



Australian Government

Department of Defence

Department of Veterans' Affairs

# DEPARTMENTS OF DEFENCE AND VETERANS' AFFAIRS

## **Human Research Ethics Committee**

**Report to the Vice Chief of the Defence Force and to the Deputy  
President, Department of Veterans' Affairs**

**REPORT 1 JANUARY – 31 DECEMBER 2020**

## 1. EXECUTIVE SUMMARY

1. The Departments of Defence and Veterans' Affairs Human Research Ethics Committee (DDVA HREC) met 10 times between 1 January 2020 and 31 December 2020.
2. One member chose not to seek reappointment to the Committee following the expiration of tenure on 30 June 2020.
3. During the reporting period, 137 new proposals were submitted for ethical review by the Committee. Additionally, the Committee received 78 resubmissions, 162 requests for amendment, and 80 requests for extensions to the period of ethical approval.
4. There were 97 adverse events reported, of which 94 were associated with one clinical trial study. The incident rate for adverse events in clinical trials is generally higher than in other fields of research and it is not uncommon to receive a larger number of adverse event notifications. Further information is available at paragraph 36.

## 2. BACKGROUND

5. The DDVA HREC was established as the institutional human research ethics Committee for the Department of Defence (Defence) and the Department of Veterans' Affairs (DVA) on 1 July 2017. The DDVA HREC is registered with the National Health and Medical Research Council (EC00460) and as an Institutional Review Board with the United States Office for Human Research Protections (00009098).
6. The DDVA HREC provides annual reports (based on a calendar year) to the Vice Chief of the Defence Force and the Deputy President, DVA in accordance with the [DDVA HREC Terms of Reference](#)<sup>1</sup>. The fourth annual report provides a summary of DDVA HREC's activities from 1 January 2020 to 31 December 2020.

## 3. MEETINGS AND EXECUTIVE SUPPORT

7. The Committee met 10 times between February and November with a planned 8 meetings initially scheduled to occur during the reporting period. One additional meeting was convened in April due to a high priority time-sensitive study, and a second additional meeting was convened due to a high workload in November. Attendance by the minimum categories of membership, as outlined in National Statement paragraph 5.1.30, was obtained for all meetings.
8. In addition to considering proposals at scheduled meetings, members provided out-of-session feedback on a number of occasions during the reporting period.
9. Secretariat support for the day-to-day functioning of the Committee was provided by the Directorate Strategic Clinical Assurance and Ethics.

## 4. MEMBERSHIP

10. Committee membership for the reporting period is provided at Table 1.

---

<sup>1</sup> DDVA HREC Terms of Reference  
[http://www.defence.gov.au/health/hrec/docs/171205\\_DDVA\\_HREC\\_Terms-of-Reference.pdf](http://www.defence.gov.au/health/hrec/docs/171205_DDVA_HREC_Terms-of-Reference.pdf)

**Table 1: Committee membership**

<b>Name</b>	<b>Category</b>
Mr Ian Tindall	Chair
Mr Tony Cotton AM	Deputy Chair
Mr Lindsay Roe	Layperson
Dr David Ugalde	Layperson
Ms Margaret Proctor	Layperson
Ms Vivienne Moyle	Layperson
Dr Carl Bryant	Professional Care/Counselling
Mr Stephen Brimstone	Professional Care/Counselling
CHAP Robert Sutherland	Pastoral Care
REV Dr Nikki Coleman	Pastoral Care
Dr Wendy Bonython	Lawyer
Ms Sara Wedgwood	Lawyer
Ms Amelia Digance	Lawyer
Dr Bert Biggs	Researcher
Dr Jane Harte	Researcher
Dr Renee Otmar	Researcher
Dr Vicki Ross	Defence Health Graduate
CAPT Nicole Curtis	Defence Health Graduate (till 30 June 2020)
Dr Chris Wilson	Contemporary Veteran

## 5. TRAINING

11. In accordance with the 'National Statement on Ethical Conduct in Human Research' (National Statement), paragraph 5.2.3(c), members are required to attend continuing education or training in research ethics at least every three years. Due to the COVID-19 pandemic, limited training was undertaken by members as various workshops and training opportunities were cancelled. Training was limited to on the job specific training via discussion of relevant matters at scheduled and sharing of relevant articles of interest.

## 6. REVIEW OF RESEARCH PROJECTS

### Consideration of new applications

12. During the reporting period, 137 new applications (114 new research proposals and 23 requests for off-label use of drugs or devices) were considered by the DDVA HREC.

13. Fifty new research applications were reviewed by the full Committee and 64 were reviewed out-of-session under non-HREC pathways. Three of the applications that were reviewed under non-HREC review pathways were deemed to be greater than low risk and were referred to the full Committee for review as resubmissions.

