born and raised in Perth. He first joined the Royal Australian Navy (RAN) to become an electrician. He subsequently departed the RAN to complete his seminary training in Western Australia and New South Wales, and, after graduation and ordination, was involved in teaching and parish work. He was recruited by the Australian Army into the Citizen Military Forces in 1971 and was later commissioned and appointed to the RAN. Monsignor Davis served on a number of HMA Ships and has attended USN Chaplains School, completed External Studies Staff Course and graduated from Joint Services Staff College with a Graduate Diploma in Strategic Studies. When the RAN Chaplain Branch was restructured in 1990, he was advanced to Senior Chaplain and subsequently selected for Principal Chaplain in 1993. In the same year he was made a Prelate of Honour with the title Reverend Monsignor by Pope John Paul II and appointed Vicar General of the Military Diocese. In 1996, he was appointed as the Chancellor for the Military Diocese of the Australian Defence Force. Monsignor Davis' last full time appointment was a Director General Chaplaincy - Navy, 1993 - 1998. During that period he was Chairman/Secretary of the Principal Chaplain's Committee - Navy, and a member of the Principal Chaplain's Advisory Group to Headquarters ADF. He was naval adviser to the Religious Advisory Committee to the Services. Monsignor Davis was appointed to ADMEC in 1994.

*Member*

## *Dr Alan Twomey*



Dr Twomey holds a Bachelor of Science degree in Applied Psychology from the University of New South Wales and a Doctorate of Philosophy from the University of Wollongong. Dr Twomey helped fund his undergraduate studies through employment in a broad range of occupations that provided him with an in-depth and broad appreciation of Australian social diversity. Prior to, and during, his postgraduate studies, Dr Twomey was employed as a research assistant, tutor and lecturer. Subsequently, Dr Twomey joined the Australian Defence Organisation where he gained administrative experience before joining the psychology stream as a research psychologist. In 1997 he became Director of Psychology (Navy) and is currently responsible for all research undertaken by the Psychology Research Group within the newly formed Defence Force Psychology Organisation. Dr Twomey's doctoral research involved completion of a major research thesis that included both empirical and theoretical components and incorporated elements of psycholinguistics, and cross cultural, cognitive and educational Psychology. It involved using diverse research methods and integrating theoretical perspectives of different academic disciplines. Dr Twomey now has more than 25 years experience in undertaking research in a wide range of areas, including 13 years in Defence. During this time he has published in a number of journals and books and has initiated many improvements to the way in which psychological research is undertaken in Defence. Dr Twomey was formally appointed to ADMEC in January 2000.

*Member*

# *The Secretariat*

## *Lieutenant Colonel Victoria Ross Executive Secretary*



Lieutenant Colonel Ross joined the Army undergraduate scheme while completing her medical training at the University of Melbourne and the Royal Melbourne Hospital. After two years working as a medical resident at the Geelong Hospital, Lieutenant Colonel Ross came into the full time Army. Lieutenant Colonel Ross has had postings to the First Field Hospital, Duntroon Medical Centre (now Canberra Area Medical Unit), Headquarters Logistic Command and now the Directorate of Clinical Policy, Defence Health Service Branch. Lieutenant Colonel Ross was awarded Fellowship of the Royal Australian College of General Practitioners in 1997 and is currently completing a Masters of Public Health through the University of New South Wales. She became Executive Secretary of ADMEC in July 1998.

## *Lieutenant Commander Trish Matthews Assistant Executive Secretary (January - June 1999)*



Lieutenant Commander Matthews completed her General Nursing Training at the Royal Brisbane Hospital (RBH) in 1985 and joined the Royal Australian Navy in 1988. Lieutenant Commander Matthews served at the hospital at HMAS Cerberus until January 1992 and then returned to the RBH to undertake an Operating Room Nurse qualification under the civil Schooling Scheme. On successful completion, Lieutenant Commander Matthews managed the Operating Room Suite at Balmoral Navy Hospital, HMAS Penguin, from September 1992 until March 1996, assisting the facility to gain civil accreditation for a second, three-year period. After having two children in rapid succession, Lieutenant Commander Matthews was employed as the Personnel Officer in Melbourne before being posted to the Directorate of Clinical Policy in January 1999. In June 1999, Lieutenant Commander Matthews left the Directorate on posting to Adelaide.

*Secretariat*



**Ms Kelly West**  
**Assistant Executive Secretary (from September 1999)**

After completing her Bachelor of Arts and Science degrees at the Australian National University, Ms West spent time as a consultant for a private sector information technology firm, before contracting to the national Defence Information Systems Call Centre. Ms West was accepted into the Department of Defence Graduate Development Program in late 1998, and throughout 1999 completed a series of job rotations within Defence, including the Defence Science and Technology Organisation; International Policy Division, and the Directorate of Clinical Policy in the Defence Health Service Branch. Following her graduation from the Program, Ms West took up her final placement with the Directorate of Clinical Policy.



**Major Rosemary Landy**  
**Minute Secretary**

Major Landy graduated with honours from the Faculty of Dentistry, University of Melbourne in 1978. She joined the Royal Australian Army Dental Corps in 1980 after having spent a year doing oral surgery. She has served in fourteen locations throughout Australia in both clinical and Command and Staff roles. She has also served in New Zealand, where she was awarded a Graduate Diploma in Oral Surgery with distinctions. Major Landy is married to an Army Officer and has two young sons.



