DEPARTMENTS OF DEFENCE AND VETERANS' AFFAIRS HUMAN RESEARCH ETHICS COMMITTEE
RESEARCH PROTOCOL AMENDMENT FORM

In the event that an approved research project requires amendment, this form must be submitted to the Departments of Defence and Veterans' Affairs Human Research Ethics Committee (DDVA HREC) by the Principal Investigator (PI).

An amendment **must not** be implemented until approval has been approved by the committee.

All completed forms are to be electronically submitted to ddva.hrec@defence.gov.au

Note: *To check a box electronically, right click on the box, and select "Properties" then mark the "Default value" as "**Checked**".*

Section 1: Project Details	
Protocol Number:	E016/007
Project Title:	Veterans MATES Program
Ethical approval date:	19 February 2016
Ethical approval expiration date:	30 Dec 2018
Date of amendment submission:	

Section 2: Investigator Details	
Name:	s47F
Organisation (command/division):	University of South Australia
Phone:	s47F
Email:	@unisa.edu.au

Section 3: Amendment Details

Explain the proposed/ intended changes *(may include changes in procedure, direction of project, source/manner of recruitment, number of participants or changes to research personnel)*

We seek permission to link the DVA administrative health claims data that we use for the Veterans' MATES program with the national death index. The national death index is maintained by the Australian Institute of Health and Welfare and includes details on cause of death. We will also seek approval to link the data from the AIHW ethics committee, where DVA approval is granted.

The National Death Index (NDI) is a Commonwealth database that contains records of deaths registered in Australia since 1980. Data comes from Registrars of Births, Deaths and Marriages in each jurisdiction, the National Coronial Information System and the Australian Bureau of Statistics.

The variables contained in the national death index are listed below

Linkage variables
Surname (including maiden names, where appropriate)

Given names (up to three given names)
Sex
Date of birth
Address at time of death
Fact of Death (FOD) variables
Date of death
State/Territory where death was registered
Year of death registration
Cause of Death (COD) variables
Underlying cause of death (as ICD9 codes until 1996, as ICD10 since 1997)
Other causes of death (as ICD10 codes since 1997)
Other variables
Indigenous status
Marital status
Region of address at time of death

Note: Cause of death variables are updated annually while all other variables listed above are updated monthly.

Reason for the changes *(include a comment on the impact on the research project and the participants at sites)*

As part of the Veterans' MATES program and related research, we undertake evaluation of health outcomes. While DVA data contains details on the date of death. The cause of death is not available. The additional data from the National Death Index includes cause of death which would enable us to determine changes in cause specific mortality as a result of interventions. The linkage will have no effect on participants in Veterans' MATES programs. The linkage will benefit the evaluation of the program and be useful for the Department, enabling analyses of cause of death to be undertaken.

Do these changes raise any ethical issues? Yes ☒ No ☐

If yes, identify the ethical issues.

There are no substantive ethical issues. AIHW have indicated they would be willing to link the data for this purpose. Ethics approval is required from the AIHW ethics committee,

which we will seek where DVA have provided approval.

Sensitive materials are handled within a set of standard operating procedures developed specifically for the project and in-line with Department of Veterans' Affairs (DVA) requirements and guidelines for secure storage, transmission and management of health data in electronic form. All staff are security "vetted", undergo regular training and are required to sign confidentiality and usage agreements detailing their responsibilities with the data.

The Quality Use of Medicines and Pharmacy Research Centre (QUMPRC), Sansom Institute, maintains all identified data within a PROTECTED environment (zone 3) that meets all physical, logical and personnel requirements laid down by the Australian Government (Department of Defence) Defense Signals Directorate (DSD) in line with current versions of the Protective Security Policy Framework (PSPF) and the Australian Government Information Security Manual (ISM) relating to the security of any information that is stored, processed or transmitted in electronic form. Four security audits per annum by either the State Security section of DVA or via an Independent Infosec Registered Assessor Program (I-RAP) are undertaken. The Centre has passed all security audits.

All data are stored on dedicated servers that reside within a C-Class security cabinet. Access to the servers is restricted to select personnel who have been cleared to a higher security level. All material is regularly backed up to tape and stored securely, in encrypted form, in an off-site safe. No identified data are released from the PROTECTED area unless approved by DVA and the security and data manager.

List all amended documents to be reviewed.

Document Title *(include version number, if applicable)* *Insert additional rows if required.*	**Version Date**
Not applicable	

Section 4: Participating Sites

Are all participating sites affected by this amendment? Yes ☐ No ☒

If no, list all affected sites below. Insert additional rows if required.

Site *(Organisation)*	**State**

An amendment to an approved research protocol may also impact the individual research sites. The Commanding Officer (CO) at each affected site (named above) must be notified of the amendment by the PI to determine if the site is impacted. Final approval to implement an amendment at a site will be issued by that site's CO.

Section 5: Declaration

I confirm that this project is being conducted in keeping with the conditions of ethical approval. I confirm that the project is being conducted in compliance with the *National Statement on Ethical Conduct in Human Research*.

I confirm that I have not received any information in any form from anyone involved in the research to suggest this report does not accurately reflect the progress of the project.

s47F	s47F
PI Signature	**PI Printed Name**
Date: 4/08/17	

1234567

DVA HUMAN RESEARCH ETHICS COMMITTEE
Proposal for Research

Note 1: When to Use This Form
This form is used for application for consideration of proposed research involving contact with the veteran community and/or access to personal information and/or data held by DVA, irrespective of whether the research is being conducted externally (not commissioned by the Department) or internally (commissioned by or on behalf of the Department).

Note 2: Definition of Personal Information
Personal information is information by which individuals can be identified. DVA held personal information includes names, contact details, and data on usage of services by individual members of the veteran community.

Note 3: Access to Personal Information Not Automatic
DVA HREC approval of an applicant's proposal does guarantee access to the DVA data/information requested. Such access is a matter for the appropriate business area of DVA. Further details regarding approval processes for access to DVA data for research purposes can be obtained by emailing research@dva.gov.au

Note 4: Submission of Application
Please submit applications electronically by completing the proforma template. Handwritten applications will not be accepted.

Part D: AGREEMENT must be signed by the Principal Researcher and can be submitted electronically (scanned copy) or in hard copy. Please ensure that all attachments are labelled correctly (e.g. research personnel CV's, consent form, ethical approval letters).

It is preferable that your submission, including all attachments is scanned as one document, depending on size of file and emailed to the Secretariat,

Please read the '*Guidelines for Researchers'* document available on the DVA HREC web page at http://www.dva.gov.au/ethics prior to completing your submission.

Part A: DETAILS OF PROJECT

A1.	**Reason for Application** *(Tick one box)*
	Study will involve contact with members of the veteran community
	Access is being sought to DVA owned personal information and/or data
X	Both of the above

A2.	**Study Title** *(Short title preferred)*
Veterans' Medicines Advice and Therapeutics Education Services (Veterans' MATES)	

A3.	**Short description of Study** *(Lay description in plain English - maximum of 100 words)*
The Veterans' Medicines Advice and Therapeutic Education Services (Veterans' MATES) program, is a veteran health literacy and health professional education program designed to improve quality use of medicines and health outcomes for veterans.	

A4.	**Principal Researcher** Title, Given Name, Surname Address (including postcode) Telephone number e-mail address	s47F University of South Australia GPO Box 2471 Adelaide SA 5001 s47F @unisa.edu.au

A5.	**Other Investigator(s)** Title, Given Name, Surname Address (including postcode) Telephone number e-mail address	s47F University of South Australia GPO Box 2471 Adelaide SA 5001 s47F s47F @unisa.edu.au s47F University of South Australia GPO Box 2471 Adelaide SA 5001 s47F @unisa.edu.au s47F h Australia GPO Box 2471 Adelaide SA 5001 s47F s47F @unisa.edu.au s47F University of South Australia GPO Box 2471 Adelaide SA 5001 s47F s47F @unisa.edu.au s47F University of South Australia GPO Box 2471 Adelaide SA 5001 s47F @unisa.edu.au s47F University of South Australia GPO Box 2471 Adelaide SA 5001 s47F @unisa.edu.au s47F University of South Australia GPO Box 2471 Adelaide SA 5001 s47F

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**Please include CVs for all relevant research personnel as an attachment to this form*

A6.	**Type of Application** *(Tick one box)*
X	Internal - research conducted by or on behalf of DVA
	External - research not commissioned or sponsored by DVA *(go to A8)*

A7.	**Name of DVA Project Sponsor** *(if applicable)*

Name of DVA Project Manager *(if applicable)*
s47E(d) (Program Manager)

A8.	Nature of Research *(Tick one box)*
	Research by academic staff member
	Research towards obtaining academic qualification
X	Other (please specify) Research contracted by DVA

A9. What are the study aims and objectives? *(Please be brief)*

The Department of Veterans' Affairs has been funding a prescriber intervention and feedback program since 1998, which since 2004 onwards has been known as the Veterans' Medicines Advice and Therapeutics Education Services (Veterans' MATES) program The original Veterans' MATES program operated from 2004 to 2015 and delivered 43 interventions to LMOs, health professionals and veterans. A new agreement was signed on the 23 Dec 2016 with the University of South Australia contracted to deliver the following services as part of the DVA Veterans' MATES program.

- Analyse DVA administrative claims data to identify, monitor and inform DVA of medication related problems and emerging health care trends
- Prepare education material on identified medication-related problems and emerging health care trends for distribution to targeted members including the veteran community and health care professionals
- Disseminate education material and research findings to the targeted groups through appropriate communication channels
- Evaluate the impacts of the education material on the targeted groups
- Govern and manage delivery of the Veterans' MATES program

A10. Give details of study methodology.

Analyse DVA administrative claims data to identify, monitor and inform DVA of medication-related problems and emerging health care trends

Veterans' MATES is contracted to deliver at a minimum of four interventions per year. Each intervention is targeted to a specific health or medication-related problem. All veterans who meet the target criteria for the specific intervention are targeted, as are the health professionals who care for the targeted veterans.

DVA data sets will be interrogated to identify potential topics for Veterans' MATES interventions, and to evaluate the success of those interventions. This will include quarterly medication utilisation analyses to identify health related issues and extent of medication-related problems. The majority of these studies will be cross-sectional designs aimed at examining utilisation by age or gender, utilisation specific to disease status and coadministration of medicines or concurrent use of health services. Analyses of trends in medicine and health service utilisation will occur using rates, time series analyses and forecasting methods to identify emerging trends and issues. Cohort, case series, survival analyses and case control studies will be used to assess health outcomes associated with changes in health service or medication utilisation as a result of the interventions.

Prepare education material on identified medication related problems and emerging health care trends for distribution to targeted members including the veteran community and health care professionals

The Veterans' MATES intervention includes educational material and targeted patient specific information delivered to veterans, their primary LMOs and other relevant health professionals as appropriate. The interventions will target all veterans who meet the criteria for the condition of interest (eg musculoskeletal pain) and materials will be provided to the veteran and their health care team. The materials for each intervention will be tailored to the behaviour change targeted in the intervention (eg reduction on inappropriate medicine use, increase in under-used services).

The patient specific feedback will include potential medication-related problems or health issues relevant to an individual veteran's care that has been identified from analysis of the DVA data. We will also use the DVA data to develop predictive analytics which would assist practitioners in predicting in advance the likely benefits or harms of a given set of treatments. Predictive models that have been validated will be incorporated into the feedback to support LMOs to review their patients.

The educational material will be tailored to the needs of the veteran community and their health care providers and will be developed by a medical writer supported by a clinical panel from a review and synthesis of the medical literature. A four page therapeutic brief will be provided for health professionals. Where the intervention targets additional health professional groups, the therapeutic brief would include sections on "practice points" and "what to tell my veteran patient" that were written specific to the role of each health professional. The materials will transition from print delivery to digital modes of delivery and as this occurs we will employ, where appropriate, follow-up reminder alerts delivered to the GP desktop at time of patient review. In addition, we will incorporate, where appropriate, quiz activities for the GP with instant feedback on answers to reinforce key messages and knowledge. Where appropriate, links to educational material via other media that are housed on the Veterans' MATES website will be included. At the time of each core and subsequent intervention, targeted veterans and health professionals will be asked to provide feedback about the intervention via a response form.

A four page "veteran brochure" will be provided to veterans. Where appropriate, additional materials providing follow up information and reinforcement messages may be provided to veterans who remain within the target groups. The sequential delivery of these materials will provide opportunity for reinforcement of key-messages and build veterans' health literacy over time. The additional materials for veterans will take advantage of existing supporting technologies including podcasts, educational videos, infographics, health information animations or decision support tools, where available. We also anticipate developing veteran tools, including self-completed questionnaires, which veterans can complete prior to visiting their general practitioner or community pharmacist. The tools will be designed to support

and empower veterans to monitor their own health and engage proactively with their health professional. General practitioners and pharmacists will be made aware of these resources via dissemination of the therapeutic material.