14. The 23 applications for the use of unregistered or off-label drugs or devices were submitted as a package and considered by the DDVA HREC at the meeting held on 30 November 2020. The Committee requested that the applicants provide additional information and at the end of the reporting period, this had not yet been provided and the application was deemed to be new applications.

15. The outcome of the assessment of risk of the 50 new research proposals considered by the full HREC, 29 were deemed to be greater than low risk, 10 were exempt from non-HREC review pathways, six were deemed to be quality assurance/evaluation activities and five were deemed to be low risk.

16. Sixty-four new applications were reviewed under non-HREC review pathways in accordance with the DDVA HREC Researcher and Administrative Guidelines paragraph 2.59. Eleven applications considered under processes for minimising duplication of ethical review (mutual recognition pathways). One application that was reviewed under the mutual recognition pathways was escalated to out-of-session review by the full HREC and subsequently deemed not to be research. The other application that was not approved under mutual recognition had already commenced and retrospective approval was unable to be granted.

17. The outcome of the remaining 53 applications that were reviewed under non-HREC review pathways, six were deemed to be research, one was withdrawn prior to ethical approval being granted, 27 were deemed to be quality assurance/evaluation activities, two were deemed to be negligible risk, 14 were deemed to be low risk and three were referred to the full HREC as they were deemed to be greater than low risk.

18. The Committee also considered 23 applications for the use of unregistered or off-label usage of medicines or devices.

19. Table 2 provides a summary of the new applications considered by the DDVA HREC during the reporting period:

**Table 2: Summary of new applications**

	Number
Greater than low risk	29
Exempt from non-HREC review	10
Low risk	19
Negligible risk	2
Quality assurance/evaluation	33
Not human research	6
Mutual recognition	11
Off label-usage of drugs and devices	23
<b>Total</b>	<b>133</b>

20. At the end of the reporting period, 17 new research applications and the applications for the use of unregistered or off-label medicines or devices were still under review.

21. A list of the approved projects is at Annex A.

## Resubmissions

22. At the beginning of the calendar year there were 13 applications from the previous reporting period that required further clarification/amendment prior to ethical approval being granted. Four of these were withdrawn and the other nine were approved.

23. There were 80 resubmissions during the reporting period. Of these, 16 were considered at a scheduled meeting and 64 were considered out-of-session.

## Waivers of consent

24. The DDVA HREC occasionally receives requests for waivers of the requirement for individual participants consent to participate in research. These requests are considered in accordance with the National Statement, the [Privacy Act 1988](#)<sup>2</sup> and other relevant guidance and/or legislation.

25. Waivers of consent are reported at research completion in accordance with the National Statement paragraph 2.3.12. There were no studies completed during the reporting period that included data obtained under a waiver of consent.

## 7. MONITORING OF APPROVED RESEARCH

26. In accordance with the National Statement Chapter 5.5, Defence and DVA have a responsibility for ensuring that research approved by their institutional ethical review body (DDVA HREC) is monitored in a manner that reflects the degree of risk to research participants. With effect 1 January 2020, the DDVA HREC was responsible for the ongoing monitoring of 198 active protocols.

27. At the end of the reporting period, 208 approved research projects were being monitored by the DDVA HREC.

### Amendments to approved projects

28. Prior to the implementation of any amendments to an approved study, Principal Investigators are to seek ethical approval of the amendment from the DDVA HREC. Amendments are initially considered out-of-session and are referred to the full HREC where required in accordance with National Statement paragraph 5.1.6.

29. During the reporting period 162 amendments were considered out-of-session and an additional amendment required full HREC review due to the nature of the amendment.

### Extensions to the period of ethical approval

30. Ethical approval is granted for the duration of the project, as indicated in the approved research proposal, or for a period of up to three years. Where the research is to extend beyond the period of ethical approval, the Principal Investigator is required to seek an extension to the period of ethical approval.

31. During the reporting period, the DDVA HREC considered 80 requests for extensions to the period of ethical approval. This is a significant increase from 2019.

### Deviations

32. During the reporting period a total of 11 deviations from approved study protocols were reported.

33. During the reporting period the DDVA HREC received notification that a study had proceeded without ethical approval. This matter was referred to Head of People Capability for investigation as a research governance matter.

---

<sup>2</sup> [Privacy Act 1988](http://www.austlii.edu.au/au/legis/cth/consol_act/pa1988108/) http://www.austlii.edu.au/au/legis/cth/consol\_act/pa1988108/

34. Ten deviation reports were received for a clinical trial. The deviations related to the following:

- a. missing test samples
- b. changes in the availability of a total of six participants (alternative collection times were arranged where possible)
- c. a participant with suspected SARS-CoV-2 infection was tested, however the saliva test was taken outside of the window period
- d. transporting issues for samples
- e. minimal medical examination of participants due to mild symptoms.

35. The Deputy Chair reviewed and noted the deviation reports and no further action, information or increased monitoring was required.