*Secretariat*

## *The History of the Australian Defence Medical Ethics Committee (ADMEC)*

After World War II, there was growing concern worldwide regarding human experimentation. This led to the Declaration of Helsinki in 1964, which defined the basic principles to be followed whenever humans are used in a research project. The National Health and Medical Research Council (NHMRC) subsequently published a statement on human experimentation in 1982. ADMEC was subsequently formed to ensure that the Defence Force complied with these guidelines. The Chief of the Defence Force (CDF) and the Secretary for Defence formed ADMEC as a non-statutory body in 1988. The documents dealing with ADMEC and its functions are:

- DI(G)ADMIN 24-3 Function, Structure and Procedures for Obtaining Clearance for Research from ADMEC
- HPD 205 Australian Defence Medical Ethics Committee

The Defence Instruction (General) was published in 1989, and was followed by the Health Policy Directive in 1994. The first meeting of ADMEC was held in November 1989. Meetings were originally held biannually or as needed, but as the amount of research conducted in Defence has grown over the years, the Committee now meets more frequently with some out of session determinations being made as required. A total of 35 meetings have been convened since its inception. The Committee met four times in 1999 and this frequency increased to five in 2000. This ninth annual report covers the period from January to December 1999.

## *Committee Members*

There has been a significant change to the Committee membership during 1999. The National Statement on Ethical Conduct in Research Involving Humans (the National Statement), issued by the National Health and Medical Research Council (NHMRC), has led to the appointment of a new, seventh member. The Committee selected, and then invited, Dr Alan Twomey, head of the Psychology Research Group, to join ADMEC. The structure of the Committee, which meets NHMRC guidelines, is detailed on page 26.

The Chair invited several guests to attend meetings in 1999:

The Assistant Surgeons General of the ADF: Commodore P.G. Habersberger, AM, RFD (Navy), Brigadier R.N. Atkinson, RFD (Army), and Air Commodore Bruce Short, RFD, (Airforce) each attended an ADMEC meeting as an understudy to the SGADF. The purpose of these visits was for the A/SGADFs to observe the duties of the SGADF and gain a deeper appreciation of how ADMEC operates.

Also, Mr Martyn Taylor, Assistant Secretary, General Investigations and Review of the Inspector General's Department, gave an informative address to ADMEC at the May meeting. Mr Taylor's talk centred on ethical issues in the workplace, ranging from the misuse of frequent flyer points to the abuse of allowances. This was a valuable interaction and provided an opportunity for an exchange of information and ideas regarding ethical issues in Defence - both with respect to health and general workplace issues.

Attendance at meetings and expenditure details are listed on pages 27 and 28 respectively.

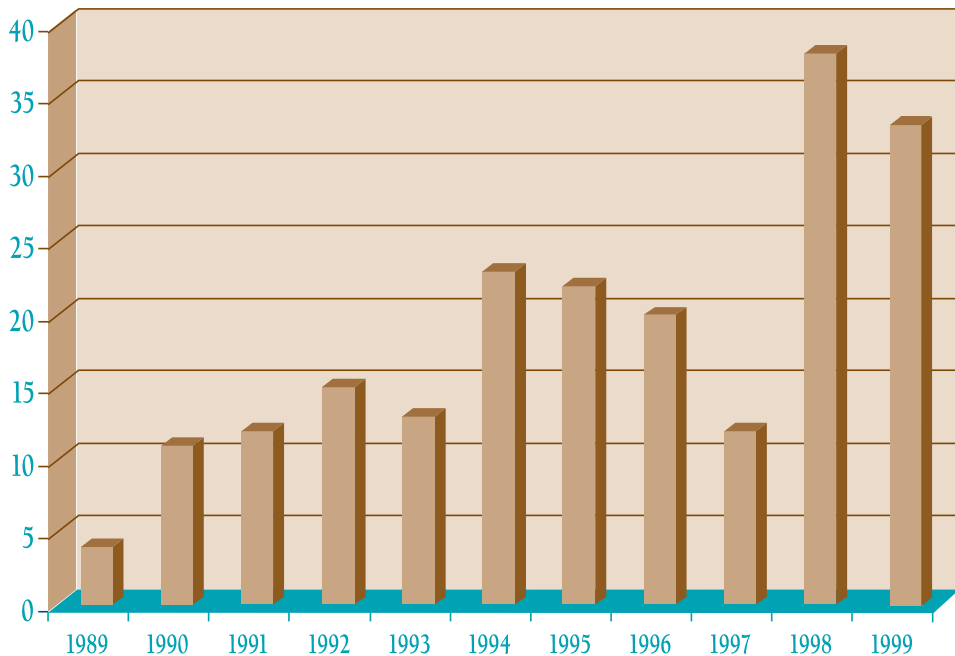
*History*

## Research Projects Considered during 1999

The Committee received 33 new protocols during the reporting period, which represents a minor decline in numbers from 1998, but continues the trend observed in 1998 towards a greater volume of research than in earlier years. These protocols are detailed on pages 23 and 24. The status of these protocols as at end December 1999 is as follows:

Protocol Status	Number
Completed	1
InProgress (approved)	20
New Protocol (for consideration)	1
Not Approved	1
Pending Approval	9
Withdrawn (by researcher)	1
<b>Total</b>	<b>33</b>

Number of New Protocols Considered By ADMEC By Year



## ADMEC-Endorsed Projects Completed During 1999<sup>1,2</sup>

### **Protocol 122/97 - A population based survey of skin cancer in North Queensland**

This study aimed to determine the rates of skin cancer in Townsville, Northern Queensland. The primary investigators were Dr Petra Buettner and Dr Bev Raasch of the School of Public Health and Tropical Medicine, James Cook University, Townsville. A population-based survey was conducted to collect epidemiological information on all excised and histologically (microscopically) confirmed skin cancers in Townsville over a three-year period. Data on the anatomical distribution of skin cancer were collected using a detailed body map. During the study period, a total of 3,536 patients with 5,945 histologically confirmed skin cancer lesions were recorded. Site specific incidence rates demonstrated that highly sun-exposed body sites are at high risk of developing skin cancer and provide, therefore, strong indirect evidence for the relationship between sun exposure and skin cancer. The interim results of this research were published in the International Journal of Cancer, with a more comprehensive article to follow. (Buettner, P. and Raasch, B., Incidence Rates of Skin Cancer in Townsville, Australia, International Journal of Cancer, No. 78, pp. 587 - 593, 1998).