For each intervention we will develop a one page lay language summary of the key messages that will be suitable for inclusion in veteran publications, either as print or digital copy.

Keeping with our knowledge of behavioural change and health promotion, key education messages for all materials will be simple, specific and offer alternative management strategies where problems have been identified. All podcast and educational videos developed will be professionally produced with assistance of the University of South Australia teaching and learning unit and marketing unit. All written materials, supporting infographics and health information animations would be developed with the assistance of a professional graphics team.

Disseminate education material and research findings to the targeted groups through appropriate communication channels

At least four interventions will be delivered each year on identified medication related problems or emerging health care issues that are relevant to veterans. For each Veterans' MATES intervention, we will develop algorithms to identify veterans to be included in the intervention based on their health service or medicine use claims within the DVA data. We will use algorithms to identify the primary LMO for veterans targeted in each intervention, based on the LMO who provides the most services to the veteran around the time of the intervention. Where possible we will also identify other members of the veteran health care team. We will, for example, identify the primary pharmacy used by the veteran and where interventions are appropriate to allied health, the primary allied health provider (e.g. physiotherapist) used by the veteran. We will also identify and include in the patient-specific feedback, where appropriate, use of non-pharmacological measures, e.g. allied health visits or lack thereof.

The interventions will initially be presented as printed material, but over the life of the program transition to digital modes. HealthLink, will be used to disseminate educational materials, including patient specific data, to general practitioners via direct desktop delivery integrated into the GP workflow. HealthLink's NEHTA compliant Direct Secure Messaging capability, would allow Veterans' MATES to send information into the GPs clinical systems. Clinical information will be sent as encrypted electronic messages.

Options to provide electronic delivery of educational materials directly to veterans will also be explored and trialled. We will seek advice, but anticipate this is likely to be possible by delivery of the materials via DVA's MyAccount. The use of SMS messaging or e-mail alerts will be piloted, where possible, to alert veterans of new information in their DVA MyAccount. Alternatively, HealthLink's platform could be used to provide secure messaging to veterans.

We will disseminate copies of the developed materials for each intervention and information about the release of subsequent interventions to key health professional and veteran organisations.

The Veterans' Affairs Pharmaceutical Advisory Centre (VAPAC) supports dissemination through a help-line and Veterans' MATES materials and face to face training of VAPAC staff will be provided prior to delivery of each intervention.

We will disseminate veteran health research by publishing in high quality peer-reviewed journals. We will also present at national and international conferences in the fields of general practice, pharmacoepidemiology, guideline development, geriatric medicine and aging, dementia, veteran health, pharmacy, nursing, health services and policy and population health.

Evaluate the impacts of the education material on the targeted groups

Stakeholder response evaluation

Stakeholder responses will be evaluated using survey data based on a one-page response form provided at the time of the intervention. As the program moves to electronic delivery, surveys will be tailored and we will have the option, where required, of asking additional questions. All surveys will be analysed using descriptive statistics and statistical tests for differences between groups. Surveys will include a response identifier, to enable us to determine responses by age and gender and to determine the differential effect of the program on veterans within various age strata or with differing health complexity. This will enable us to determine the success of the program as the demographic profile of the veteran community changes.

Impact on medication and health service use

Cohort studies and time series analysis will be used to determine the effect of providing the health intervention, where appropriate, these will be stratified by veteran age and gender to determine the impact of the program across the different cohorts of veterans. The time series models will be used to predict what would have happened in the post-intervention period had the intervention not occurred. The difference in the predicted and actual time series data points will be used to project cost savings. We will compare the trends in time series data in the DVA population to an appropriate control group, where possible. Control groups will be obtained from either the DVA data, or PBS 10% sample data, which is now available to UniSA. Propensity score-based weighting methods will be used to reduce the risk of bias. In addition to these methods, we will develop methods to monitor changes in doses and changes in service mix. In some instances the interventions result in increases in medicine use for some individuals and decreases for others. For this reason, the evaluations will be extended to include measures of 'service mix', which will encompass whole of health measures such as encounters with health professionals and utilisation of allied health services.

Linkage with the national death index will further inform our health outcome

studies. These studies which are based on cohort studies and include time to event studies (survival analysis) such as time to next hospital event or time to death, as well as the frequency of events within specified time intervals. We will use cause of death data, obtained from the national death index file, to undertake
1) time to cause specific death and counts of cause specific death
(For example, time to death from cancer after first initiating cancer medicines, time to non-cancer deaths after first initiating cancer medicines, time to death for heart failure after first diagnosis of heart failure etc),
2) adjust for the competing risk of death (so enabling combined endpoints to be measured. For example, time to next cardiovascular hospital event or cardiovascular death; time to next respiratory hospital event or respiratory system death).

In order to evaluate the differential effect, if any, of transition to electronic delivery, we will use a phased implementation of electronic delivery. States (or Local areas) will be randomly allocated to one of three modes of delivery 1) electronic delivery 2) paper delivery or 3) both electronic and paper delivery. The paper delivery only group will serve as the control group. Evaluation measures will include measures of changes in behaviour (e.g. numbers of veterans now receiving appropriate care) and changes in LMO or health practitioner knowledge. Preference for delivery mode will also be ascertained. There is potential for electronic delivery to facilitate behaviour change, by alerts, but not improve knowledge (similarly to how we forget phone numbers once they are placed in electronic devices). It will be important for the program to both maintain and improve health practitioner knowledge given the complex medical history of many veterans.

The long-term goals of the program are also to change behaviour of the prescribers not only in the intervention period but also in the future as new patients present to that GP. We will develop methods to investigate whether the educational models have changed prescribing behaviours over time. Methods such as CUSUM models will be investigated to determine whether practice changes for a GP after the intervention by looking at what the GP does for consecutive patients who meet the intervention criteria in the future, but who weren't targeted in the intervention.

A cost consequence approach will be used for the economic evaluation of the Veterans' MATES program. To strengthen our economic evaluation, Marginal Structural Models (MSM) will be used to account for potential time varying confounders in multiple follow up periods when investigating behaviour change after the intervention. Appropriate adjustment for potential selection bias acting on the intervention is likely to result in more accurate effect estimates and therefore more accurate estimates of potential savings achieved by the implementation of the Veterans' MATES interventions.

Governance and management
The consortium will be managed by way of a Program Executive Committee and UniSA program team will be responsible for day to day running of the program. A veteran and a practitioner reference group will be convened to support program planning.

An over-arching program management plan will be the master planning document for the program. An annual work plan will support planning for all releases of educational materials In preparation for the development of all educational materials, a Topic Plan and intervention timeline will be developed.
The Topic Plan will identify:

- The medication related problem or emerging health care issue
- Relevant target groups
- Key messages
- Key objectives
- Description of intervention including health education materials to be developed through the core intervention and the veteran-centred intervention if appropriate
- Dissemination methods
- Evaluation methods to be used to evaluate each of the identified objectives

All plans will be approved by DVA prior to implementation and communications will be subject to DVA approval prior to public release.

A11. Summarise sample size and selection details. (*Must include, if relevant:*

- *sample frame/eligibility for selection;*
- *sample size; and*
- *method of selection.)*

All veterans in Australia who meet the target criteria for the interventions will be included. On average, this is approximately 30,000 veterans per intervention, and over the contract period is expected to include all veterans in the eligible treatment population receiving at least one intervention; approximately 240,000 veterans.
All health professionals who meet the target criteria for the intervention and provide care to Australian veterans will be included. On average, this is approximately 10,000 general practitioners, 2,600 directors of residential aged-care and 8,500 pharmacies or pharmacists per intervention.

A12.	**Does the project involve approaching members of the veteran community directly (face to face, by telephone, by mail, etc)?** *(Tick Yes or No: If yes, explain and provide details of:* • *how potential participants will be identified and recruited;* • *how initial contact will be made;* • *who will make contact; and* • *how consent will be obtained.)*
☒ Yes	• Potential participants will be identified through the DVA administrative claims data based on the results of the algorithms created to identify the target groups. • Contact will be made via mail directly to the veteran and through the Veterans' Primary General Practitioner and, where relevant, other health care provider (Practice Nurse, specialists, pharmacist, Residential Aged Care Facility Director, carer). Over the life of the contract, the program will progress to digital modes of delivery as outlined in section A10. • No research staff will make direct contact with veterans. • DVA has indicated that there is expressed consent from veterans to allow this contact to occur. Participants are free to opt out of the program with no effects on their status or benefits from DVA and are advised of this in each mail out.

A13.	**Have you attached copies of proposed introductory letters, consent forms, survey instruments and other pertinent documentation?** *(Tick Yes or No or N/A: If no, state why not, and when they will be provided.)*
☒ Yes	Attached • Sample introductory letters • Sample prescriber feedback • Sample response forms for health practitioners and veterans All documents are modified in accordance with the module topic, the attached documents are a mock-up only and do not contain reference to any real persons.

A14.	**Does the research involve possible physical risk to participants (eg new medications, vigorous exercise program)?** *(Tick Yes or No: If yes, explain and provide details of protective measures to be taken.)*
☒ No	

A15.	**Does the research involve possible emotional stress for the participant?** *(Tick Yes or No: If yes, explain and provide details of protective measures to be taken.)*
☒ Yes	The program provides educational material on medicine and health interventions to veterans and health care providers. In providing information there is always a risk that some health information may be interpreted negatively. To minimise this risk, we have comprehensive risk management strategies including multiple levels of oversight by clinicians, practitioners and veterans including a clinical panel to support the medical writer in developing materials, independent peer review of materials, an Editorial Committee (made up of representatives from key medical associations approved by DVA) to provide further review of all materials, veteran and practitioner reference groups to consult about key health issues affecting the veteran community. All participants have the ability to opt out at any time. In addition, care is taken to avoid targeting groups where distress may occur, (for example, routine exclusion of veterans receiving palliative care)

A16.	**Is there any risk of social, legal or financial harm to the participant?** *(Tick Yes or No: If yes, explain and provide details of protective measures to be taken.)*
☒ No	

A17.	**Does the research involve invasive procedures, the administration of foreign substances or the withdrawal of medication or medical treatment?** *(Tick Yes or No: If yes, clarify who will administer these procedures.)*
☒ No	The program provides therapeutic information for health care practitioners treating veterans which may include advice on prescribing or medical treatment. Any decision to initiate, change or cease medicines or health services is at the discretion of the treating doctor. No treatment will be administered or changed by the research team.

A18. Does the research involve access to DVA owned personal information? *(Tick Yes or No: If yes, explain and provide explicit details of what DVA owned information and/or data is required.*

☒ Yes

Under the Deed of Agreement for the provision of Veterans' MATES services dated 23rd December 2015,
DVA will provide the contractor with:

(a) DVA administrative claims data (hereafter referred to as "DVA data") including the following datasets:
   i. Medical (GPs, Specialists, Diagnostics);
   ii. Allied health (e.g. Psychologists, Social Workers, Occupational Therapists, Dentists);
   iii. Private and public hospital admissions (Major Diagnostic Category, Diagnosis Related Group, International Classification of Diseases;
   iv. Pharmacy (by Anatomic Therapeutic Chemical levels);
   v. Veterans' Home Care;
   vi. Coordinated Veterans' Care (CVC)
   vii. Community Nursing; and
   viii. Rehabilitation Appliance Program Treatment Operation Review System.

A19. What is the projected timetable?

Deed of Agreement for the provision of Veterans' MATES services dated 23rd December 2015 will run until 30th June 2018, with an option for a 3 year extension

A20. What are the particular benefits of the study for the veteran community?

The program is commissioned by DVA and aimed specifically at improving the health of veterans by providing educational materials to veterans and their health care professionals.

A21. Details of funding sources *(Amount and source).*

The Department of Veterans' Affairs has commissioned this work under the Deed of Agreement for the provision of Veterans' MATES services dated 23rd Dec 2015. s47G

A22. Does the source of funding entail any potential conflict of interest for the researcher or DVA? *(Tick Yes or No: If yes, explain and provide details of protective measures to be taken.)*

☒ No

Part B: PRIVACY CONSIDERATIONS

As the Department is bound to comply with the requirements of the *Privacy Act 1988* it must comply with the Australian Privacy Principles (APPs).

The Commonwealth Privacy Commissioner under section 95 of the Privacy Act 1988 has approved guidelines for the protection of privacy in the conduct of medical research.

The guidelines apply to research involving personal information obtained from a Commonwealth agency, the disclosure of which might involve a breach of one or more APPs.

In order that your proposal can be assessed in accordance with the privacy guidelines, please address each of the following points B1-B19.

B1.	Will the study involve collection and/or use of personal information? (Refer APP 3 and 6).
☒ Yes	

B2.	Will consent be sought from individuals regarding the collection and/or use of their personal information, including health information? If no, please state any reasons why it may be impracticable to seek consent from individuals regarding the collection/use of their health information (refer APP 3 and 6).
☒ No	DVA has indicated that there is expressed consent from veterans to allow this contact to occur.