### **Adverse Events**

36. Researchers are required to report serious adverse events to the DDVA HREC within 72 hours and adverse events within 30 calendar days. During the reporting period, the DDVA HREC received notification of 97 adverse events.

37. Ninety-four adverse events related to 26 of the 44 participants taking part in a clinical trial of preventive medicine. The closure report of December 2020 stated that all adverse events were determined to be non-clinically significant and were reported to be resolved at the close of the study. As outlined in paragraph 4, incident rate for adverse events in clinical trials is generally higher than in other fields of research and it is not uncommon to receive a larger number of adverse event notifications. Table 3 summarises the relationship of reported adverse events to the investigational medicinal product and to the illness.

**Table 3: Summary of adverse events reported for participants in the clinical trial**

<b>Relationship to medicinal product being trialled</b>		<b>Relationship to illness being treated by the medicinal product</b>	
Not related	43	Not related	13
Unlikely related	40	Unlikely related	73
Possibly related	9	Possibly related	8
Related	2	Related	0

38. One adverse event related to a study of physical performance in hot conditions. One participant who had recently been unwell had a coughing fit and vomited partway through the heat test. The test was stopped and the participant quickly recovered.

39. Two adverse events related to a longitudinal civilian public health study. The adverse event concerned two participants who received forms regarding the study with other people's details on them. The incidents did not relate to study data and was an error in manual handling processes. Processes to ensure similar errors are not made in the future were implemented by the research team.

40. During the reporting period the DDVA HREC did not receive notification of any serious adverse events.

### **Desktop Audits**

41. During the reporting period, the Secretariat conducted desktop audits of 27 research proposals. Three audits raised no concerns and the remaining 24 identified discrepancies, missing documentation, missing governance approvals and delays in provision of progress reports. The Secretariat requested that the Principal Investigator provide clarity on or submit missing documentation.

42. The audits also identified a study that was approved by the DDVA HREC that should have been referred to the Defence People Research Low Risk Ethics Panel.

### **Progress & Final Reports**

43. As a condition of approval, and in accordance with National Statement paragraph 5.5.5, researchers are required to submit reports at least annually to the relevant ethical review body/ies. The Secretariat provides a compliance register to DDVA HREC as a standing agenda item at each meeting. The report includes an update on reports received, those that are outstanding and those that are due in the near future.

44. In accordance with the National Statement paragraph 5.5.5, researchers are required to submit a final report at the completion of their research. During the reporting period, the Committee received 51 final reports. A list of the completed research is at Annex B.

### **Complaints**

45. No complaints were submitted to the DDVA HREC during the reporting period.

## 8. COMPARISON

46. Table 3 provides an overview of the DDVA HREC activities for the reporting period in comparison to the 2018 and 2019 calendar years.

**Table 3: Comparison of activities between 2018, 2019 and 2020 calendar years**

	2018	2019	2020
New Applications	77	91	137
Human research proposals	77	91	114
Applications for the use of unregistered or off label therapeutic goods	0	0	23
Resubmissions	85	57	78
Amendments	103	135	162
Extensions to the period of ethical approval	35	36	80
Adverse Events	3	5	97 <sup>3</sup>
Serious Adverse Events	1	1	0
Complaints	0	1	0
Deviations	0	1	11
Applications monitoring at end of year	164	198	208
Number of DDVA HREC Committee meetings	11	8	10

47. The new submissions, amendments and extensions of ethical approval are increasing significantly. Due to the number of protocols extended rather than completed, the number of studies requiring monitoring continues to grow.

## 9. CONCLUSION

48. The workload of the DDVA HREC continues to increase as the Committee matures. There has been a significant increase in the number of new applications received and in turn the number of resubmissions required. There has also been a significant increase in the number of amendments and requests for extensions to the period of ethical approval.

49. The large number of adverse events are related to the conduct of a clinical trial and it is not uncommon to receive a larger number of reports of this nature for this field of research.

50. The Chair and Secretariat will continue to monitor the number of applications being received for review under non-HREC review pathways to determine if this is an ongoing trend or more temporary in nature. If the trend proves to be ongoing, further discussions will be had with institutional delegates about possible alternative review pathways for quality assurance/evaluation activities and low or negligible risk activities.