### **Protocol 123/97 - Bone mineralisation response to extreme gravitational force (+Gz)**

This project was a collaborative study between the University of the Sunshine Coast and the Australian Institute of Aviation Medicine, coordinated by Dr Fiona Morris. Publication of this article is pending in the Journal of Aviation, Space and Environmental Medicine. Bone is a metabolically active tissue that responds to high strain loading. The purpose of this study was to examine the bone response to high +Gz force loading generated during high performance flying. The bone response to +Gz force loading was monitored in 10 high performance RAAF pilots and 10 age-height-weight matched control subjects. The pilots were completing the one-year flight-training course at RAAF Base Pearce, Western Australia. The pilots flew the Pilatus PC-9 aircraft, routinely sustaining between 2.0 and 6.0 +Gz. Bone Mineral Density (BMD) and bone mineral content (BMC) were measured at baseline and at 12 months, using the Hologic QDR 2000+ bone densitometer. After controlling for change in total body weight and fat mass, the pilots experienced a significant increase in BMD for thoracic spine, pelvis and total body in the magnitude of 11.0%, 4.9% and 3.7% respectively. However, no significant changes in BMD were observed in the pilots' lumbar spine, arms or legs. No bone mineral changes were observed at any site in the control subjects. These findings suggest that site specific BMD is increased in response to head to seat +Gz forces generated during high performance flying in a PC-9.

<sup>1</sup> All but one of these studies were commenced prior to 1999.

<sup>2</sup> Each researcher was contacted to clear the information presented prior to its inclusion in our Annual Report.

*Projects*

## **Protocol 151/98 - Field in vitro drug resistance and sensitivity testing in areas of Papua New Guinea**

The purpose of this project, conducted by Major Scott Kitchener and Major Peter Nasveld of the Army Malaria Institute (AMI), was to test for drug resistance to a number of commonly used antimalarial compounds in the local communities of Arawa, Buka, Tonu and Konga on the island of Bougainville. The data indicated that the ratio of falciparum malaria to vivax malaria was 4:1. Where high levels of falciparum malaria were found in blood samples, the samples were cultured against a range of antimalarial drugs of varying concentrations using the in vitro method. Ten antimalarial compounds of relevance to AMI and local health authorities were tested: chloroquine, quinine, mefloquine (Larium), pyrimethamine (a component of Fansidar), artesunate, dihydroartemisinin, atovaquone, cycloguanil, pyronaridine and WR99210. Parasite sensitivity to all these drugs is still being tested, however, it was detected almost immediately that there is a high level of resistance to chloroquine and pyrimethamine, both used widely in PNG for treatment of malaria. Reassuringly, parasites were sensitive to quinine and mefloquine, which are currently used routinely for treatment and prophylaxis in Australian troops. These findings led to recommendations regarding appropriate treatment of PNG citizens with malaria. Finally, it was found that the rapid diagnostic kits used in the field were effective in detecting falciparum malaria, though less effective in detecting vivax malaria.

## **Protocol 163/98 - Efficacy of a self supporting low profile bed net for personal protection against mosquitoes**

This project, conducted by Major Stephen Frances and Major Robert Cooper of the Army Malaria Institute (AMI) analysed the effectiveness of current ADF-issued bed nets against new, self-erecting bed nets developed by the US Army. Also, the researchers evaluated whether bed nets impregnated with permethrin were more useful. Overall, the research showed that both types of bed net provided a greater protection from mosquitoes that may carry malaria than no protection at all. The data showed the importance of the sleeper minimising contact with the net during the night. These data are being prepared for publication.

## **Protocol 164/98 - A randomised/ double blind/ placebo controlled evaluation of a loading dose- monthly regimen of etaquine (WR238605) for chemosuppression of Plasmodium falciparum and Plasmodium vivax in Thai Army soldiers**

A new antimalarial, tafenoquine (formerly known as WR238605 or etaquine), was trialed in this study. This clinical trial was a collaborative study between the US Army, Thai components of the Armed Forces Research Institute of Medical Sciences (Bangkok) and the Army Malaria Institute (AMI). The principal investigators were Lieutenant Colonel Doug Walsh from the US Army, Colonel Chirapa Eamsila from the Thai Army and Lieutenant Colonel Michael Edstein from the AMI. The US Army and SmithKline Beecham initially developed tafenoquine as a potential replacement for primaquine.

*Protocols*

Tafenoquine was evaluated for its prophylactic value in preventing both falciparum and vivax malaria in Thai soldiers deployed along the Thai-Cambodian border because of its potent activity against all stages of the malaria parasite. The Thai soldiers were randomised to receive either tafenoquine capsules or placebo ('dummy') capsules (soldiers receiving 'dummy' capsules being the control group). The trial was 'double blinded', ie: neither the researchers or the soldiers knew who was receiving which treatment until after the results had been gathered and analysed. Those who received tafenoquine were given a loading dose of 1200mg base tafenoquine over 3 days following with 400mg tafenoquine monthly over 5 months. At the completion of the study, 29 soldiers had contracted malaria infections: 8 had falciparum malaria, 20 had vivax malaria, and one mixed infection. Of these, 28 of the 29 infected soldiers were of the placebo (control) group, and the remaining soldier who contracted vivax malaria was on tafenoquine, though had blood concentrations of tafenoquine twofold less than the soldiers treated with tafenoquine who had not contracted malaria. Thus, 99% (100 of 101) of the Thai soldiers on tafenoquine were protected against malaria. The treatment had only minor side effects such as nausea and mild diarrhoea. Tafenoquine given monthly proved highly efficacious and safe in protecting Thai soldiers from both falciparum and vivax malaria. The findings from this study was reported at the 48th Annual Meeting of the American Society of Tropical Medicine and Hygiene, 28 November - 2 December 1999, Washington DC. A final paper is presently being prepared by the investigators for publication in an international journal.