B3.	Will steps be taken to de-identify participant personal information prior to or following its collection? If no, please state the reasons why de-identified information cannot achieve the relevant purpose or why it may be impracticable to de-identify the personal information.
☒ No	Identified data are required to enable direct patient-related feedback on prescribing to be relayed to veterans' Local Medical Officers.

B4.	Can participants have the option not to identify themselves or to use a pseudonym? If no, please state why this is impracticable (refer APP 2).
☒ No	Identified data are required to enable direct patient-related feedback on prescribing to be relayed to veterans' Local Medical Officers but a participant can elect to be exempted from the process (i.e opt-out).

B5.	State the specific uses to which the personal information acquired or developed during the study will be put (refer APP 3 and 6).
	The personal data provided by DVA will enable the research team to track medicine and health service use and provide direct patient related feedback to their Local Medical Officer, and education materials to other health professionals and veterans. Personal information will not be used for any other purpose.

B6.	If additional personal information is to be collected will it be used for any other purpose? If yes, please specify purpose (refer APP 3 and 6).
☒	Yes. One page response forms, will be collected in the form of questionnaire responses and will be used for the purposes of evaluating the activities of the program. The response forms will be coded with a barcode containing information on the module and participant (via unique identifier created for that particular module) to enable evaluation of the program

B7.	If personal information in the possession of DVA is to be used, is the use for the purpose that it was originally collected for (yes/no)? (Refer APP 3 and 6).
☒	Yes. Expressed consent is obtained for the data to be used for improving health care.

B8.	If the use is for another purpose, is the use permitted by any of the exceptions in APP 6? If yes, please state which exception and explain why.
☒	No

B9.	State the estimated time of retention of the personal information acquired (if the research is health and medical research the personal information should be kept for a minimum of 5 years).
	All personal information and other program materials will be held in a secure facility at the University of South Australia for the life of the program to be returned to DVA in accord with the program disengagement plan.

B10.	State the security procedures that will be applied to the personal information acquired (data should be protected against misuse, interference, loss, unauthorised access, modification and disclosure) (refer APP 11).
	The data management procedures, and the security arrangements put in place by the project team to store, handle and process such information will be in accordance with the security standards set out in the specified sections of the Australian Government Protective Security Policy Framework (PSPF) and the Australian Government IT Security Manual. These two references are the core of the project Security Framework Manuals which prescribe all the physical, logical, personnel and risk management procedures. The project team is bound by the rules of the University of South Australia Human Research Ethics Committee and the Australian privacy Principles. Sensitive material will be handled within a set of Standard Operating Procedures (SOPs) developed specifically for the project and in line with DVA requirements and guidelines. All people associated with the project data have been cleared to the appropriate Security level for their function. Any of the selected staff with administrative rights have Base Line Security clearances that are current until 2020. All people associated with the project undergo specialised training and are bound by confidentiality and usage agreements. All identified material is kept in secure locations and any breaches will be addressed in a formal manner within a disciplinary process. All material will be regularly backed up at short intervals to counter for systems failure and kept in encrypted form and only made available to people authorised to the required level of security. The project team will ensure that the physical locations and systems used for the transfer, analysis and storage of Departmental data and other sensitive material continue to meet the -security standards for "In Confidence" material and will continue to undergo quarterly departmental security audits.

B11.	State how the acquired data will be stored and controlled. (Departmental procedures and *Archives Act 1983* requirements are to be followed if accessing DVA held data. Please also note, if applicable, terms of any disclosure agreement between DVA and the researcher which governs use and disclosure of personal information obtained from DVA.)
	Data will be stored on a central, dedicated server in a secure setting as required in the Australian Government Protective Security Policy Framework (PSPF). Access to the server will be restricted to defined personnel (with the appropriate clearances and permissions) and on defined computer terminals within the secure environment (conditioned for secure work in this environment). All personnel will work under the requirements of the appropriate security levels and sign the appropriate "User agreement" and "Deed of Confidentiality". There will be three distinct security levels (physically and logically) known as: Zone 3 - designed to store and process non-nationally unclassified data with dissemination limiting markers up to and including 'Sensitive-Personal'. Zone 2 - designed to store and process unclassified data with dissemination limiting markers up to and including 'For Official Use'. Zone 1 – all unsecured areas outside the secured project area in the public domain

B12.	List the personnel who will have access to the personal information.
	Identifiable data will be accessible to selected staff who have signed a Deed of Confidentiality, a Usage Agreement and have been cleared to the appropriate Security level for their function. Any of the selected staff with administrative rights possess Base Line Security clearances that are current until 2020. The following staff currently meet this criteria: s47F Base Line Security Access is in the process of being sought for the following staff: s47F

B13.	If sub-contractors are to have access to the personal information, do their contracts include appropriate privacy clauses?
☒	Yes.

B14.	Is any of the personal information to be disclosed outside DVA? If yes, state which exception/s in APP 6 permits the disclosure.
☒	Yes. The mailing address of each participant in a module is required to be supplied to the Secure distribution house for the purposes of delivering the educational material.

B15.	State what will be done with the personal information on completion of the study, including audio/video recorded material and the proposed method of disposal of the personal information, having regard to relevant retention requirements and to the *Archives Act 1983* for Commonwealth records.
	All personal information and other program materials will be held in a secure facility at the University of South Australia for the life of the program and to be returned to DVA in accord with the program disengagement plan.

B16.	Will the final results be published. If yes, please specify in what form. For example, de-identified case studies, aggregate statistical table or other. (Please include details of intended publications, if known).
☒	Yes. Evaluation and data analytic results are expected to be published in the medical literature. Only summary data and non-identified analyses will be used in publications. All publications will be subject to DVA approval prior to submission.

B17.	Will the final results be made available to other researchers? If yes, please state in what form.
☒	Yes Publications, as approved by the DVA Program Manager or delegate, will be made available in the academic literature

B18.	Will any personal information be disclosed to overseas recipients? If yes, please list the names of the countries in which the personal information will be sent and the steps taken to comply with APP 8.
☒	No

B19.	Does the proposed research involve any breach of the APPs? If yes, please state the APPs concerned and provide reasons for believing that the public interest in the research outweighs, to a substantial degree, the public interest in complying with the APPs (see s 3.3 of the *Guidelines under s 95 of the Privacy Act 1988*).
☒	No

Part C: FINAL CHECKLIST

C1.	Final Checklist (Tick Yes or No for each item: *If yes to any item, see also Item C2.*)	
A	o Yes ☒ No	Is deception of any kind used?
B	o Yes ☒ No	Does the research involve collection, use or disclosure of personal, health-related or other sensitive information, without the prior consent of the subjects of that information?
C	☒ Yes o No	Will the research involve access to data stores subject to privacy legislation?
D	o Yes ☒ No	Will any data or personal information be preserved for possible future use by yourself or other researchers?
E	o Yes ☒ No	Will participants have pictures taken of them (e.g. photographs, video recordings)?
F	o Yes ☒ No	If interviews are conducted, will they be audio/video-recorded?
G	o Yes ☒ No	Will participants be asked to perform any acts or make any statements which might diminish their self-esteem or cause them to experience embarrassment or regret?
H	o Yes ☒ No	Will any procedures be used with potentially unpleasant or harmful effects either of a physical, psychological, social, legal or financial nature, to the participant?
I	o Yes ☒ No	Does the research involve any stimuli, tasks, investigations or procedures which may be experienced by participants as stressful, noxious, aversive or unpleasant during or after the research procedures?
J	o Yes ☒ No	Will the research involve the use of no-treatment or placebo control conditions?
K	o Yes ☒ No	Will any samples of body fluids or body tissue be obtained specifically for the research?
L	o Yes ☒ No	Will participants be fingerprinted, DNA 'fingerprinted', or have any kind of uniquely identifying biological marker recorded?
M	o Yes ☒ No	Is there any risk of criminal or civil liability to the participant or researcher as a result of the research?
N	o Yes ☒ No	Does the source of funding cause any potential conflict of interest for the researcher?
O	o Yes ☒ No	Is a data Integrating Authority required for this research?
P	o Yes ☒ No	Are there any other ethical issues involved in the research?

C2.	If the answer to any of the questions in Item C1 is yes, please explain and justify your response (*or state where in this application the explanation and justification is provided*).
In order to fulfil the requirements of the Deed of Agreement for the provision of Veterans' MATES services, dated 23rd December 2015, DVA will provide the contractor with DVA administrative claims data (hereafter referred to as "DVA data") including the following datasets: i. Medical (GPs, Specialists, Diagnostics); ii. Allied health (e.g. Psychologists, Social Workers, Occupational Therapists, Dentists); iii. Private and public hospital admissions (Major Diagnostic Category, Diagnosis Related Group, International Classification of Diseases; iv. Pharmacy (by Anatomic Therapeutic Chemical levels); v. Veterans' Home Care; vi. Coordinated Veterans' Care (CVC) vii. Community Nursing; and viii. Rehabilitation Appliance Program Treatment Operation Review System.	

C3.	General supporting comments (*include here any information that might assist the DVA HREC to better assess your application e.g. details of other ethical approvals*).

Part D: AGREEMENT

This agreement relates to a study titled .....(Insert short title).....

I, ... acknowledge that the information contained in this form is true and accurate, and I undertake to ensure the security and privacy of the personal information entrusted to me in accordance with the arrangements described in this form.

....

Principal Researcher Date

Privacy Act 1988
AUSTRALIAN PRIVACY PRINCIPLES

1 Australian Privacy Principle 1—open and transparent management of personal information

1.1 The object of this principle is to ensure that APP entities manage personal information in an open and transparent way.

Compliance with the Australian Privacy Principles etc.

1.2 An APP entity must take such steps as are reasonable in the circumstances to implement practices, procedures and systems relating to the entity's functions or activities that:

(a) will ensure that the entity complies with the Australian Privacy Principles and a registered APP code (if any) that binds the entity; and

(b) will enable the entity to deal with inquiries or complaints from individuals about the entity's compliance with the Australian Privacy Principles or such a code.

APP Privacy policy

1.3 An APP entity must have a clearly expressed and up-to-date policy (the APP privacy policy) about the management of personal information by the entity.

1.4 Without limiting subclause 1.3, the APP privacy policy of the APP entity must contain the following information:

(a) the kinds of personal information that the entity collects and holds;

(b) how the entity collects and holds personal information;

(c) the purposes for which the entity collects, holds, uses and discloses personal information;

(d) how an individual may access personal information about the individual that is held by the entity and seek the correction of such information;

(e) how an individual may complain about a breach of the Australian Privacy Principles, or a registered APP code (if any) that binds the entity, and how the entity will deal with such a complaint;

(f) whether the entity is likely to disclose personal information to overseas recipients;

(g) if the entity is likely to disclose personal information to overseas recipients—the countries in which such recipients are likely to be located if it is practicable to specify those countries in the policy.

Availability of APP privacy policy etc.

1.5 An APP entity must take such steps as are reasonable in the circumstances to make its APP privacy policy available:

(a) free of charge; and

(b) in such form as is appropriate.

Note: An APP entity will usually make its APP privacy policy available on the entity's website.

1.6 If a person or body requests a copy of the APP privacy policy of an APP entity in a particular form, the entity must take such steps as are reasonable in the circumstances to give the person or body a copy in that form.

2 Australian Privacy Principle 2—anonymity and pseudonymity

2.1 Individuals must have the option of not identifying themselves, or of using a pseudonym, when dealing with an APP entity in relation to a particular matter.

2.2 Subclause 2.1 does not apply if, in relation to that matter:

(a) the APP entity is required or authorised by or under an Australian law, or a court/tribunal order, to deal with individuals who have identified themselves; or

(b) it is impracticable for the APP entity to deal with individuals who have not identified themselves or who have used a pseudonym.

3 Australian Privacy Principle 3—collection of solicited personal information

Personal information other than sensitive information

3.1 If an APP entity is an agency, the entity must not collect personal information (other than sensitive information) unless the information is reasonably necessary for, or directly related to, one or more of the entity's functions or activities.

3.2 If an APP entity is an organisation, the entity must not collect personal information (other than sensitive information) unless the information is reasonably necessary for one or more of the entity's functions or activities.

Sensitive information

3.3 An APP entity must not collect sensitive information about an individual unless:

(a) the individual consents to the collection of the information and:

(i) if the entity is an agency—the information is reasonably necessary for, or directly related to, one or more of the entity's functions or activities; or

(ii) if the entity is an organisation—the information is reasonably necessary for one or more of the entity's functions or activities; or

(b) subclause 3.4 applies in relation to the information.

3.4 This subclause applies in relation to sensitive information about an individual if:

(a) the collection of the information is required or authorised by or under an Australian law or a court/tribunal order; or

(b) a permitted general situation exists in relation to the collection of the information by the APP entity; or

(c) the APP entity is an organisation and a permitted health situation exists in relation to the collection of the information by the entity; or

(d) the APP entity is an enforcement body and the entity reasonably believes that:

(i) if the entity is the Immigration Department—the collection of the information is reasonably necessary for, or directly related to, one or more enforcement related activities conducted by, or on behalf of, the entity; or

(ii) otherwise—the collection of the information is reasonably necessary for, or directly related to, one or more of the entity's functions or activities; or

(e) the APP entity is a non-profit organisation and both of the following apply:

(i) the information relates to the activities of the organisation;

(ii) the information relates solely to the members of the organisation, or to individuals who have regular contact with the organisation in connection with its activities.