---

<sup>3</sup> The incident rate for adverse events in clinical trials is generally higher than in other fields of research and it is not uncommon to receive a larger number of adverse event notifications



## ANNEX A – APPROVED PROTOCOLS

Protocol number and title	Principal Investigator and Institution	Aim
117-19 How the Australian Army can get ahead of the curve on humanitarian civil-military coordination	<b>Ms Beth Eggleston</b> Humanitarian Advisory Group	This research aims to understand how aid agencies and the Australian Army can better protect civilians and deliver humanitarian relief during disasters.
157-19 Surveillance and characterisation of infectious pathogens affecting Defence personnel	<b>CAPT Christopher Moller</b> Australian Defence Force Malaria & Infectious Disease Institute	This study aims to: <ul style="list-style-type: none"> <li>a. determine the epidemiological patterns of disease and transmission of infectious disease pathogens that affect Defence personnel</li> <li>b. phenotypically and genotypically characterise infectious disease pathogens responsible for causing illness in Defence personnel.</li> </ul>
173-19 Biomarkers of physical and psychological performance	<b>Prof Mark Hutchinson</b> University of Adelaide	This research aims to identify biomarkers of physical and psychological performance from blood measurements.
174-19 A multi-systems approach to demand and resilience resource profiles within the at-sea deployment setting	<b>Dr Monique Crane</b> Macquarie University	The project aims to: <ul style="list-style-type: none"> <li>a. develop a tool specifically designed for Navy personnel to measure demands and resources in the at sea deployment setting,</li> <li>b. explore the role of personal resilience in job and cognitive performance when experiencing cumulative stressors and adverse conditions.</li> </ul>
175-19 Fatigue: A Human Factors investigation into military aviation maintenance management to Maximise Safety and Increase Productivity	<b>David Mahoney</b> Griffith University	The aim of this study is to identify new management strategies and maximise workplace safety and productivity, in turn, raising morale.
179-19 Performance Characteristics Associated with Expertise in Close Quarter Battle	<b>Prof G. Gregory Haff</b> Edith Cowan University	The aim of this study is to provide a cross-sectional analysis of the physical performance characteristics of special forces operators in order to relate them to performance on a simulated close quarter battle task and nine performance tests.

<b>Protocol number and title</b>	<b>Principal Investigator and Institution</b>	<b>Aim</b>
180-19 Australian Human Rights Commission and Defence Collaboration Royal Australian Navy Clearance Diver Project	<b>Natasha de Silva</b> Australian Human Rights Commission	The aim of this project is to support the Clearance Diver community to define their community, its strengths and priorities, and explore opportunities to fortify and strengthen the Clearance Diver Branch for the future.
184-19 Understanding how occupations completed as part of everyday life influence health and adjustment during the transition from military service	<b>Dr Brett Gordon</b> La Trobe University	The aim of this study is to explore former service members' experiences of participating in occupations during their transition from military service and how they influence health and adjustment.
185-19 Design & Innovation Research Engagement: Understanding the role of design in the ADF	<b>Dr Cara Wrigley</b> University of Sydney	The research in this study aims to explore the ways in which design thinking, design innovation and human centred design is applied, adopted and experienced in the Royal Australian Air Force (RAAF) and the broader Australian Defence Force (ADF). It aims to investigate the ways in which design thinking, design innovation and human centred design might strategically and tactically assist the ADF.
195-20 The Lost Soldier	<b>Dr Nicola Burton</b> Griffith University	The aim of this study is to conduct an on-line survey study to explore military identity, psychological flexibility and psycho-social functioning in a group of ex-serving military personnel.
199-20 Military Veteran entrepreneurs' transitions	<b>Dr Saskia de Klerk</b> University of the Sunshine Coast	This research aims to outline the strategies that successful veteran entrepreneurs use to start their own business, identify the kinds of support that the individual veteran entrepreneurs accessed and utilised, and identify current support programs and offerings
203-20 How can families improve help-seeking for veterans and emergency services first	<b>Prof Sharon Lawn</b> Flinders University	This study aims to understand the role of families in supporting early help-seeking among veterans and first responders with emerging mental health issues, and to better understand how families can be supported to recognise signs of mental health issues and how to respond examine how family

Protocol number and title	Principal Investigator and Institution	Aim
responders with current or emerging mental health needs?		members can be included in the way organisations respond to mental health concerns, and what resources, programs and training family members may benefit from in this important role.
204-20 Surveillance of Vector Borne and Environmentally-acquired pathogens infecting Defence Force members in Australia and overseas	<b>CAPT Jennifer Kookan</b> Australian Defence Force Malaria & Infectious Disease Institute	This study aims to establish a disease surveillance program to detect and monitor exposure to and presence of vector borne and environmentally-acquired pathogens in Defence personnel travelling within Australia and overseas.
205-20 Energy demands of Australian Special Forces personnel	<b>Prof David Bishop</b> Victoria University	This study aims to evaluate the daily energy needs, and macronutrient intake and timing of Australian Special Forces personnel during an intense period of training
208-20 Hope in Hobbies: Exploring the Views and Perceptions of Australian Veterans with Posttraumatic Stress Disorder on the use of Model Kit Building to Improve Their Quality of Life	<b>Dr John Oldroyd</b> Australian Catholic University	This study aims to: <ul style="list-style-type: none"> <li>a. identify key characteristics of model kit building that contribute to the improvement of veteran's quality of life</li> <li>b. add to the growing body of knowledge surrounding the various factors that contribute to the improved health and welfare of Australian veterans.</li> </ul>
209-20 International Dataset Collective	<b>Dr Andrea Phelps</b> Phoenix Australia	This study aims to examine similarities, differences, and complexities of prevalence rates, comorbidities, and risk factors related to the mental health and well-being of veterans in a much more nuanced manner.
210-20 Kinematic analysis of soldier fatigue	<b>Dr Gregory Peoples</b> University of Wollongong	This study aims to determine the key physical/physiological markers that respond or modify according to neuromuscular fatigue related to physical training and compare the fatigue and strength based outcomes.