### **Protocol 169/98 - The study of leptospirosis and scrub typhus in troops using the Tully Training Area**

This project was coordinated by Dr Brad McCall of the Health Assessment Section, Number Four Preventative Medicine Company (4PMC), with the support and participation of the World Health Organisation (WHO) Collaborating Centre for Reference and Research on Leptospirosis, Queensland Health Scientific Services. The aim of the project was to examine the high prevalence of leptospirosis and scrub typhus found in rodents in the Tully Training Area (TTA), as these diseases can be transmitted to man and cause non-battle casualties. The exposure period coincided with high rainfall, flooding and a high incidence of leptospirosis in surrounding communities of North Queensland. The study concluded that proper adherence to chemoprophylactic regimens and a comprehensive, continuous education program would significantly reduce seroconversion rates of leptospirosis and rickettsial diseases. As part of the study, the 4PMC team devised a health education brief for commanders detailing environmental threats, staying healthy (including adherence to the prophylactic [drug] regimen) and potential risk factors to be aware of in the TTA.

*Protocols*

## Protocol 179/99 - The incidence of deep vein thrombosis following lower limb surgery

The aim of this project, carried out by Corporal Joanne Marks while studying at the Queensland University of Technology (QUT), was to investigate a means by which the incidence of deep vein thrombosis (DVT) may be reduced in patients having elective lower limb surgery. The researcher carried out a retrospective analysis of the incidence of DVT in a 'healthy' and 'low risk' population, namely, ADF personnel. The findings suggest that even in a 'low risk' population, DVT incident rates remain the same as the general population. A literature search found that the use of doppler ultrasound with compression displayed marginally higher specificity and sensitivity than other procedures when investigating DVT. Having said this, a combination of procedures appeared to yield the best results to detect and treat DVT. The author recommended that a systematic and objective DVT risk assessment strategy be adopted before and after lower limb surgery as the most conclusive way of preventing DVT.

### Protocol Status as at 31 December 1999

The status of ADMEC Protocols as at 31 December 1999 is tabulated below. A complete audit of all ADMEC files in September 1999 resulted in a change of status for many early protocols. So, while in the 1998 Annual Report there were 28 protocols classified as Closed (where the result of the research is unknown), this number has been reduced to zero. Close examination of the files revealed that they were in fact either Completed (research complete, final report received), or Finalised (not commenced, not completed or no correspondence received for over one year).

Status	1999	Total to End 1999	Active	Inactive
Approval Withdrawn		6		6
Closed		0		0
Completed	1	55		55
File Missing		1		1
Finalised		45		45
In Progress	20	53	53	
not Approved	1	14		14
Not Submitted		1		1
Pending	9	13	13	
Withdrawn	1	15		15
New Protocol	1	1	1	
<b>Total</b>	<b>33</b>	<b>204</b>	<b>67</b>	<b>137</b>

## Activities and Initiatives

### Guidelines for Researchers.

A set of guidelines prepared by the Committee Secretariat with input from Committee members has been drafted over 1999, with the final publication of the document planned for 2000. The guidelines state what is expected of researchers when submitting protocols, ethical considerations to be taken into account when designing a research project and other information relating to ADMEC. This document clearly states ADMEC's requirements in an easy to follow format, with the NHMRC Guidelines forming the basis. Also, the guidelines provide information to researchers who previously may have thought that ethical approval was not required, as their research was not biomedical in nature eg: social work and social issues research.

### Audit of research files.

During 1999, the ADMEC Secretariat conducted a thorough audit of all research proposals submitted to ADMEC since its inception. This involved contacting researchers who had not contacted ADMEC in over a year, requesting copies of publications where research has been published, and following up on research not approved by ADMEC. Auditing ADMEC files ensures accountability and greater efficacy of the monitoring of research registered with ADMEC.

### Major Researchers in Defence

Major researchers within Defence who have had protocols considered by ADMEC include:

- **Army Malaria Institute (AMI)**

- Areas of research include prevention and treatment of vector borne disease through pharmacological agents (e.g. medications - both vaccines and oral medicines, and insect repellents) or physical means (e.g. bed nets, protective clothing).

- **Submarine and Underwater Medicine Unit (SUMU)**

- Areas of research include prevention and treatment of decompression illness (the 'bends'), evaluation of equipment and validity of diving tables.

- **Royal Australian Air Force Institute of Aviation Medicine (RAAF AVMED)**

- Both AVMED and individuals with an interest in Aviation Medicine have studied various effects of hypoxia (diminished availability of oxygen to body tissues) and gravitational forces (+Gz) on aircrew, their physiology and performance.

- **Defence Science and Technology Organisation (DSTO)**

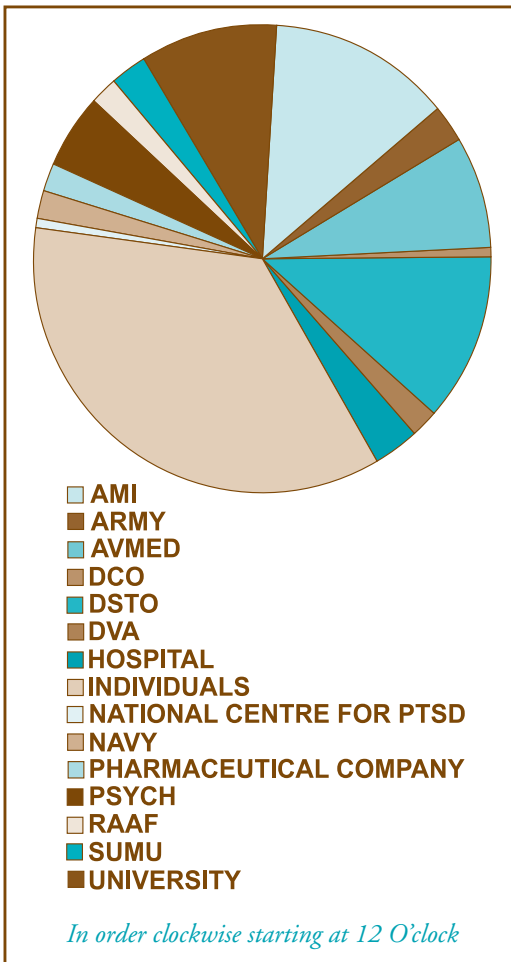
- Various departments within DSTO have been researching the physiological responses of soldiers under different climatic and work conditions, evaluating equipment for use in the field and investigating options for optimum nutrition of soldiers.