Note: For *permitted general situation*, see section 16A. For *permitted health situation,* see section 16B – extracted at end of this document.

Means of collection

3.5 An APP entity must collect personal information only by lawful and fair means.

3.6 An APP entity must collect personal information about an individual only from the individual unless:

(a) if the entity is an agency:

(i) the individual consents to the collection of the information from someone other than the individual; or

(ii) the entity is required or authorised by or under an Australian law, or a court/tribunal order, to collect the information from someone other than the individual; or

(b) it is unreasonable or impracticable to do so.

Solicited personal information

3.7 This principle applies to the collection of personal information that is solicited by an APP entity.

4. Australian Privacy Principle 4—dealing with unsolicited personal information

4.1 If:

(a) an APP entity receives personal information; and

(b) the entity did not solicit the information;

the entity must, within a reasonable period after receiving the information, determine whether or not the entity could have collected the information under Australian Privacy Principle 3 if the entity had solicited the information.

4.2 The APP entity may use or disclose the personal information for the purposes of making the determination under subclause 4.1.

4.3 If:

(a) the APP entity determines that the entity could not have collected the personal information; and

(b) the information is not contained in a Commonwealth record;

the entity must, as soon as practicable but only if it is lawful and reasonable to do so, destroy the information or ensure that the information is de-identified.

4.4 If subclause 4.3 does not apply in relation to the personal information, Australian Privacy Principles 5 to 13 apply in relation to the information as if the entity had collected the information under Australian Privacy Principle 3.

5 Australian Privacy Principle 5—notification of the collection of personal information

5.1 At or before the time or, if that is not practicable, as soon as practicable after, an APP entity collects personal information about an individual, the entity must take such steps (if any) as are reasonable in the circumstances:

(a) to notify the individual of such matters referred to in subclause 5.2 as are reasonable in the circumstances; or

(b) to otherwise ensure that the individual is aware of any such matters.

5.2 The matters for the purposes of subclause 5.1 are as follows:

(a) the identity and contact details of the APP entity;
(b) if:
(i) the APP entity collects the personal information from someone other than the individual; or
(ii) the individual may not be aware that the APP entity has collected the personal information;
the fact that the entity so collects, or has collected, the information and the circumstances of that collection;
(c) if the collection of the personal information is required or authorised by or under an Australian law or a court/tribunal order—the fact that the collection is so required or authorised (including the name of the Australian law, or details of the court/tribunal order, that requires or authorises the collection);
(d) the purposes for which the APP entity collects the personal information;
(e) the main consequences (if any) for the individual if all or some of the personal information is not collected by the APP entity;
(f) any other APP entity, body or person, or the types of any other APP entities, bodies or persons, to which the APP entity usually discloses personal information of the kind collected by the entity;
(g) that the APP privacy policy of the APP entity contains information about how the individual may access the personal information about the individual that is held by the entity and seek the correction of such information;
(h) that the APP privacy policy of the APP entity contains information about how the individual may complain about a breach of the Australian Privacy Principles, or a registered APP code (if any) that binds the entity, and how the entity will deal with such a complaint;
(i) whether the APP entity is likely to disclose the personal information to overseas recipients;
(j) if the APP entity is likely to disclose the personal information to overseas recipients—the countries in which such recipients are likely to be located if it is practicable to specify those countries in the notification or to otherwise make the individual aware of them.

6 Australian Privacy Principle 6—use or disclosure of personal information

Use or disclosure

6.1 If an APP entity holds personal information about an individual that was collected for a particular purpose (the primary purpose), the entity must not use or disclose the information for another purpose (the secondary purpose) unless:
(a) the individual has consented to the use or disclosure of the information; or
(b) subclause 6.2 or 6.3 applies in relation to the use or disclosure of the information.

Note: Australian Privacy Principle 8 sets out requirements for the disclosure of personal information to a person who is not in Australia or an external Territory.

6.2 This subclause applies in relation to the use or disclosure of personal information about an individual if:
(a) the individual would reasonably expect the APP entity to use or disclose the information for the secondary purpose and the secondary purpose is:
(i) if the information is sensitive information—directly related to the primary purpose; or
(ii) if the information is not sensitive information—related to the primary purpose; or
(b) the use or disclosure of the information is required or authorised by or under an Australian law or a court/tribunal order; or
(c) a permitted general situation exists in relation to the use or disclosure of the information by the APP entity; or
(d) the APP entity is an organisation and a permitted health situation exists in relation to the use or disclosure of the information by the entity; or
(e) the APP entity reasonably believes that the use or disclosure of the information is reasonably necessary for one or more enforcement related activities conducted by, or on behalf of, an enforcement body.

Note: For *permitted general situation*, see section 16A. For *permitted health situation,* see section 16B – extracted at end of this document.

6.3 This subclause applies in relation to the disclosure of personal information about an individual by an APP entity that is an agency if:
(a) the agency is not an enforcement body; and
(b) the information is biometric information or biometric templates; and
(c) the recipient of the information is an enforcement body; and
(d) the disclosure is conducted in accordance with the guidelines made by the Commissioner for the purposes of this paragraph.

6.4 If:

(a) the APP entity is an organisation; and
(b) subsection 16B(2) applied in relation to the collection of the personal information by the entity;

the entity must take such steps as are reasonable in the circumstances to ensure that the information is de-identified before the entity discloses it in accordance with subclause 6.1 or 6.2.

Written note of use or disclosure

6.5 If an APP entity uses or discloses personal information in accordance with paragraph 6.2(e), the entity must make a written note of the use or disclosure.

Related bodies corporate

6.6 If:
(a) an APP entity is a body corporate; and
(b) the entity collects personal information from a related body corporate;

this principle applies as if the entity's primary purpose for the collection of the information were the primary purpose for which the related body corporate collected the information.

Exceptions

6.7 This principle does not apply to the use or disclosure by an organisation of:
(a) personal information for the purpose of direct marketing; or
(b) government related identifiers

7 Australian Privacy Principle 7—direct marketing

Direct marketing

7.1 If an organisation holds personal information about an individual, the organisation must not use or disclose the information for the purpose of direct marketing.

Note: An act or practice of an agency may be treated as an act or practice of an organisation, see section 7A.

Exceptions—personal information other than sensitive information

7.2 Despite subclause 7.1, an organisation may use or disclose personal information (other than sensitive information) about an individual for the purpose of direct marketing if:
(a) the organisation collected the information from the individual; and
(b) the individual would reasonably expect the organisation to use or disclose the information for that purpose; and
(c) the organisation provides a simple means by which the individual may easily request not to receive direct marketing communications from the organisation; and
(d) the individual has not made such a request to the organisation.

7.3 Despite subclause 7.1, an organisation may use or disclose personal information (other than sensitive information) about an individual for the purpose of direct marketing if:
(a) the organisation collected the information from:
(ii) the individual and the individual would not reasonably expect the organisation to use or disclose the information for that purpose; or
(ii) someone other than the individual; and
(b) either:
(ii) the individual has consented to the use or disclosure of the information for that purpose; or
(ii) it is impracticable to obtain that consent; and
(c) the organisation provides a simple means by which the individual may easily request not to receive direct marketing communications from the organisation; and
(d) in each direct marketing communication with the individual:
(ii) the organisation includes a prominent statement that the individual may make such a request; or
(ii) the organisation otherwise draws the individual's attention to the fact that the individual may make such a request; and
(e) the individual has not made such a request to the organisation.

Exception—sensitive information

7.4 Despite subclause 7.1, an organisation may use or disclose sensitive information about an individual for the purpose of direct marketing if the individual has consented to the use or disclosure of the information for that purpose.

Exception—contracted service providers

7.5 Despite subclause 7.1, an organisation may use or disclose personal information for the purpose of direct marketing if:
(a) the organisation is a contracted service provider for a Commonwealth contract; and

(b) the organisation collected the information for the purpose of meeting (directly or indirectly) an obligation under the contract; and
(c) the use or disclosure is necessary to meet (directly or indirectly) such an obligation.

Individual may request not to receive direct marketing communications etc.

7.6 If an organisation (the first organisation) uses or discloses personal information about an individual:
(a) for the purpose of direct marketing by the first organisation; or
(b) for the purpose of facilitating direct marketing by other organisations;
the individual may:
(c) if paragraph (a) applies—request not to receive direct marketing communications from the first organisation; and
(d) if paragraph (b) applies—request the organisation not to use or disclose the information for the purpose referred to in that paragraph; and
(e) request the first organisation to provide its source of the information.

7.7 If an individual makes a request under subclause 7.6, the first organisation must not charge the individual for the making of, or to give effect to, the request and:
(a) if the request is of a kind referred to in paragraph 7.6(c) or (d)—the first organisation must give effect to the request within a reasonable period after the request is made; and
(b) if the request is of a kind referred to in paragraph 7.6(e)—the organisation must, within a reasonable period after the request is made, notify the individual of its source unless it is impracticable or unreasonable to do so.

Interaction with other legislation

7.8 This principle does not apply to the extent that any of the following apply:
(a) the *Do Not Call Register Act 2006;*
(b) the *Spam Act 2003;*
(c) any other Act of the Commonwealth, or a Norfolk Island enactment, prescribed by the regulations.

8 Australian Privacy Principle 8—cross-border disclosure of personal information

8.1 Before an APP entity discloses personal information about an individual to a person (the overseas recipient):
(a) who is not in Australia or an external Territory; and
(b) who is not the entity or the individual;
the entity must take such steps as are reasonable in the circumstances to ensure that the overseas recipient does not breach the Australian Privacy Principles (other than Australian Privacy Principle 1) in relation to the information.

Note: In certain circumstances, an act done, or a practice engaged in, by the overseas recipient is taken, under section 16C, to have been done, or engaged in, by the APP entity and to be a breach of the Australian Privacy Principles.

8.2 Subclause 8.1 does not apply to the disclosure of personal information about an individual by an APP entity to the overseas recipient if:
(a) the entity reasonably believes that:
(ii) the recipient of the information is subject to a law, or binding scheme, that has the effect of protecting the information in a way that, overall, is at least substantially similar to the way in which the Australian Privacy Principles protect the information; and
(ii) there are mechanisms that the individual can access to take action to enforce that protection of the law or binding scheme; or
(b) both of the following apply:
(i) the entity expressly informs the individual that if he or she consents to the disclosure of the information, subclause 8.1 will not apply to the disclosure;
(i) after being so informed, the individual consents to the disclosure; or
(c) the disclosure of the information is required or authorised by or under an Australian law or a court/tribunal order; or
(d) a permitted general situation (other than the situation referred to in item 4 or 5 of the table in subsection 16A(1)) exists in relation to the disclosure of the information by the APP entity; or
(e) the entity is an agency and the disclosure of the information is required or authorised by or under an international agreement relating to information sharing to which Australia is a party; or
(f) the entity is an agency and both of the following apply:

(ii) the entity reasonably believes that the disclosure of the information is reasonably necessary for one or more enforcement related activities conducted by, or on behalf of, an enforcement body;
(ii) the recipient is a body that performs functions, or exercises powers, that are similar to those performed or exercised by an enforcement body.

Note: For *permitted general situation*, see section 16A. For *permitted health situation,* see section 16B – extracted at end of this document.

9 Australian Privacy Principle 9—adoption, use or disclosure of government related identifiers

Adoption of government related identifiers

9.1 An organisation must not adopt a government related identifier of an individual as its own identifier of the individual unless:
(a) the adoption of the government related identifier is required or authorised by or under an Australian law or a court/tribunal order; or
(b) subclause 9.3 applies in relation to the adoption.

Note: An act or practice of an agency may be treated as an act or practice of an organisation, see section 7A.

Use or disclosure of government related identifiers

9.2 An organisation must not use or disclose a government related identifier of an individual unless:
(a) the use or disclosure of the identifier is reasonably necessary for the organisation to verify the identity of the individual for the purposes of the organisation's activities or functions; or
(b) the use or disclosure of the identifier is reasonably necessary for the organisation to fulfil its obligations to an agency or a State or Territory authority; or
(c) the use or disclosure of the identifier is required or authorised by or under an Australian law or a court/tribunal order; or
(d) a permitted general situation (other than the situation referred to in item 4 or 5 of the table in subsection 16A(1)) exists in relation to the use or disclosure of the identifier; or
(e) the organisation reasonably believes that the use or disclosure of the identifier is reasonably necessary for one or more enforcement related activities conducted by, or on behalf of, an enforcement body; or
(f) subclause 9.3 applies in relation to the use or disclosure.