<b>Protocol number and title</b>	<b>Principal Investigator and Institution</b>	<b>Aim</b>
212-20 The effect of high and low perceived anxiety and prior combat experience on marksmanship behaviours of combat soldiers	<b>Assoc Prof Tim Doyle</b> Macquarie University	This research aims to validate the current training approach for combat shooting transfer under high perceived pressure and operationally relevant environments.
223-20 Gut Microbiome and Warfighter Performance	<b>Dr Matthew Cooke</b> Swinburne University of Technology	This research aims to: <ul style="list-style-type: none"> <li>a. identify the impact of military-relevant stressors on the War fighter gut microbiota and its link to cognitive performance and readiness</li> <li>b. develop a predictive tool to identify War fighters at greater risk from stress-induced gut symbiosis and associated changes in cognitive performance and mental well-being.</li> </ul>
224-20 The employment outcome of musculoskeletal surgery in ADF trainees	<b>Dr Darrell Duncan</b> Joint Health Command	This research aims to determine whether ADF trainees who undergo musculoskeletal surgery complete their initial employment training.
228-20 Cognitive training with Brain Stimulation	<b>Prof Paul E. Dux</b> University of Queensland	This research aims to assess the benefits of combined cognitive training and transcranial direct current stimulation in an Army setting, allowing for both individual and group level analyses of the efficacy of stimulation to augment performance in military personnel.
229-20 Examining suicide crises among Defence related persons	<b>Assoc Prof Ed Heffernan</b> Queensland Centre for Mental Health Research	The aim of this research is to better understand and meet the needs of current serving and ex-serving members of the ADF who come into contact with police or paramedics as a result of a suicidal crisis.
232-20 Surf therapy for current and ex-serving veterans	<b>Dr Arianne Reis</b> University of Western Sydney	The research aims to assess the impact of a tailored surf therapy program for veterans on mental health and wellbeing indicators.

Protocol number and title	Principal Investigator and Institution	Aim
238-20 Deliberately Differentiated Package Program – APS Communication Engineers	<b>Matthew Stanton</b> Directorate of People Intelligence & Research	This study aims to explore factors underlying workforce sustainability challenges affecting APS Communication Engineers.
241-20 Multi-Site, Randomized, Open-Label, Parallel-Group, Placebo-Controlled Study to Assess the Chemoprophylactic Efficacy of Chloroquine Against SARS-CoV-2 in Healthcare Workers at High-Risk of Exposure	<b>CAPT Christopher Moller</b> Australian Defence Force Malaria & Infectious Disease Institute	This study aims to investigate the antimalarial drug chloroquine’s ability to reduce symptom duration and severity of SARS-CoV-2 infection.
242-20 Army Logistic Training Centre COVID-19 Workplace Analysis Survey	<b>COL Matt Patching</b> Army Logistic Training Centre	This study aims to understand the capacity and constraints of the workforce and identify opportunities to further support arrangements for personnel during the COVID-19 pandemic.
245-20 Evaluation of rapid tests for COVID-19	<b>Dr Ania Gubala</b> Defence Science & Technology Group	The purpose of this study is to perform further testing of samples collected from ADF personnel for SARS-CoV-2 diagnostics, in order to evaluate alternate rapid detection technologies and provide advice to the ADF on their performance. This will include tests that are more easily accessible locally in Australia to help reduce the ADF’s reliance on the public health system and on international reagents.
246-20 Trajectories of resilience in the Royal Military College	<b>Dr Monique Crane</b> Macquarie University	The aim is to collate the data from three past trials of resilience training at the Royal Military College in order to: <ul style="list-style-type: none"> <li>a. describe different mental health trajectories of Cadets over time and</li> <li>b. understand the relationships between symptom and resource clusters using network modelling techniques.</li> </ul>