- **Psychology Research Group (PRG) and the Directorate of Strategic Personnel Planning and Research (DSPPR)**

- PRG's main tasks comprise the assessment of the human factors of the ADO, the development of selection techniques, eg: psychometric or aptitude tests, and the evaluation of the utility and validity of psychological tests. PRG also acts as a consultant to other areas of the ADO on matters of selection, training and retention of staff.
- DSPPR provides the Defence Organisation with a consolidated personnel research capability to support strategic work force planning and strategic personnel planning. DSPPR also provides advice and assistance in relation to the evaluation of personnel management policies and practices.

Most other researchers have been individuals completing Masters theses or Doctoral dissertations, practicing clinicians or epidemiologists with a special interest in the area researched. All research involving ADF personnel, as either researchers or subjects, that is brought forward for consideration by ADMEC must have some benefit to the ADF.

### Researchers Registered with ADMEC

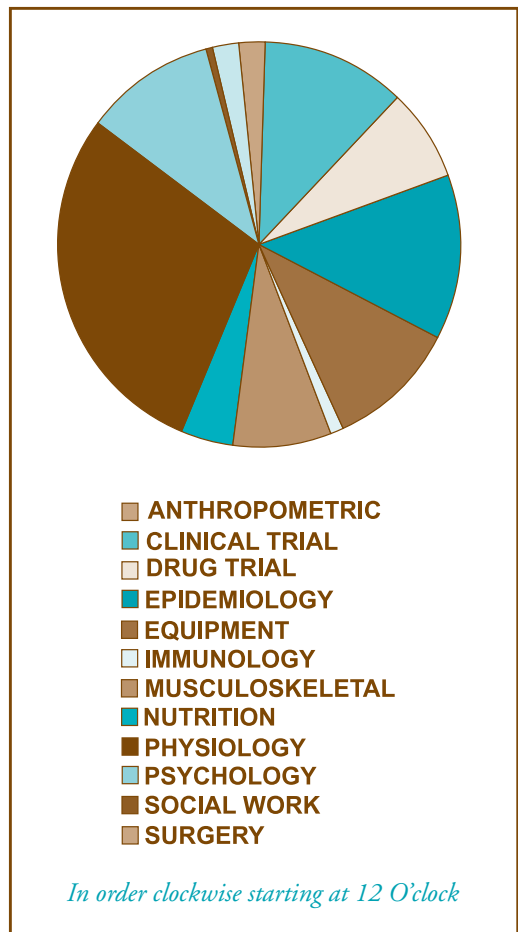


This graph displays the various organisations which have conducted research monitored by ADMEC. Individuals conducting research for their Master’s thesis or Doctoral dissertation form the largest group, followed closely by the Defence Science and Technology Organisation (DSTO) and the Army Malaria Institute.

The next largest groups are researchers affiliated with Australian university departments and the RAAF Aviation Medicine Unit at RAAF Base Edinburgh, South Australia. To date, lesser amounts of research have been conducted by a variety of organisations, including other RAAF units, pharmaceutical companies, hospitals, the Department of Veteran’s Affairs and the Defence Community Organisation.

An indication of the areas being researched in Defence is given in the graph below.

### Areas of Research in Defence



## *ADMEC'S Approach to Research Protocols*

ADMEC's primary function is to assess all submitted protocols to determine whether that research is ethical. ADMEC also evaluates the study methodology and applies the Privacy Principles to each protocol. The Committee pays particular attention to the issues of informed consent, quantification of risk, voluntary participation and that there be no detriment to the careers or medical care of volunteers if they choose to withdraw or not participate in the project. There are a number of reasons why a protocol may not be approved. ADMEC does not generally give retrospective approval. The Committee is also reluctant to allow ADF personnel to participate in the collection of safety data for new drugs (pharmaceuticals) or in drug trials where there is no clear benefit to the individual or the ADF. This was the case with one of the protocols submitted during 1999. The Committee also does not approve protocols that have an inadequate study design and would not produce scientifically valid results, or projects that are likely to have adverse outcomes to the volunteers or their military careers. Similarly, where a researcher requests access to records maintained by the ADF (eg. medical documents), ADMEC pays particular attention to the Section 95 Guidelines of the Privacy Act 1988. If ADMEC determines that the benefit of the research does not outweigh privacy considerations, then the protocol will not be approved.

## *What happens to research that is not approved by ADMEC?*

Since its establishment in 1988, 14 research protocols have been denied ethical approval by ADMEC, 13 of these prior to 1999. At the request of the Minister Assisting the Minister for Defence, ADMEC investigated the final outcome of these protocols. In particular, ADMEC sought clarification of whether the research had been abandoned, progressed and conducted in non-Defence populations, or approval sought from an alternate body. Thirteen letters were sent out in late 1999 requesting this information and also seeking feedback regarding the submission and approval process, as a quality assurance measure. The following outcomes were determined. One researcher had moved to the USA and was no longer contactable. Another researcher who submitted a protocol in 1990 could not locate any records in relation to that protocol and could not remember it. One protocol was never fully submitted as the researcher had been advised that ethical clearance was not required. Four researchers had sought retrospective approval of research that they had already conducted. As previously stated, ADMEC does not approve protocols in retrospect. Three researchers did not respond. The outcomes reported by the final 3 researchers are detailed below.

### **Protocol 68/94: WR238605, A new 8-aminoquinoline, as an alternative to primaquine in soldiers developing plasmodium vivax infections.**

This project was a proposed clinical trial of a new type of antimalarial prophylactic, WR238605 Succinate. The main existing eradicator of malaria, primaquine, requires a daily complicated regimen and has a variety of side-effects.