Note 1: An act or practice of an agency may be treated as an act or practice of an organisation, see section 7A.
Note 2: For *permitted general situation*, see section 16A. For *permitted health situation,* see section 16B – extracted at end of this document.

Regulations about adoption, use or disclosure

9.3 This subclause applies in relation to the adoption, use or disclosure by an organisation of a government related identifier of an individual if:
(a) the identifier is prescribed by the regulations; and
(b) the organisation is prescribed by the regulations, or is included in a class of organisations prescribed by the regulations; and
(c) the adoption, use or disclosure occurs in the circumstances prescribed by the regulations.

Note: There are prerequisites that must be satisfied before the matters mentioned in this subclause are prescribed, see subsections 100(2) and (3).

10 Australian Privacy Principle 10—quality of personal information

10.1 An APP entity must take such steps (if any) as are reasonable in the circumstances to ensure that the personal information that the entity collects is accurate, up-to-date and complete.

10.2 An APP entity must take such steps (if any) as are reasonable in the circumstances to ensure that the personal information that the entity uses or discloses is, having regard to the purpose of the use or disclosure, accurate, up-to-date, complete and relevant.

11 Australian Privacy Principle 11—security of personal information

11.1 If an APP entity holds personal information, the entity must take such steps as are reasonable in the circumstances to protect the information:
(a) from misuse, interference and loss; and
(b) from unauthorised access, modification or disclosure.

11.2 If:
(a) an APP entity holds personal information about an individual; and
(b) the entity no longer needs the information for any purpose for which the information may be used or disclosed by the entity under this Schedule; and
(c) the information is not contained in a Commonwealth record; and

(d) the entity is not required by or under an Australian law, or a court/tribunal order, to retain the information;

the entity must take such steps as are reasonable in the circumstances to destroy the information or to ensure that the information is de-identified.

12 Australian Privacy Principle 12—access to personal information

Access

12.1 If an APP entity holds personal information about an individual, the entity must, on request by the individual, give the individual access to the information.

Exception to access—agency

12.2 If:

(a) the APP entity is an agency; and

(b) the entity is required or authorised to refuse to give the individual access to the personal information by or under:

(i) the *Freedom of Information Act*; or

(i) any other Act of the Commonwealth, or a Norfolk Island enactment, that provides for access by persons to documents;

then, despite subclause 12.1, the entity is not required to give access to the extent that the entity is required or authorised to refuse to give access.

Exception to access—organisation

12.3 If the APP entity is an organisation then, despite subclause 12.1, the entity is not required to give the individual access to the personal information to the extent that:

(a) the entity reasonably believes that giving access would pose a serious threat to the life, health or safety of any individual, or to public health or public safety; or

(b) giving access would have an unreasonable impact on the privacy of other individuals; or

(c) the request for access is frivolous or vexatious; or

(d) the information relates to existing or anticipated legal proceedings between the entity and the individual, and would not be accessible by the process of discovery in those proceedings; or

(e) giving access would reveal the intentions of the entity in relation to negotiations with the individual in such a way as to prejudice those negotiations; or

(f) giving access would be unlawful; or

(g) denying access is required or authorised by or under an Australian law or a court/tribunal order; or

(h) both of the following apply:

(i) the entity has reason to suspect that unlawful activity, or misconduct of a serious nature, that relates to the entity's functions or activities has been, is being or may be engaged in;

(ii) giving access would be likely to prejudice the taking of appropriate action in relation to the matter; or

(i) giving access would be likely to prejudice one or more enforcement related activities conducted by, or on behalf of, an enforcement body; or

(j) giving access would reveal evaluative information generated within the entity in connection with a commercially sensitive decision-making process.

Dealing with requests for access

12.4 The APP entity must:

(a) respond to the request for access to the personal information:

(i) if the entity is an agency—within 30 days after the request is made; or

(ii) if the entity is an organisation—within a reasonable period after the request is made; and

(b) give access to the information in the manner requested by the individual, if it is reasonable and practicable to do so.

Other means of access

12.5 If the APP entity refuses:

(a) to give access to the personal information because of subclause 12.2 or 12.3; or

(b) to give access in the manner requested by the individual;

the entity must take such steps (if any) as are reasonable in the circumstances to give access in a way that meets the needs of the entity and the individual.

12.6 Without limiting subclause 12.5, access may be given through the use of a mutually agreed intermediary.

Access charges

12.7 If the APP entity is an agency, the entity must not charge the individual for the making of the request or for giving access to the personal information.

12.8 If:

(a) the APP entity is an organisation; and

(b) the entity charges the individual for giving access to the personal information;

the charge must not be excessive and must not apply to the making of the request.

Refusal to give access

12.9 If the APP entity refuses to give access to the personal information because of subclause 12.2 or 12.3, or to give access in the manner requested by the individual, the entity must give the individual a written notice that sets out:

(a) the reasons for the refusal except to the extent that, having regard to the grounds for the refusal, it would be unreasonable to do so; and

(b) the mechanisms available to complain about the refusal; and

(c) any other matter prescribed by the regulations.

12.10 If the APP entity refuses to give access to the personal information because of paragraph 12.3(j), the reasons for the refusal may include an explanation for the commercially sensitive decision.

13 Australian Privacy Principle 13—correction of personal information

Correction

13.1 If:

(a) an APP entity holds personal information about an individual; and

(b) either:

(i) the entity is satisfied that, having regard to a purpose for which the information is held, the information is inaccurate, out-of-date, incomplete, irrelevant or misleading; or

(ii) the individual requests the entity to correct the information;

the entity must take such steps (if any) as are reasonable in the circumstances to correct that information to ensure that, having regard to the purpose for which it is held, the information is accurate, up-to-date, complete, relevant and not misleading.

Notification of correction to third parties

13.2 If:

(a) the APP entity corrects personal information about an individual that the entity previously disclosed to another APP entity; and

(b) the individual requests the entity to notify the other APP entity of the correction;

the entity must take such steps (if any) as are reasonable in the circumstances to give that notification unless it is impracticable or unlawful to do so.

Refusal to correct information

13.3 If the APP entity refuses to correct the personal information as requested by the individual, the entity must give the individual a written notice that sets out:

(a) the reasons for the refusal except to the extent that it would be unreasonable to do so; and

(b) the mechanisms available to complain about the refusal; and

(c) any other matter prescribed by the regulations.

Request to associate a statement

13.4 If:

(a) the APP entity refuses to correct the personal information as requested by the individual; and

(b) the individual requests the entity to associate with the information a statement that the information is inaccurate, out-of-date, incomplete, irrelevant or misleading;

the entity must take such steps as are reasonable in the circumstances to associate the statement in such a way that will make the statement apparent to users of the information.

Dealing with requests

13.5 If a request is made under subclause 13.1 or 13.4, the APP entity:

(a) must respond to the request:

(i) if the entity is an agency—within 30 days after the request is made; or

(ii) if the entity is an organisation—within a reasonable period after the request is made; and

(b) must not charge the individual for the making of the request, for correcting the personal information or for associating the statement with the personal information (as the case may be).

16B Permitted health situations in relation to the collection, use or disclosure of health information

Collection—provision of a health service

1 A permitted health situation exists in relation to the collection by an organisation of health information about an individual if:

(a) the information is necessary to provide a health service to the individual; and

(b) either:

(i) the collection is required or authorised by or under an Australian law (other than this Act); or

(ii) the information is collected in accordance with rules established by competent health or medical bodies that deal with obligations of professional confidentiality which bind the organisation.

Collection—research etc.

2. A permitted health situation exists in relation to the collection by an organisation of health information about an individual if:

(a) the collection is necessary for any of the following purposes:

(i) research relevant to public health or public safety;

(ii) the compilation or analysis of statistics relevant to public health or public safety;

(iii) the management, funding or monitoring of a health service; and

(b) that purpose cannot be served by the collection of information about the individual that is de-identified information; and

(c) it is impracticable for the organisation to obtain the individual's consent to the collection; and

(d) any of the following apply:

(i) the collection is required by or under an Australian law (other than this Act);

(ii) the information is collected in accordance with rules established by competent health or medical bodies that deal with obligations of professional confidentiality which bind the organisation;

(iii) the information is collected in accordance with guidelines approved under section 95A for the purposes of this subparagraph.

Use or disclosure—research etc.

3. A permitted health situation exists in relation to the use or disclosure by an organisation of health information about an individual if:

(a) the use or disclosure is necessary for research, or the compilation or analysis of statistics, relevant to public health or public safety; and

(b) it is impracticable for the organisation to obtain the individual's consent to the use or disclosure; and

(c) the use or disclosure is conducted in accordance with guidelines approved under section 95A for the purposes of this paragraph; and

(d) in the case of disclosure—the organisation reasonably believes that the recipient of the information will not disclose the information, or personal information derived from that information.

Use or disclosure—genetic information

4. A permitted health situation exists in relation to the use or disclosure by an organisation of genetic information about an individual (the first individual) if:

(a) the organisation has obtained the information in the course of providing a health service to the first individual; and

(b) the organisation reasonably believes that the use or disclosure is necessary to lessen or prevent a serious threat to the life, health or safety of another individual who is a genetic relative of the first individual; and

(c) the use or disclosure is conducted in accordance with guidelines approved under section 95AA; and

(d) in the case of disclosure—the recipient of the information is a genetic relative of the first individual.

Disclosure—responsible person for an individual

5. A permitted health situation exists in relation to the disclosure by an organisation of health information about an individual if:

(a) the organisation provides a health service to the individual; and

(b) the recipient of the information is a responsible person for the individual; and

(c) the individual:

(i) is physically or legally incapable of giving consent to the disclosure; or

(ii) physically cannot communicate consent to the disclosure; and

(d) another individual (the carer) providing the health service for the organisation is satisfied that either:

(i) the disclosure is necessary to provide appropriate care or treatment of the individual; or
(ii) the disclosure is made for compassionate reasons; and

(e) the disclosure is not contrary to any wish:
(i) expressed by the individual before the individual became unable to give or communicate consent; and
(ii) of which the carer is aware, or of which the carer could reasonably be expected to be aware; and

(f) the disclosure is limited to the extent reasonable and necessary for a purpose mentioned in paragraph (d).

The Guidelines approved under Section 95 of the Privacy Act 1988 provide a framework for human research ethics committees (HRECs) and those involved in conducting research, the compilation or analysis of statistics or health service management, to weigh the public interest in research, or the compilation or analysis of statistics, or health service management activities against the public interest in the protection of privacy. The guidelines contain procedures to follow in preparing proposals to be submitted to an HREC for approval to collect, use or disclose health information held by organisations without consent from the individual(s) involved and guidelines for HRECs to follow when considering proposals. Available at https://www.nhmrc.gov.au/guidelines/publications/pr1.

OFFICE OF THE AUSTRALIAN INFORMATION COMMISSIONER GPO Box 5218, SYDNEY, NSW, 2001
Telephone 1300 363 992 TTY 133 677, ask for 1300 363 992 Fax (02) 9284 9666

From: s47F @unisa.edu.au>
Sent: Monday, 7 August 2017 2:46 PM
To: ddvahrec s47F
Cc: s47E(d) va.gov.au'; s47E(d) s47F 'ethics.committee@dva.gov.au'
Subject: RE: 170807 - A/EO - s47F Request for Additional Information - Research Protocol Amendment - E016/007 Veterans' MATES [SEC=UNCLASSIFIED]
Attachments: Ethics DVA E016-007 MATES Application 0116 updated for NDI data (ID 21730).docx

Categories: Blue Category

Hi s47E(d)

I have attached the original Veterans MATES ethics request application. I have highlighted in yellow the section where I have made changes to indicate how we will use the data from the National Death Index for the program.

With regards to your question, yes the NDI database is the one that was used in the study that AIHW did to estimate the Incidence of Suicide in Ex-Serving Australian Defence Force Members.

Kind regards

s47F

From: s47E(d) @defence.gov.au] **On Behalf Of** ddvahrec
Sent: Monday, 7 August 2017 7:33 AM
To: s47F @unisa.edu.au>
Cc: s47F @unisa.edu.au>; s47E(d) @dva.gov.au' s47E(d) @dva.gov.au>; s47E(d) @dva.gov.au>; s47F s47F @unisa.edu.au>; 'ethics.committee@dva.gov.au' <ethics.committee@dva.gov.au>; ddvahrec <ddva.hrec@defence.gov.au>
Subject: 170807 - A/EO - s47F Request for Additional Information - Research Protocol Amendment - E016/007 Veterans' MATES [SEC=UNCLASSIFIED]

UNCLASSIFIED

Dear s47F

Can you please provide the updated research protocol for consideration with your request for amendment. Can I please also clarify if the NDI database is the one that relates to the Estimation of Incidence of Suicide in Ex-Serving Australian Defence Force Members.