Protocol number and title	Principal Investigator and Institution	Aim
247-20 Use of Swiss 8 in Contemporary ex-serving ADF members	<b>Assoc Prof Carole James</b> University of Newcastle	<p>The aim of this study is to:</p> <ol style="list-style-type: none"> <li>a. evaluate the effectiveness of the Swiss 8 app in reducing the self-reported symptoms of psychological distress and improving the quality of life in contemporary ex-serving ADF members over a period of 3 months.</li> <li>b. evaluate whether any differences exist in the self-report mental health outcomes between two groups a) People who use the Swiss 8 app (Swiss 8) b) People who receive fortnightly peer support phone calls whilst using the Swiss 8 app (Swiss 8 +)</li> <li>c. evaluate the differences in the amount of usage of the Swiss 8 app between Swiss 8 and Swiss 8 +</li> <li>d. evaluate the relationship between the amount of usage of the Swiss 8 app and the self-report mental health outcomes</li> <li>e. explore user perceptions and satisfaction with the Swiss 8 app over a 3-month period, accounting for demographic and service-related factors.</li> </ol>
248-20 Prevalence of Postnatal Depression in Partners of Australian Defence Force Personnel	<b>Mrs Kymberly Lillis</b> Central Queensland University	<p>This aim of this research is to:</p> <ol style="list-style-type: none"> <li>a. determine the prevalence of postnatal depression in partners of ADF personnel</li> <li>b. compare the prevalence rate of postnatal depression to other women in Australia</li> <li>c. examine potential contributors to the development of postnatal depression in partners of ADF personnel.</li> </ol>
251-20 A digital diagnostics paradigm for PTSD	<b>Prof Meaghan O'Donnell</b> University of Melbourne	<p>This study primarily aims to develop and evaluate an evidence-informed digital diagnostic paradigm that uses machine learning and a range of data types to diagnose posttraumatic stress disorder (PTSD). Secondly, it aims to replicate previously identified between-group differences in physiological responsiveness using a novel data acquisition paradigm.</p>

Protocol number and title	Principal Investigator and Institution	Aim
253-20 Profiling injuries suffered by female soldiers of the Australian Army	<b>Assistant Prof Ben Schram</b> Bond University	The aims of this research is to profile the injuries suffered by female soldiers and compare them to the injuries suffered by their male colleagues.
260-20 Psychotropic polypharmacy in PTSD	<b>Dr Rebecca Mellor</b> Gallipoli Medical Research Foundation	The aim of this study is to: <ul style="list-style-type: none"> <li>a. investigate the extent of psychotropic polypharmacy in patients with PTSD upon admission to an Australian in-patient mental health treatment facility</li> <li>b. identify potential risks associated with polypharmacy including possible drug-drug or drug-disease interactions.</li> </ul>
263-20 Trans diagnostic Intervention for Remote Ex-military and first-responders	<b>Dr Winnie Lau</b> Phoenix Australia	The aim of this randomised controlled trial is to test the feasibility, acceptability and efficacy of a novel, sleep intervention delivered via telehealth to veterans and first responders (e.g. paramedics, fire-fighters, police) with sleep disorders and disturbances.
265-20 The transition from the Australian Defence Force into civilian status	<b>Assoc Prof Samantha Ashby</b> University of Newcastle	The aim of this study is to examine the experience of transitioning from the ADF into a veteran status and civilian life.
267-20 Sensor Monitoring of Gait	<b>Dr James Lee</b> Charles Darwin University	The aim of this project will be to assess inertial sensors ability to identify changes in gait biomechanics in Australian Army soldier during tactical movement.
268-20 Intervention for Post-Military Transition	<b>Dr Nicola Burton</b> Griffith University	The aim of this study is to investigate whether a novel group Schema Therapy intervention improves psycho-social functioning in a group of transitioned military personnel.

Protocol number and title	Principal Investigator and Institution	Aim
270-20 Baseline study of current and future availability of Ex-Service Organisation Advocacy services	<b>Prof Ilan Katz</b> University of New South Wales	This research aims to develop a baseline profile of the size, composition, capacity and needs to the current workforce of advocates working for Ex-Service Organisations and to examine what is required to better support both the veteran community and advocates now and in the future to make advocacy more sustainable.
271-20 Evaluation of a culturally informed, transdiagnostic, skills-based Group Emotional And Relationship Skills (GEARS) intervention for military, veteran and first responders with mental health injuries	<b>Dr Jonathan Lane</b> University of Tasmania	This research aims to evaluate a 12-week skills-based program for emotional regulation and resilient functioning for military, veteran and first responder personnel.
272-20 Transition to University and beyond: Evaluation of a university Veterans' Engagement and Education Program	<b>Dr Dannielle Post</b> University of South Australia	This research aims to: <ul style="list-style-type: none"> <li>a. understand the Veteran community, ADF members, first responders (including police, paramedics and fire fighters) and their families experiences of the Veterans' Engagement and Education Program (VEEP) at University of South Australia (UniSA).</li> <li>b. investigate the physical and mental wellbeing of the Veteran community, ADF members, first responders (including police, paramedics and fire fighters) and their families registered with UniSA's Veterans Engagement and Education Program.</li> <li>c. understand the effectiveness of the VEEP in meeting the preferences, needs and support for transition of the Veteran community, ADF members, first responders (including police, paramedics and fire fighters) and their families studying at UniSA.</li> </ul>