*Protocols*

The prophylactic WR238605 Succinate aimed to replace primaquine and perhaps provide a simpler, more effective drug to treat malaria. Safety concerns were the prime reason for ADMEC's denial of approval in this case. WR238605 Succinate had not been clinically tested on humans before, only on dogs, rabbits and monkeys. Also of some concern, the protocol did not outline a plan for the documentation and retention of the medical records of volunteers for future analysis of any long-term effects of WR238605 Succinate. Subsequently, this research project was abandoned and did not proceed.

#### **Protocol 142/98: Seasonal allergic conjunctivitis trial.**

The objective of this proposed study was to compare how effective and safe ketotifen eye drops were compared with a placebo and levocabastine, a standard treatment of seasonal allergic conjunctivitis (hay fever). An international pharmaceutical company sponsored the principal investigators. ADMEC denied ethical approval of this study on ADF personnel, again, because of safety reasons. The Committee also felt that the conduct of this project would be inappropriate in the ADF population. The project was already running nationally when ADMEC approval was sought. The project continued and ultimately recruited 750 patients from 320 general practitioners in seven different centres. Ethical clearance was sought and granted by The Royal Australian College of General Practitioners Research and Evaluation Ethics Committee. The study demonstrated that the drug was efficacious. It is expected that the investigation product will be available in Australia late 2000.

#### **Protocol 143/98: A double blind, randomised, placebo-controlled study of Ro64-0796**

The objectives of this study were to investigate the clinical efficacy, antiviral efficacy and the safety and tolerability of a new drug, Ro64-0796, in the treatment of influenza. Ethical clearance was not granted by ADMEC for three reasons. Firstly, the Committee had previously decided that approval for drug research would only be given in rare circumstances where the ADF has specific requirements for such drugs, eg. anti-malarials. Secondly, the committee felt that the research proposal was ethically flawed on the grounds of safety, in particular with respect to the lack of disclosure of risks currently known. Lastly, the Committee highlighted that it did not support ADF personnel being used to expand population numbers in the collection of safety data for clinical drug trials. The New Zealand Ministry of Health and the Royal Australian College of General Practitioners, as well as other ethics committees, subsequently approved the study for conduct in the general population.

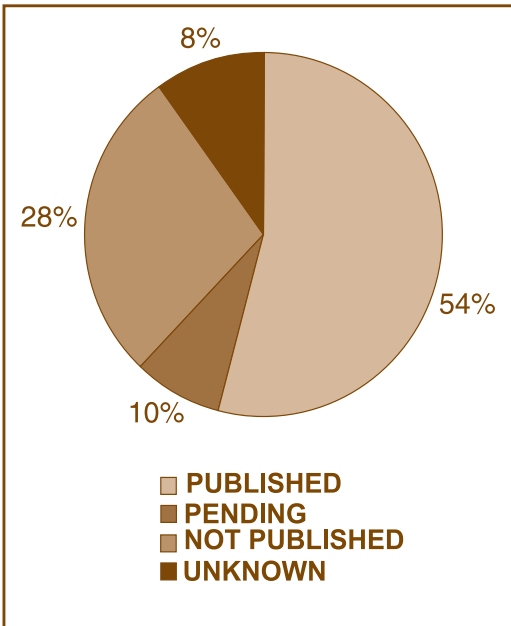
The pharmaceutical company and the sponsor have been responsible for the successful conduct of similar studies of Ro64-0796 in Europe and North America throughout 1998 and 1999. Data from these studies have now been analysed and the sponsor will submit these to various worldwide regulatory authorities to demonstrate both the safety and efficacy of Ro64-0796 in their marketing applications.

*Protocols*

### Publication of Completed Research

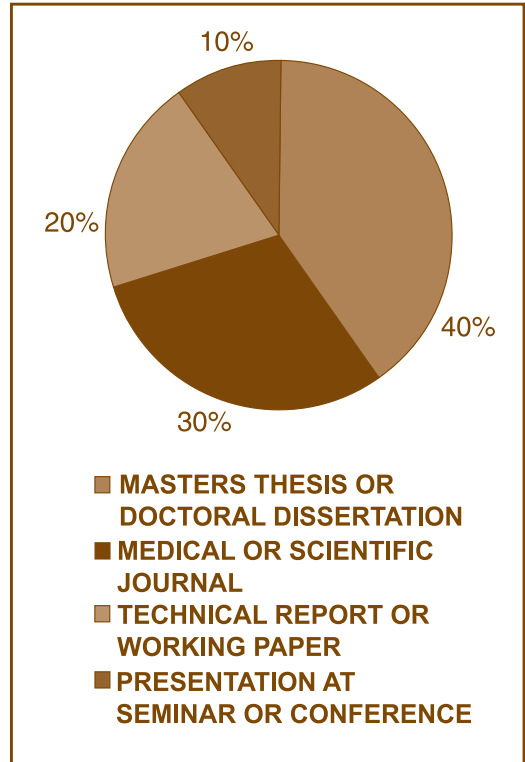
It is a condition of ADMEC approval of a project that the researchers intend to publish the results in an accessible medium except where security implications prevent this. Research can be published in a number of formats: as a Masters thesis or Doctoral dissertation, in various medical and scientific journals, in technical reports, or as part of a presentation at a seminar or conference. The graph below represents the proportions of completed research projects that have been published. Of the protocols registered with ADMEC that have been completed, 64% have been published or are in the process of being published.

### Publication Status of Completed Protocols



The next graph provides a break down of the media in which this research has been published.