Kind regards

s47E(d)
A/Executive Officer
Departments of Defence and Veterans' Affairs Human Research Ethics Committee
Health Research Coordination
Strategic Health Coordination | Joint Health Command

Department of Defence
s47E(d)
Ph: s47E(d)
Email: s47E(d) @defence.gov.au

From: s47F @unisa.edu.au]
Sent: Friday, 4 August 2017 4:11 PM
To: ddvahrec
Cc: s47F s47E(d) @dva.gov.au;s47E(d) s47F
Subject: Research Protocol Amendment Form Request - E016/007

Please find attached a research project amendment request for DVA Research Protocol number E016/007, for your consideration.

Kind regards,
s47F

s47F
Veterans' MATES Program
Quality Use of Medicines and Pharmacy Research Centre
Sansom Institute I School of Pharmacy and Medical Sciences I University of South Australia
GPO Box 2471 ADELAIDE SA 5001
Phone: s47F I Fax: s47F I Email: s47F @unisa.edu.au

CRICOS Provider No. 00121B

Australian Government
Department of Defence
Department of Veterans' Affairs

Departments of Defence and Veterans' Affairs Human Research Ethics Committee
CP3-6-036, Campbell Park Offices, PO Box 7912, Canberra BC ACT 2610

2017/1102173

DDVA HREC/OUT/2017/R30937304

9 August 2017

s47F
University of South Australia

Dear s47F

E016/007 ***Veterans' Medicines Advice and Therapeutics Education Services***

The amendment to this project to link DVA administrative health claims data used as part of the Veterans' MATES program with the National Death Index, submitted on 4 August 2017 was approved out-of-session by the Chair of the Departments of Defence and Veterans' Affairs Human Research Ethics Committee (DDVA HREC) on 9 August 2017.

You must forward a copy of this letter to all Principal Investigators and to your institution. Please note that all requirements of the original ethical approval for this project still apply.

Should you wish to discuss this matter, please contact the DDVA HREC Secretariat on s47E(d) or ddva.hrec@defence.gov.au.

The DDVA HREC wishes you every continued success in your research.

Yours sincerely

s22

s47E(d)
A/Executive Officer

For
s47E(d)
Chair, Departments of Defence and Veterans' Affairs Human Research Ethics Committee

The Departments of Defence and Veterans' Affairs Human Research Ethics Committee is constituted and operates in accordance with the *National Statement on Ethical Conduct in Human Research (2007).*

DEPARTMENTS OF DEFENCE AND VETERANS' AFFAIRS HUMAN RESEARCH ETHICS COMMITTEE
RESEARCH PROJECT PROGRESS REPORT

The 'National Statement on Ethical Conduct in Human Research' section 5.5.5 requires researchers to provide progress reports to the relevant ethical review body/ies and institution/s.

In accordance with the signed Principal Investigator's Report, progress reports are to be submitted to Departments of Defence and Veterans' Affairs Human Research Ethics Committee on a six-monthly basis. **Progress Reports are to be submitted by 1 June and 1 December of each calendar year for the duration of the study.**

Reports are to be signed by the 1st listed Principal Investigator. Failure to submit a progress report may result in withdrawal of ethical approval.

Completed reports are to be emailed to ddva.hrec@defence.gov.au

Note: *To check a box electronically, right click on the box, and select "Properties" then mark the "Default value" as "**Checked".***

Section 1: Research Project Details

Protocol Number:	E016/007
Project Title:	Veterans MATES Program
Ethical approval date:	19 February 2016
Ethical approval expiration date:	30 Dec 2018
Anticipated completion date:	30 Dec 2018
Is this student research?	**Yes** ☐ **No** ☒

Section 2: Investigator details

Principal Investigator	
Name:	s47F
Organisation (command/division):	University of South Australia
Phone:	s47F
Email:	@unisa.edu.au

Student (where applicable)	
Name:	
Organisation (command/division):	
Phone:	
Email:	

Additional Investigators

List any investigators who have joined the research team since ethical approval was granted (for new research projects) or since the date of the previous Progress Report. Indicate whether each new investigator is listed on a Research Protocol Amendment Form.
If an amendment form was not submitted a request for amendment form must be submitted and include an explanation as to why it was not submitted previously.
Insert additional rows as required.

Name	**Institution**	**Amendment Form**
		Yes ☐ No ☐
		Yes ☐ No ☐

		Yes ☐	No ☐
		Yes ☐	No ☐

Section 3: Research Project Progress Summary

Research project commencement/initiation date:	The contract for the Veterans MATES program was authorised in December 2015 and governance structures were established.

If the research project has not commenced, provide an explanation:
If a research project does not commence within 12 months of receiving ethical approval, the ethical approval will lapse unless there is a valid reason.

Current status of research project

Has the study started?		Yes ☒ No* ☐
If yes, what was the actual start date?		
Is the study ongoing and <u>open to enrolment?</u>		Yes ☐ No ☒
Ongoing but <u>closed to enrolment</u> *(Choose one)*	Active follow-up continues ☐ Long-term follow-up continues ☐ Ongoing analysis only ☒	
If no, do you plan to start this project? **Submission of a Final Report form is also required if there is no intention to start the project.*		Yes ☐ *No ☐
If yes, what is the expected start date?		

Provide a brief summary of the essential aspects of progress or results to date:

2016 Topic 1 "Dementia and changes in behaviour" was distributed in August 2016. Evaluation of changes in medicine use as a result of the topic found the module to be successful in reducing the number of veterans using risperidone for dementia and the time they were taking it for. In addition, we reduced the rate of initiation of this medication in the target population. There did not appear to be inappropriate therapeutic shift to other antipsychotics.
2016 Topic 2 "Reviewing the Medicine Routine" was distributed in November 2016. Evaluation of stakeholder responses indicated the material was well received and provided needed therapeutic information. LMO's indicated they would refer patients for a home medicines review and ask the pharmacist to review the dosing schedule, particularly for patients they thought had difficulty managing their medicines. Many of the veterans targeted reported that they understood why they had been prescribed their medications and did not find directions for taking their medicines confusing. Veterans with multiple difficulties and those with higher number of medicines dispensed in the previous year were more likely to indicate that they would make an appointment to talk with their doctor about having a home medicine review.
2017 Topic 1 "Optimising management of chronic obstructive pulmonary disease" was distributed in March 2017 to 7499 LMOs, 2504 residential aged-care facilities, 8320 pharmacies and accredited pharmacists, as well as 13266 veterans.
Collectively, the responses to this topic indicate that the materials were well received and provided needed therapeutic information. LMOs and pharmacists reported that they would recommend pulmonary rehabilitation to their patients with COPD. The majority of RACF respondents indicated that they would arrange an exercise programs to support pulmonary rehabilitation within their facilities. In addition, health professionals indicated they would

provide reviews and education around the administration and management of inhaled devices. Veteran respondents with COPD were targeted effectively and reported finding the information useful. It also promoted action in veterans with many indicating they would talk to their doctor about pulmonary rehabilitation. 2017 Topic 2 "Wound management" was distributed in June 2017 to 14178 LMOs, 2504 residential aged-care facilities, 8363 pharmacies and accredited pharmacists, as well as 52778 veterans in July 2017. Evaluation will commence later in the year.

Is extension of ethical approval required?	Yes ☐ No ☒
If yes, please indicate when the extension is being requested until and include reasons for the request for extension. ***Note:*** *An extension in excess of three years will not be granted. Any studies that require extensions longer than that period will need to submit an additional request for extension closer to the period of expiration of the revised period of ethical approval.*	
Are records being maintained in accordance with the approved protocol?	Yes ☒ No ☐
Is the research project being conducted according to the protocol?	Yes ☒ No ☐
Are all conditions of ethical approval being met?	Yes ☒ No ☐

Section 4: Participant Summary	
Participant recruitment target:	Not applicable
Recruitment to date:	
Is recruitment on target:	Yes ☐ No ☐
If recruitment is not on target, provide an explanation:	
Withdrawn to date:	
Provide reason(s) for withdrawal:	
Advise participant numbers if multiple reasons apply:	
Do you plan to increase the planned recruitment of participants into the study? ***Any increase in planned recruitment should be notified to the Committee as a substantial amendment for ethical review*	Yes** ☐ No ☐

Section 5: Site Information	
Do you plan to increase the total number of sites proposed for the study? *Note: A request for amendment will be required.*	Yes ☐ No ☒
Has research been discontinued from any site?	Yes ☐ No ☒

Section 6: Adverse Events	
Have there been Adverse Events or Serious Adverse Events occur since the last report?	Yes ☐ No ☒
If yes, please explain:	

If yes, has formal notification been submitted to the Departments of Defence and Veterans' Affairs HREC? *If no, you will need to submit and Adverse Event/Serious Adverse Event Form.*	Yes ☐ No ☐

Section 7: Complaints	
Have any participants, researchers or others expressed any complaint about the project?	Yes ☐ No ☒
If yes, please summarise:	
Have any participants claimed to have suffered harm or injury?	Yes ☐ No ☒
If yes, please summarise:	

Section 8: Clinical Trials		
Is the study a clinical trial? ***If no, go to Section 9***		Yes ☐ No* ☒
Is the study registered on a publicly accessible register?		Yes ☐ No* ☐
If yes, provide the name of the register and the registration number.		Registration Number:
If no:		
a.	What is the reason for non-registration?	
b.	What are you intentions for registration?	

Section 9: Other Issues	
Are there any other developments in the project that you wish to report to the Committee?	Yes ☒ No ☐
If yes, please provide details: An amendment to this project to link DVA administrative health claims data used as part of the Veterans' MATES program with the National Death Index, submitted on 4 August 2017 was approved out-of-session by the Chair of the Departments of Defence and Veterans' Affairs Human Research Ethics Committee (DDVA HREC) on 9 August 2017.	
Are there any ethical issues on which further advice is required?	Yes ☐ No ☒
If yes, please provide details:	

Section 10: Declaration	
I confirm that this project is being conducted in keeping with the conditions of ethical approval, and accurately reflects the status of the above research project. I confirm that the project is being conducted in compliance with the *National Statement on Ethical Conduct in Human Research*. I confirm that I have not received any information in any form from anyone involved in the project to suggest this report does not accurately reflect the progress of the project to date.	

PI Signature s47F	**PI Printed Name:** s47F
Date:	**25/08/2017**

From: s47E(d)
Sent: 2017 1:44 PM
To: ddvahrec; s47F 'Ethics.Committee'
Cc: s47F
Subject: 170829 - DDVA HREC-s47F Acknowledgment of Progress Report - E016/007 Veterans' MATES Program [SEC=UNCLASSIFIED]

Categories: File

UNCLASSIFIED

Dear s47F

Thank you for submitting your Progress Report on 25 August 2017 for protocol E016/007.
Your report was reviewed by the Deputy Chair of DDVA HREC and no concerns were raised.

Your next Progress Report is due by **1 June 2018.**

Kind regards

s47E(d)

s47E(d) Research Administrative Officer
f Defence and Veterans' Affairs Human Research Ethics Committee
Directorate of Health Research Co-ordination
Joint Health Command
Department of Defence

s47E(d) Campbell Park | PO Box 7912 Canberra BC ACT 2610 Australia
s47E(d) | E. ddva.hrec@defence.gov.au

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IMPORTANT: This email remains the property of the Department of Defence and is subject to the jurisdiction of section 70 of the Crimes Act 1914. If you have received this email in error, you are requested to contact the sender and delete the email.

From: s47F @unisa.edu.au]
Sent: Friday, 25 August 2017 11:22 AM
To: ddvahrec; 'Ethics.Committee'
Cc: s47F
Subject: 170825 - s47F - DDVA HREC - Progress Report - E016/007 Veterans' MATES Program

Hi s47E(d)

Please find attached bi-annual progress report E016/007 Veteran MATES Program for consideration at your next meeting.

Kind regards,
s47F

s47F
Veterans' MATES Program
Quality Use of Medicines and Pharmacy Research Centre
Sansom Institute I School of Pharmacy and Medical Sciences I University of South Australia
GPO Box 2471 ADELAIDE SA 5001
Phone: s47F I Fax: s47F I Email: s47F @unisa.edu.au

CRICOS Provider No. 00121B

DEPARTMENTS OF DEFENCE AND VETERANS' AFFAIRS HUMAN RESEARCH ETHICS COMMITTEE
RESEARCH PROTOCOL AMENDMENT FORM

In the event that an approved research project requires amendment, this form must be submitted to the Departments of Defence and Veterans' Affairs Human Research Ethics Committee (DDVA HREC) by the Principal Investigator (PI).

An amendment **must not** be implemented until approval has been granted by the committee.

All completed forms are to be electronically submitted to ddva.hrec@defence.gov.au

Section 1: Project Details	
Protocol Number:	E016/007
Project Title:	Veterans MATES Program
Ethical approval date:	19 February 2016
Ethical approval expiration date:	30 Dec 2018
Date of amendment submission:	14 May 2018

Section 2: Investigator Details	
Name:	s47F
Organisation (command/division):	University of South Australia (UniSA)
Phone:	s47F
Email:	@unisa.edu.au

Section 3: Amendment Details

Explain the proposed/ intended changes *(may include changes in procedure, direction of project, source/manner of recruitment, number of participants or changes to research personnel)*

An additional seven personnel who have involvement in the research, service delivery or administration of the program have been added.