Protocol number and title	Principal Investigator and Institution	Aim
273-20 Moral Injury Outcome Scale Reliability	<b>Prof David Forbes</b> Phoenix Australia	The study aims to test the reliability and validity of a recently developed Moral Injury Outcome Scale.
277-20 The Wellness Action Through Checking Health Project	<b>Dr Lisa Dell</b> Phoenix Australia	The aim of this project is to inform how Defence clinicians identify and manage members presenting with subthreshold symptoms in primary care.
279-20 The development of a musculoskeletal injury surveillance framework for the recording and reporting of injuries in military special operation forces	<b>Dr Lauren Fortington</b> Edith Cowan University	This research aims to explore the methods to record and report key items of injury surveillance in a SOF context and to develop recommendations on a framework to improve injury surveillance.
281-20 Military Training Load Model Development	<b>Assoc Prof Timothy Doyle</b> Macquarie University	This research aims to: <ul style="list-style-type: none"> <li>a. undertake field testing of Australian soldiers conducting combat-related activities to quantify the physiological and biomechanical load of soldiering</li> <li>b. develop a machine-learning based tool to visualise data and identify at-risk personnel.</li> </ul>
289-20 Contextual Information processing and combat training	<b>Assoc Prof Tim Doyle</b> Macquarie University	This research aims to determine potential relationships between individual accuracy in identifying contextually relevant information and subsequent performance on a combat training course.

Protocol number and title	Principal Investigator and Institution	Aim
297-20 The Incidence and Characteristics of Aural Barotrauma in ADF Divers Participating in the Scuba Air Divers Course	<b>Assoc Prof Dale Edwards</b> University of Tasmania	This research aims to determine the incidence of aural barotrauma and impact on training experienced by ADF personnel undertaking the Scuba Air Divers course.
298-20 Secondary preventive cardiovascular medicine use following revascularisation	<b>Prof Sallie-Anne Pearson</b> University of New South Wales	This research aims to: <ul style="list-style-type: none"> <li>a. identify the number of patients who are dispensed appropriate secondary preventive medicines following revascularisation with a coronary artery bypass graft or percutaneous coronary intervention</li> <li>b. identify patient and hospital-level predictors of post-discharge dispensing of secondary preventive medicines following revascularisation</li> <li>c. estimate adherence to secondary preventive medicines following revascularisation and long term</li> <li>d. identify patient and hospital-level predictors of adherence to secondary preventive medicines</li> <li>e. estimate the effect of adherence to secondary preventive medicines following revascularisation.</li> </ul>
306-20 Window into wellbeing: Investigating factors which influence the well-being of Australian Defence Force partners	<b>Dr Alex Russell</b> Central Queensland University	The study aims to examine which risk and protective factors unique to military life (such as deployment and relocation) are associated with subjective wellbeing.

## ANNEX B – COMPLETED RESEARCH

Protocol number and title	Institution
190-19 Equipment trial: confidence check for the work of breathing of the oxygen hose used by C-17 loadmasters conducting high altitude parachute operations	<b>Dr Adrian Smith</b> Royal Australian Air Force Institute of Aviation Medicine
16-005 Maintenance of mosquito colonies using human blood fed through an artificial membrane	<b>CAPT Christopher Peatey</b> Australian Defence Force Malaria and Infectious Disease Institute
E016/003 Assessment of sleep duration and quality by actigraphy in a subset from the cohort in the Vietnam veteran PTSD-01 Study	<b>Dr Robyn O’Sullivan</b> Greenslopes Private Hospital
E016/006 A pilot study investigating the psychological outcomes of the online Post War: Survive to Thrive Program for currently serving and ex-military personnel	<b>Dr Madeline Romaniuk</b> Ramsay Health
E016/010 Detailed Polysomnography in Vietnam veterans with and without post-traumatic stress disorder	<b>Dr Robyn O’Sullivan</b> Greenslopes Private Hospital
746-14 Defence Relationship Health - deployment impact experience. A prospective study of the impact of deployment on the intimate relationships of Australian Army personnel	<b>Mrs Kerri-Ann Welch</b> Queensland University of Technology

<b>Protocol number and title</b>	<b>Institution</b>
840-16 A Phase IB experimental study to assess the in vivo Safety and response to Chloroquine of Plasmodium Vivax isolate HMPBS02-Pv in healthy participants with induced blood stage malaria infection	<b>Prof James McCarthy</b> Australian Defence Force Malaria and Infectious Disease Institute
733-13 Reducing the Costs to the ADF of Musculoskeletal Injury in Recruit Training: A Retrospective Injury Audit and Prospective Investigation of Preventative Musculoskeletal Pre-Conditioning	<b>Assoc Prof Belinda Beck</b> Griffith University
800-15 Four Oceans	<b>Mr Sean Andrews</b> University of New South Wales
812-15 The Dawn Horizon: Constructing an Air Force Identity at The Australian Defence Force Academy	<b>GPCAPT Jarrod Pendlebury</b> University of Sydney
838-16 Social Media as a Force Multiplier: A Study of Military Best	<b>Assoc Prof Kevin Foster</b> Monash University
16-021 Testing of serum samples from ADF personnel affected by the Ross River virus outbreaks at Shoalwater Bay Qld in March 2016 and May/June 2017	<b>Dr Aneta Gubala</b> Defence Science Technology Group, Australian Defence Force Malaria and Infectious Disease Institute
E016/026 Understanding why obstructive sleep apnoea is so common in people suffering from PTSD	<b>Prof Sean Drummond</b> Monash University