### Publication Media for Completed ADMEC Protocols



Journals in which ADMEC cleared research has been published include, but are not limited to, the following:

- Australian and New Zealand Journal of Surgery
- Aviation, Space and Environmental Medicine Journal
- Journal of Applied Physiology
- Journal of Clinical Infectious Diseases
- Journal of Hand Therapy
- Journal of Medical Entomology
- Medical Journal of Australia
- Military Medicine (USA)

## New Research Protocols Received and Considered by ADMEC in 1999

Protocol number	Research Title <sup>3</sup>	Status
172/99	Recovery of aerobic capacity following acute infectious mononucleosis infection ( <i>glandular fever</i> ) in an adolescent population	In Progress
173/99	Effects of exposure to high +Gz ( <i>gravitational</i> ) forces on the gender of pilot offspring	Pending
174/99	Effect of the menstrual cycle on visual performance under hypoxic and hypobaric ( <i>reduced oxygen concentration and pressure</i> ) conditions	In Progress
175/99	Assessment of stress levels in Collins class submariners	In Progress
176/99	The impact of injury or illness, and the subsequent notification of medical discharge, on the families of soldiers in the Australian Regular Army	In Progress
177/99	Establishment of a continuing injury and illness surveillance database for recruits and staff at the Army Recruit Training Centre - Kapooka	In Progress
178/99	The application of biofeedback to enhance precision shooting	In Progress
179/99	The incidence of deep vein thrombosis following lower limb surgery	Completed
180/99	A placebo-controlled evaluation of a weekly and monthly regimen of tafenaquine for chemosuppression of Plasmodium falciparum and Plasmodium vivax malaria in Melanesian subjects	Withdrawn
181/99	Relationship between perception of life events and injuries in Australian Army recruits	In Progress
182/99	Evaluation of a salivary stress test - laboratory based exercise and environmental stress study	Pending
183/99	The chronic effects of occupational stressors on the work performance of recruit training staff at the Army Recruit Training Centre (ARTC)	In Progress
184/99	Study of the thoracolumbar movement and anthropometric measurement data collection in a population of Australian Defence Force Academy Cadets	In Progress
185/99	The efficacy of cryotherapy ( <i>the therapeutic use of cold</i> ) following arthroscopic knee surgery	In Progress
186/99	Nutrition and physiology study- Exercise Pelopor Finn: Task no. JNT 98/099	In Progress
187/99	A new method of measuring ankle range of motion	In Progress
188/99	Test and validation of an ankle volumetric measuring device and the effect of lower limb elevation, dependency and cooling on ankle volume in healthy subjects	In Progress
189/99	The naval anthropometric ( <i>body size measurement</i> ) project	In Progress
190/99	Reducing endotoxic effects as a strategy for improving heat tolerance during work in tropical heat	Pending
191/99	Nasal biopsy ( <i>sampling of nasal tissue</i> ) for research on nerve regeneration	Pending
192/99	Blister preventive intervention	Pending

Protocol number	Research Title <sup>3</sup>	Status
193/99	Countermeasure to an identified hazard for anterior cruciate ligament rupture in recruits	In Progress
194/99	Evaluation of tafenoquine for the prophylaxis of malaria for maritime operators	Pending
195/99	Evaluation of tafenoquine for the prophylaxis of malaria in non-immune Australian Soldiers	Pending
196/99	Evaluation of the Japanese Encephalitis vaccine by dual intradermal route of administration ( <i>injection into the skin</i> )	Pending
197/99	Vector borne ( <i>insect borne</i> ) disease investigation- generic	Pending
198/99	Compassionate posting stress study	In Progress
199/99	Submariner stress and fatigue- Exercise Lungfish 99	In Progress
200/99	Study in healthy adults to evaluate Q-Vax ( <i>Q fever vaccine, CSL limited</i> )	Not Approved
201/99	Nutrition, physiology and psychology data capture during Operation Warden	In Progress
202/99	Pharmacodynamics ( <i>study of actions of drugs</i> ) of doxycycline in operationally deployed ADF personnel	In Progress
203/99	Rest cycles for JIRU (Joint Incident Response Unit) personnel during routine operations in IPE (Individual Protective Ensembles)	In Progress
204/99	Study to determine the effectiveness of orthotics in the treatment of flat feet in recruits	New Protocol

<sup>3</sup> Words in italics have been added by the author for the purpose of clarification

Protocols

## *Future Activities Of ADMEC*

### **Increased meeting times**

There has been a significant increase in the amount of research undertaken in Defence using ADF personnel in recent times and many more queries about ADMEC and its activities over the last year. To accommodate increased participation in Defence research and to be more responsive to researchers, ADMEC will meet 5 times in 2000 to consider research proposals. The number of meetings may be further increased in the future, with the growth of research conducted by and for the ADF and the Australian Defence Organisation (ADO).

### **Researcher Audits**

In 2000, the Committee plans to conduct audits of researchers' files and practices. This will facilitate and improve ADMEC's monitoring of Defence research, in accordance with NHMRC guidelines.

### **National Statement on Ethical Conduct in Research Involving Humans - National Health and Medical Research Council (NHMRC)**

In 1999, the NHMRC issued a new, comprehensive document titled: "National Statement on Ethical Conduct in Research Involving Humans" (the National Statement) made in accordance with the National Health and Medical Research Council Act 1992 ('the Act').

One of the new requirements of the National Statement was the stipulation of two additional core members to be appointed to Human Research Ethics Committees (HRECs) [see 2.6(c) and 2.6(d) in the National Statement]. This new member must have knowledge of, and current experience in, the professional care, counselling or treatment of people (eg: medical practitioner, clinical psychologist, social worker, or nurse, as appropriate).

For ADMEC, this meant appointing a new committee member, Dr Alan Twomey, Head of the Psychology Research Group. Dr Twomey's Curriculum Vitae can be found on p.9.

The National Statement has combined a number of previously separately published documents and also outlines comprehensively the membership and operations of HRECs, thorough guidelines on the storage, handling and privacy of information held by HRECs, and on various components of health and medical research. For example, the statement lists guidelines for research involving clinical trials; children and young people, people with an intellectual or mental impairment, and people highly dependent on medical care.