Reason for the changes *(include a comment on the impact on the research project and the participants at sites)*

Four staff are engaged in the roles of s47F . Two staff have been employed in new roles to support the digital health strategy within the program. We have also added s47F who is the research centre manager, as she has oversight of the whole of the Centre's business, of which Veterans' MATES is a part. Roles for new personnel are as follows:

s47F

s47F (Service provided via sub-contract arrangement with s47F role is to facilitate the development, implementation and evaluation of the digital health platform of the Veterans'MATES program.)

s47F (All staff listed in original application are still involved in the Veteran MATES Program.)
Do these changes raise any ethical issues? ☐ Yes ☑ No
If yes, identify the ethical issues.
List all amended documents to be reviewed.

Document Title *(include version number, if applicable)* *Insert additional rows if required.*	**Version Date**
s47F _ CV	
s47F Resume	
s47F Resume	
s47F CV	
s47F CV	
s47F CV	
s47F Resume	

Section 4: Participating Sites

Are all participating sites affected by this amendment? ☑ Yes ☐ No
If no, list all affected sites below. Insert additional rows if required.

Site *(Organisation)*	**State**

An amendment to an approved research protocol may also impact the individual research sites. The Commanding Officer (CO) at each affected site (named above) must be notified of the amendment by the PI to determine if the site is impacted. Final approval to implement an amendment at a site will be issued by that site's CO.

Section 5: Declaration

I confirm that this project is being conducted in keeping with the conditions of ethical approval. I confirm that the project is being conducted in compliance with the *National Statement on Ethical Conduct in Human Research*.

I confirm that I have not received any information in any form from anyone involved in the research to suggest this report does not accurately reflect the progress of the project.

s47F	s47F
PI Signature	**PI Printed Name**
Date: 29 May 2018	

From: s47E(d) on behalf of ddvahrec
Sent: Wednesday, 30 May 2018 12:05 PM
To: s47F
Cc: ddvahrec; s47F
Subject: 20180530 (1205h) - Eo s47F Acknowledgement of Progress Report & extension to period of ethical approval - E016/007 Veterans' MATES Program

UNCLASSIFIED

Dear s47F

Thank you for submitting the Progress Report for the above mentioned study. I have reviewed the report on behalf of the Departments of Defence and Veterans' Affairs Human Research Ethics Committee and no concerns were raised. An extension to the period of ethical approval has been granted until **30 May 2021** (noting the guidance in the DDVA HREC Researcher and Administrative Guidelines). If you require another extension beyond this date please submit a request for an extension closer to the date of expiration of ethical approval.

Your next Progress Report is due by **1 December 2018.**

In relation to the request for amendment, a separate email will be sent regarding this.

Kind regards

s47E(d)
Executive Officer, Departments of Defence and Veterans' Affairs Human Research Ethics Committee
s47E(d) Campbell Park Offices, PO Box 7911, Canberra BC ACT 2610
Phone: s47E(d)
Website: http://www.defence.gov.au/health/hrec/

From s47F @unisa.edu.au]
Sent: Wednesday, 30 May 2018 9:38 AM
To: ddvahrec
Subject: FW: 20180525 - AO - s47F further information for Progress Report & Research Protocol Amendment form - E016/007 Veterans' MATES Program [SEC=UNCLASSIFIED]

Hi s47E(d)

Please find attached updated reports as requested. I also would like to send some additional attachments but my first attempt indicated the documents were too large. Details below.

Regards,
s47F

From s47F
Sent: Wednesday, 30 May 2018 9:04 AM
To: 'ddvahrec' <ddva.hrec@defence.gov.au>
Cc: 'Ethics.Committee' <ETHCOM@dva.gov.au>;s47F @unisa.edu.au)
s47F @unisa.edu.au>; s47F @unisa.edu.au>
Subject: RE: 20180525 - AO s47F further information for Progress Report & Research Protocol Amendment form - E016/007 Veterans' MATES Program [SEC=UNCLASSIFIED]

Dear s47E(d)

Please find attached Research Progress Report and Research Protocol Amendment Form, both updated with additional information as requested.

Also, please find attached 2017 Veterans'MATES Report with accompanying cover letter. Both of these documents form part of additional background information referenced in the Research Progress Report.

Kind regards,
s47F

From: s47E(d) @defence.gov.au] **On Behalf Of** ddvahrec
Sent: Friday, 25 May 2018 1:35 PM
To: s47F @unisa.edu.au>; ddvahrec <ddva.hrec@defence.gov.au>
Cc: 'Ethics.Committee' <ETHCOM@dva.gov.au>;s47F @unisa.edu.au>;s47F
s47F @unisa.edu.au>
Subject: 20180525 - AO - s47F - further information for Progress Report & Research Protocol Amendment form - E016/007 Veterans' MATES Program [SEC=UNCLASSIFIED]

UNCLASSIFIED

Dear s47F

Thank you for submitting your progress report, protocol amendment and CVs. We require some further information for each of these forms which I have listed below:

Research Protocol Amendment
Section 3 - Amendment Details:
The amendment states that a number of research personnel are being replaced. Please advise who is no longer involved in the project?
Can you please advise on what roles the new personnel are specifically responsible for?

Research Project Report
Section 3 – please list the start date of the protocol
Provide a brief summary of the essential aspects of progress or results:
Thank you for providing the current outcomes. Could you please provide some further background information about what has occurred such as, when was data obtained; what years does it relate too etc.

Kind regards,

s47E(d)
Administration Officer, Departments of Defence and Veterans' Affairs Human Research Ethics Committee
s47E(d) Campbell Park Offices, PO Box 7911, Canberra BC ACT 2610
Phone: s47E(d)
(Please note that I work at Defence on Wednesdays only)

From: s47F @unisa.edu.au]
Sent: Monday, 14 May 2018 3:48 PM
To: ddvahrec
Cc: 'Ethics.Committee'; s47F
Subject: DDVA HREC - Progress Report & Research Protocol Amendment form - E016/007 Veterans' MATES Program

Good afternoon,

Please find attached the following items for consideration at your next meeting:

- bi-annual Progress Report E016/007 Veteran MATES Program
- Research Protocol Amendment Form including CVs for additional personnel.

Kind regards,

s47F

s47F
Veterans' MATES Program
Quality Use of Medicines and Pharmacy Research Centre
Sansom Institute I School of Pharmacy and Medical Sciences I University of South Australia
GPO Box 2471 ADELAIDE SA 5001
Phone: s47F I Fax: s47F I Email: s47F @unisa.edu.au

CRICOS Provider No. 00121B

Australian Government
Department of Defence
Department of Veterans' Affairs

Departments of Defence and Veterans' Affairs Human Research Ethics Committee
CP3-7-038 Campbell Park Offices, PO Box 7912, Canberra BC ACT 2610

2017/1102173

DDVA HREC/OUT/2018/R34628197

30 May 2018

s47F
University of South Australia

Dear s47F

E016/007 Veterans' Medicines Advice and Therapeutic Education Services

The amendment to this project submitted on 14 May 2018 was considered out-of-session by me on behalf of the Departments of Defence and Veterans' Affairs Human Research Ethics Committee (DDVA HREC).

I have approved the inclusion of the following research personnel:

- s47F
-
-
-

I have also noted the request to include s47F s47F and s47F on the research team. I am culum vitae for these personnel prior to approval of their inclusion on the project, noting the guidance in National Statement paragraph 1.1(e). Can you please also what role s47F holds on the s47F

Should you wish to discuss this matter, please contact the DDVA HREC Secretariat on s47 E(d s47E(d) or ddva.hrec@defence.gov.au.

Yours sincerely

s22

s47E(d)
Executive Officer, Departments of Defence and Veterans' Affairs Human Research Ethics Committee

DEPARTMENTS OF DEFENCE AND VETERANS' AFFAIRS HUMAN RESEARCH ETHICS COMMITTEE
RESEARCH PROJECT PROGRESS REPORT

The 'National Statement on Ethical Conduct in Human Research' section 5.5.5 requires researchers to provide progress reports to the relevant ethical review body/ies and institution/s.

In accordance with the signed Principal Investigator's Assurance, progress reports are to be submitted to Departments of Defence and Veterans' Affairs Human Research Ethics Committee on a six-monthly basis. **Progress Reports are to be submitted by 1 June and 1 December of each calendar year for the duration of the study.**

Reports are to be signed by the 1st listed Principal Investigator. Failure to submit a progress report may result in withdrawal of ethical approval.

Note: Failure to complete all relevant fields will result in the report being returned and the additional information being requested.

Completed reports are to be emailed to ddva.hrec@defence.gov.au

Section 1: Research Project Details

Protocol Number:	E016/007
Project Title:	Veterans MATES Program
Ethical approval date:	19 February 2016
Ethical approval expiration date:	30 Dec 2018
Anticipated completion date:	30 June 2021
Is this student research?	☐ Yes ☑ No

Section 2: Investigator details

Principal Investigator	
Name:	s47F
Organisation (command/division):	University of South Australia (UniSA)
Phone:	s47F
Email:	@unisa.edu.au

Student (where applicable)	
Name:	
Organisation (command/division):	
Phone:	
Email:	

Additional Investigators			
List any investigators who have joined the research team since ethical approval was granted (for new research projects) or since the date of the previous Progress Report. Indicate whether each new investigator is listed on a Research Protocol Amendment Form. If an amendment form was not submitted a request for amendment form must be submitted and include an explanation as to why it was not submitted previously. *Insert additional rows as required.*			
Name		**Institution**	**Amendment Form**
s47F		University of SA	Yes ☒ No ☐
		University of SA	Yes ☒ No ☐
		University of SA	Yes ☒ No ☐
		University of SA	Yes ☒ No ☐
		University of SA	Yes ☒ No ☐
		University of SA	Yes ☒ No ☐
		University of SA	Yes ☒ No ☐

Section 3: Research Project Progress Summary		
Current status of research project		
Has the study started?		☑ Yes ☐ No
If no, please provide an explanation: ***Note:*** *If a research project does not commence within 12 months of receiving ethical approval, the ethical approval will lapse unless there is a valid reason.*		
If yes, what was the actual start date?		The contract between Australian Government Department of Veterans' Affairs (DVA) and UniSA was fully executed on 23 December, 2015. Ethics was granted on 19 February, 2016 and the first intervention was disseminated in August 2016.
Is the study ongoing and <u>open to enrolment?</u>		☐ Yes ☑ No
Ongoing but <u>closed to enrolment</u> *<u>(Choose one)</u>*	☐ Active follow-up continues ☐ Long-term follow up ☑ Ongoing analysis only	
If no, do you plan to start this project? *Note: Submission of a Final Report form is also required if there is no intention to start the project.*		☐ Yes ☐ No
If yes, what is the expected start date?		
Provide a brief summary of the essential aspects of progress or results to date: Our agreement with DVA, executed on the 23 Dec 2016, contracts us to deliver a minimum of four interventions per year. Each intervention is targeted to a specific health or medication-related problem. All veterans who meet the target criteria for the specific intervention are targeted, as are the health professionals who care for the targeted veterans. DVA provides us with the DVA administrative claims data (DVA data) consistent with requirements that meets all physical, logical and personnel requirements laid down by the Australian Government (Department of Defence) Defence Signals Directorate (DSD) in line		

with current versions of the Protective Security Policy Framework (PSPF) and the Australian Government Information Security Manual (ISM) relating to the security of any information that is stored, processed or transmitted in electronic form. Four security audits per annum by either the State Security section of DVA are undertaken.. The DVA data are updated monthly. We will continue to receive the DVA data into the future for the life of the program.
In addition to the summary below of progress to date, please also find attached our Veterans'MATES Report 2017 along with the cover letter.

2016 Topic 1 "Dementia and changes in behaviour" was distributed in August 2016. Evaluation of changes in medicine use as a result of the topic found the module to be successful in reducing the number of veterans using risperidone for dementia and the time they were taking it for. In addition, we reduced the rate of initiation of this medication in the target population. There did not appear to be inappropriate therapeutic shift to other antipsychotics.

2016 Topic 2 "Reviewing the Medicine Routine" was distributed in November 2016. Evaluation revealed an increase in the rate of home medicine reviews as a result of the program.

2017 Topic 1 "Optimising management of chronic obstructive pulmonary disease" was distributed in March 2017 to GPs, residential aged-care facilities (RACF), pharmacies and accredited pharmacists, as well as to veterans. The topic aimed to improve use of pulmonary rehabilitation services amongst veterans with COPD. An increase in physiotherapy services for this cohort has been observed as well as increases in clinics where pulmonary rehabilitation is provided.

2017 Topic 2 "Wound management" was distributed in June 2017 GPs, residential aged-care facilities, pharmacies and accredited pharmacists, as well as to veterans in July 2017. Responses to this topic indicate the materials were well received and suggest actions were promoted by health professionals in relation to the appropriate use of moisturisers for skin tears and compression therapy for venous leg ulcers. The topic successfully promoted the DVA wound care module and the services and treatments available to veterans.