<b>Protocol number and title</b>	<b>Institution</b>
17-013 Development of a biomechanical model of the cervical spine muscle-tendon loads for aircrew wearing helmets with night vision equipment	<b>Dr Phil Newman</b> University of Canberra
015-17 Examining the role of systematic reflection on enhancing resilience	<b>Dr Monique Crane</b> Macquarie University
054-18 Development of social marketing communications to prevent/reduce risky supplement use in the Australian Army	<b>Prof Sharyn Rundle-Thiele</b> Griffith University
071-18 Exploring cognitive processes in treatment seeking veterans - The ECOG study	<b>Dr Mark Hinton</b> University of Melbourne - Phoenix Australia
152-19 Veteran access to healthcare	<b>Dr Jenny Setchell</b> Vanguard Health
18-005 Quantifying neck muscle workload in fast jet pilots	<b>Dr Philip Newman</b> University of Canberra
833-16 & E017/002 The experience of male sexual assault survivors within the Australian Defence Forces (ADF)	<b>Prof Patrick O'Leary</b> Griffith University; University of NSW
E016/004 From soldier to civilian: A qualitative analysis of cultural reintegration and psychological adjustment to civilian life following military service	<b>Dr Madeline Romaniuk</b> Gallipoli Medical Research Foundation

<b>Protocol number and title</b>	<b>Institution</b>
E016/015 Evaluating the effectiveness of theta burst stimulation as a treatment for PTSD in an Australian veteran population - pilot study	<b>Prof David Forbes</b> Phoenix Australia; University of Melbourne
16-022 1 Close Health Battalion - Clinical Notes Review	<b>Ms Paula Bowman</b> Queensland University of Technology
E017/020 The role of anger in symptom persistence and relapse in PTSD	<b>Dr David Berle</b> University of Tasmania
17-004 Change in selected mental health indicators amongst soldiers undergoing Army Rehabilitation Programs	<b>MAJ Tim Robinson</b> Flinders University
17-007 A scoping study into the prevalence and operational significance of back pain and neck pain in Air Mobility Group aircrew	<b>Dr Adrian Smith</b> RAAF Institute of Aviation Medicine
17-010 A scoping study into the prevalence and operational significance of back pain and neck pain in ADF Rotary Wing	<b>Dr Adrian Smith</b> RAAF Institute of Aviation Medicine
177-19 Noise and Living at Sea	<b>Dr Jane Whitelaw</b> University of Wollongong
034-18 The Impacts and implications of postings on Royal Australian Air Force Personnel and their families	<b>Dr Stephen Smith</b> University of Newcastle

<b>Protocol number and title</b>	<b>Institution</b>
035-18 A War Within: Making sense of suicide through narratives with former Australian Defence Force Members	<b>Prof Myfanwy Maple</b> University of New England
092-18 Experiences of ADF medical practitioners on live tissue trauma training	<b>Dr Mandy Moffat</b> University of Dundee
18-004 The effect of potential traumatic event type on measures of mental health in Australian Defence Force members completing critical incident mental health support screening 3-6 months post exposure	<b>Ms Dianne Lissner</b> Charles Sturt University
117-19 Noise and living at sea: An assessment of 24-hour noise exposure aboard a RAN Huon-Class Minehunter Coastal	<b>Ms Beth Eggleston</b> Humanitarian Advisory Group
127-19 Characterisation of arbovirus infection in Defence personnel.	<b>Dr Wen Liu</b> Australian Defence Force Malaria and Infectious Disease Institute
189-19 Wearable activity monitor validation Study	<b>Prof G. Gregory Haff</b> Edith Cowan University
645-11 Review of physical standards of applicants and recruits and their relationship to that of incumbents	<b>Dr Jace Drain</b> Defence Science & Technology Group
808-15 Deployed Women: Australian uniformed and civilian female personnel in peace and security operations	<b>Prof Mark Moran</b> University of Queensland

<b>Protocol number and title</b>	<b>Institution</b>
134-19 Organisational Climate Survey	<b>Dr Martine Cosgrove</b> Defence People Group
262-20 Productivity & Workforce Management Survey	<b>Dr Martine Cosgrove</b> Defence People Group