It also provides guidelines about maintaining the privacy and confidentiality of personal information or material of research participants.

# Australian Defence Medical Ethics Committee

## Structure

POSITION	INCUMBANT
<b>Chair</b>	Major General John Pearn, AM RFD.
At least one member who is a lay man, who has no affiliation with the Department of Defence, are not currently involved in medical, scientific or legal work, and who are preferably from the community in which the organisation is located	Mr David Dillon
At least one member who is a lay woman, who has no affiliation with the Department of Defence, are not currently involved in medical scientific or legal work, and who are preferably from the community in which the organisation is located	Mrs Elizabeth Grant, AM
At least one member with knowledge of, and current experience in, the areas of research that are regularly considered by the HREC	Colonel Peter Warfe, CSC.
At least one member with knowledge of, and current experience in, the professional care, counseling or treatment of people	Dr Alan Twomey
At least one member who is a minister of religion, or a person who performs a similar role, in a community such as an Aboriginal elder	Monsignor Max Davis, AM VG
At least one member who is a lawyer	The Honourable Justice Terence Higgins

### THE ADMEC SECRETARIAT

Executive Secretary	Lieutenant Colonel Victoria Ross
Assistant Executive Secretary	Lieutenant Commander Trish Matthews
	Ms Kelly West
Minute Secretary	Major Rosemary Landy
Administrative Support	Mrs Morag Norenbergs

# *Australian Defence Medical Ethics Committee-Attendances 1999*

## **Monday 15 February - 1630 Hours**

### In Attendance

Chair: Major General J.H. Pearn, AM, RFD

### Executive

Secretary: Major V.R. Ross

Members: Colonel P.G. Warfe, CSC  
The Honourable Justice T. Higgins  
Mr D. Dillon  
Mrs E. Grant, AM  
Monsignor M. Davis, AM, VG

### Minute

Secretary: Major R. A. Landy

### Invited

guests: Air Commodore B. Short,  
RFD, Assistant Surgeon General  
- Air Force

## **Monday 23 August - 1630 Hours**

### In Attendance

Chair: Major General J. H. Pearn, AM, RFD

### Executive

Secretary: Major V.R. Ross

Members: Colonel P.G. Warfe, CSC  
The Honourable Justice T. Higgins  
Mr D. Dillon  
Mrs E. Grant, AM

### Minute

Secretary: Major R. A. Landy

### Invited

guests: Brigadier R. Atkinson, RFD,  
Assistant Surgeon General -  
Army

## **Monday 24 May - 1630 Hours**

### In Attendance

Chair: Major General J.H. Pearn, AM, RFD

### Executive

Secretary: Major V.R. Ross

Members: Colonel P.G. Warfe, CSC  
The Honourable Justice T. Higgins  
Mr D. Dillon  
Mrs E. Grant, AM  
Monsignor M. Davis, AM, VG

### Minute

Secretary: Major R.A. Landy

### Invited

Guests: Commodore P. Habersberger,  
AM, RFD, Assistant Surgeon  
General - Navy  
Mr S. Taylor, Inspector  
General's Department

## **Monday 07 December - 1630 Hours**

### In Attendance

Chair: Major General J. H. Pearn, AM, RFD

### Executive

Secretary: Major V.R. Ross

Members: Colonel P.G. Warfe, CSC  
The Honourable Justice T. Higgins  
Mr D. Dillon  
Mrs E. Grant, AM  
Monsignor M. Davis, AM, VG  
Dr A. Twomey

### Minute

Secretary: Major R.A. Landy

### Apologies:

*Attendances*

## AUSTRALIAN DEFENCE MEDICAL ETHICS COMMITTEE – EXPENSES 1999<sup>1</sup>

Meeting	February	May	August	December	TOTAL
Major General J. H. Pearn <sup>2</sup> Sitting Fee Travel	2485.85	1174	911.50	1143.50	5714.85
Mrs E. Grant Sitting Fee Travel	247	247	247	247	988
The Honourable Justice T. Higgins Sitting Fee Travel	247	247	247	247	988
Mr D. Dillon Sitting Fee Travel	247 244.25	247 244.25	247 244.25	247 244.25	988 977
Refreshments	86.40	82.50	90.50	75.00	334.40
Journal of Medical Ethics <sup>3</sup>					330.33
1998 Annual Report					2,288.00
TOTAL <sup>4</sup>	3557.50	2241.75	1987.25	2203.75	\$12, 608.58

<sup>1</sup> Uniformed members of ADMEC and the Secretariat did not incur additional costs.

<sup>2</sup> Travel to Canberra in February 1999 included performance of other duties of SGADF.

<sup>3</sup> ADMEC subscribed to the Journal of Medical Ethics at an annual rate of £132.00

<sup>4</sup> Stationery, postage and telephone costs have not been included.

### AUSTRALIAN DEFENCE MEDICAL ETHICS COMMITTEE—CONTACT DETAILS

As a part of the continuing refurbishment of Campbell Park Offices, the ADMEC Secretariat, as part of the Defence Health Service Branch, has relocated. New contact details for ADMEC are as follows:

**Executive Secretary**  
**Australian Defence Medical Ethics Committee**  
**CP2 - 7 - 66**  
**Department of Defence**  
**CANBERRA ACT 2600**  
**Ph: 02 62663925**  
**Fax: 02 62664982**  
**E-mail: hlthpol@bigfoot.com**

### More Information

More information regarding ADMEC can be found in the following documents, which are accessible through the Defence Manager's Toolbox:

- DI(G)ADMIN 24-3 Function, Structure and Procedures for Obtaining Clearance for Research from ADMEC
- HPD 205 Australian Defence Medical Ethics Committee

Or, visit our web site at

<http://www.bigfoot.com/~dhsb>

The Defence Health Service Branch is currently developing its site on the Defence intranet. This site can be accessed at <http://defweb.cbr.defence.gov.au/dpedhsb>, where there are links to ADMEC.