2017 Topic 3 "Reducing the burden of chronic pain" was distributed in September 2017 to GPs, pharmacists and psychologists. Veteran educational material was mailed across two mailings in October and November, 2017. This was the first Veterans' MATES module that targeted psychologists working with veterans. The response rate from psychologists indicated that they thought the materials would be helpful in providing treatment for their veteran patients with chronic pain. They also reported that receiving future modules would be beneficial. The module provided new information to veterans and health professionals regarding the role of opioids in long-term treatment of pain and the therapeutic benefits of understanding pain.

2017 Topic 4 "Management of depression in veterans" was distributed to GPs and pharmacists in December 2017 and to veterans in January, 2018. The materials were well received with majority of health professionals finding the materials helpful in understanding when it might be appropriate to review the duration of antidepressant therapy.

2018 Topic 1 "Medicines and falls" was distributed to GPs, pharmacists, RACFs and veterans in April 2018. Evaluation will commence later in the year.

Is an extension to the period of ethical approval required?	☑ Yes ☐ No

If yes, please indicate when the extension is being requested until and include reasons for the request for extension. ***Note:*** *An extension in excess of three years will not be granted. Any studies that require extensions longer than that period will need to submit an additional request for extension closer to the period of expiration of the revised period of ethical approval.* An extension of 30 months is requested through to 30 June 2021. The Agreement between the DVA and UniSA for the provision of Veterans' MATES services, with an end date of 30 December 2018, included an option for a 3 year extension. DVA has exercised its option to extend the Agreement by 30 months to 30 June, 2021.The variation to the Agreement is now fully executed.

Are records being maintained in accordance with the approved protocol?	☑ Yes ☐ No
If no, please provide details:	
Is the research project being conducted according to the protocol?	☑ Yes ☐ No
If no, please provide details:	
Are all conditions of ethical approval being met?	☑ Yes ☐ No
If no, please provide details:	

Section 4: Participant Summary	
Participant recruitment target:	N/A
Recruitment to date:	
Is recruitment on target:	☐ Yes ☐ No
If recruitment is not on target, provide an explanation:	
Withdrawn to date:	
Provide reason(s) for withdrawal:	
Advise participant numbers if multiple reasons apply:	
Do you plan to increase the planned recruitment of participants into the study? *Note: Any increase in planned recruitment should be notified to the Committee as a substantial amendment for ethical review*	☐ Yes ☐ No

Section 5: Site Information	
Do you plan to increase the total number of sites proposed for the study? *Note: A request for amendment will be required.*	☐ Yes ☑ No
Has research been discontinued from any site?	☐ Yes ☑ No
If yes, please provide details:	

Section 6: Adverse Events	
Have there been Adverse Events or Serious Adverse Events occur since the last report?	☐ Yes ☑ No
If yes, please summarise:	
If yes, has formal notification been submitted to the Departments of Defence and Veterans' Affairs HREC? *If no, you will need to submit and Adverse Event/Serious Adverse Event Form.*	☐ Yes ☐ No

Section 7: Complaints	
Have any participants, researchers or others expressed any complaint about the project?	☐ Yes ☑ No
If yes, please summarise:	
Have any participants claimed to have suffered harm or injury?	☐ Yes ☑ No
If yes, please summarise:	

Section 8: Clinical Trials		
Is the study a clinical trial? *If no, go to Section 9*		☐ Yes ☑ No
Is the study registered on a publicly accessible register?		☐ Yes ☐ No
If yes, provide the name of the register and the registration number.		
If no:		
a.	What is the reason for non-registration?	
b.	What are you intentions for registration?	

Section 9: Other Issues	
Are there any other developments in the project that you wish to report to the Committee?	☑ Yes ☐ No
If yes, please provide details: An amendment to this project to link DVA administrative health claims data used as part of the Veterans' MATES program with the National Death Index (NDI), submitted on 4 August 2017 was approved out-of-session by the Chair of the Departments of Defence and Veterans' Affairs Human Research Ethics Committee (DDVA HREC) on 9 August 2017. An application to the Australian Institute of Health and Welfare ethics committee to link to the NDI was submitted in April 2018 for consideration.	
Are there any ethical issues on which further advice is required?	☐ Yes ☑ No
If yes, please provide details:	

Section 10: Declaration	
I confirm that this project is being conducted in keeping with the conditions of ethical approval, and accurately reflects the status of the above research project. I confirm that the project is being conducted in compliance with the *National Statement on Ethical Conduct in Human Research*. I confirm that I have not received any information in any form from anyone involved in the project to suggest this report does not accurately reflect the progress of the project to date.	
s47F	s47F

PI Signature	**PI Printed Name**
Date:	**29 May 2018**

From: s47F @unisa.edu.au>
Sent: Thursday, 7 June 2018 12:05 PM
To: ddvahrec
Cc: s47F
Subject: 20180607 (1205h) - s47F DDVA HREC - additional information - protocol amendment - E016/007
Attachments: DDVA-Research-Protocol-Amendment-20180601 (ID 25507).pdf; s47F s47F _Resume.pdf; s47F _Resume.pdf; s47F CV.pdf

Categories: File

Dear s47E(d)

Please find attached an updated protocol amendment with additional information as requested. Also, please find attached CVs/resumes for:

- s47F
-
-

Kind regards,
s47F

s47F
Veterans' MATES Program
Quality Use of Medicines and Pharmacy Research Centre
Sansom Institute I School of Pharmacy and Medical Sciences I University of South Australia
GPO Box 2471 ADELAIDE SA 5001
Phone: s47F I Fax: s47F I Email: s47F @unisa.edu.au

CRICOS Provider No. 00121B

From s47E(d) @defence.gov.au] **On Behalf Of** ddvahrec
Sent: Wednesday, 30 May 2018 2:08 PM
To: s47F @unisa.edu.au>
Cc: s47F @unisa.edu.au>; ddvahrec <ddva.hrec@defence.gov.au>
Subject: 20180530 - Approval of amendment (some personnel) - further information for others - E016/007 [SEC=UNCLASSIFIED]

UNCLASSIFIED

Dear s47F
Attached is the letter advising of outcome of the request for a protocol amendment to include additional personnel on the above mentioned study.
Kind regards

s47E(d)
Executive Officer, Departments of Defence and Veterans' Affairs Human Research Ethics Committee

s47E(d) Campbell Park Offices, PO Box 7911, Canberra BC ACT 2610
Phone: s47E(d)
Website: http://www.defence.gov.au/health/hrec/

DEPARTMENTS OF DEFENCE AND VETERANS' AFFAIRS HUMAN RESEARCH ETHICS COMMITTEE
RESEARCH PROTOCOL AMENDMENT FORM

In the event that an approved research project requires amendment, this form must be submitted to the Departments of Defence and Veterans' Affairs Human Research Ethics Committee (DDVA HREC) by the Principal Investigator (PI).

An amendment **must not** be implemented until approval has been granted by the committee.

All completed forms are to be electronically submitted to ddva.hrec@defence.gov.au

Section 1: Project Details	
Protocol Number:	E016/007
Project Title:	Veterans MATES Program
Ethical approval date:	19 February 2016
Ethical approval expiration date:	30 Dec 2018
Date of amendment submission:	14 May 2018

Section 2: Investigator Details	
Name:	s47F
Organisation (command/division):	University of South Australia (UniSA)
Phone:	s47F
Email:	@unisa.edu.au

Section 3: Amendment Details

Explain the proposed/ intended changes *(may include changes in procedure, direction of project, source/manner of recruitment, number of participants or changes to research personnel)*

An additional seven personnel who have involvement in the research, service delivery or administration of the program have been added.

Reason for the changes *(include a comment on the impact on the research project and the participants at sites)*

Four staff are engaged in the roles of s47F Two staff have been employed in new roles to support the digital health strategy within the program. We have also added s47F who is the research centre manager, as she has oversight of the whole of the Centre's business, of which Veterans' MATES is a part. Roles for new personnel are as follows:

s47F

s47F . (Service provided via sub-contract arrangement with s47G . s47F role is to facilitate the development, implementation and evaluation of the digital health platform of the Veterans'MATES program.)

s47F (All staff listed in original application are still involved in the Veteran MATES Program.)
Do these changes raise any ethical issues? ☐ Yes ☑ No
If yes, identify the ethical issues.
List all amended documents to be reviewed.

Document Title *(include version number, if applicable)* *Insert additional rows if required.*	**Version Date**
s47F _ CV	
s47F Resume	
s47F Resume	
s47F CV	
s47F CV	
s47F CV	
s47F Resume	

Section 4: Participating Sites

Are all participating sites affected by this amendment? ☑ Yes ☐ No
If no, list all affected sites below. Insert additional rows if required.

Site *(Organisation)*	**State**

An amendment to an approved research protocol may also impact the individual research sites. The Commanding Officer (CO) at each affected site (named above) must be notified of the amendment by the PI to determine if the site is impacted. Final approval to implement an amendment at a site will be issued by that site's CO.

Section 5: Declaration

I confirm that this project is being conducted in keeping with the conditions of ethical approval. I confirm that the project is being conducted in compliance with the *National Statement on Ethical Conduct in Human Research*.

I confirm that I have not received any information in any form from anyone involved in the research to suggest this report does not accurately reflect the progress of the project.

s47F	s47F
PI Signature	**PI Printed Name**
Date: 29 May 2018	

Australian Government
Department of Defence
Department of Veterans' Affairs

Departments of Defence and Veterans' Affairs Human Research Ethics Committee
CP3-7-038 Campbell Park Offices, PO Box 7912, Canberra BC ACT 2610

2017/1102173

DDVA HREC/OUT/2018/R3475075

8 June 2018

s47F
University of South Australia

Dear s47F

E016/007 Veterans' Medicines Advice and Therapeutic Education Services

Thank you for providing the additional information in support of the protocol amendment that was submitted on 14 May 2018. I have reviewed the more detailed curriculum vitae for s47F s47F and have approved the amendment on behalf of the Departments of Defence and Veterans' Affairs Human Research Ethics Committee (DDVA HREC).

You must forward a copy of this letter to all Principal Investigators and to your institution. Please note that all requirements of the original ethical approval for this project still apply.

Should you wish to discuss this matter, please contact the DDVA HREC Secretariat on s47E(d) or ddva.hrec@defence.gov.au.

The DDVA HREC wishes you every continued success in your research.

Yours sincerely
s22

s47E(d)
Executive Officer, Departments of Defence and Veterans' Affairs Human Research Ethics Committee

DEPARTMENTS OF DEFENCE AND VETERANS' AFFAIRS HUMAN RESEARCH ETHICS COMMITTEE
RESEARCH PROTOCOL AMENDMENT FORM

In the event that an approved research project requires amendment, this form must be submitted to the Departments of Defence and Veterans' Affairs Human Research Ethics Committee (DDVA HREC) by the Principal Investigator (PI).

An amendment **must not** be implemented until approval has been granted by the committee.

All completed forms are to be electronically submitted to ddva.hrec@defence.gov.au

Section 1: Project Details	
Protocol Number:	E016/007
Project Title:	Veterans MATES Program
Ethical approval date:	19 February 2016
Ethical approval expiration date:	30 May 2021
Date of amendment submission:	12 November 2018

Section 2: Investigator Details	
Name:	s47F
Organisation (command/division):	University of South Australia (UniSA)
Phone:	s47F
Email:	@unisa.edu.au

Section 3: Amendment Details	
Explain the proposed/ intended changes *(may include changes in procedure, direction of project, source/manner of recruitment, number of participants or changes to research personnel)*	
An additional person who has involvement in the research of the program has been added.	
Reason for the changes *(include a comment on the impact on the research project and the participants at sites)*	
Additional staff member, s47F has been engaged in a s47F for work with predictive analytics. s47F s47F (All staff listed in original application are still involved in the Veteran MATES Program.)	
Do these changes raise any ethical issues?	☐ Yes ☑ No
If yes, identify the ethical issues.	
List all amended documents to be reviewed.	
Document Title *(include version number, if applicable)* *Insert additional rows if required.*	**Version Date**
s47F CV	

Section 4: Participating Sites

Are all participating sites affected by this amendment? ☑ Yes ☐ No

If no, list all affected sites below. Insert additional rows if required.

Site *(Organisation)*	**State**

An amendment to an approved research protocol may also impact the individual research sites. The Commanding Officer (CO) at each affected site (named above) must be notified of the amendment by the PI to determine if the site is impacted. Final approval to implement an amendment at a site will be issued by that site's CO.

Section 5: Declaration

I confirm that this project is being conducted in keeping with the conditions of ethical approval. I confirm that the project is being conducted in compliance with the *National Statement on Ethical Conduct in Human Research*.

I confirm that I have not received any information in any form from anyone involved in the research to suggest this report does not accurately reflect the progress of the project.

s47F	s47F
PI Signature	**PI Printed Name**
Date: 5 Nov 2018	

Veterans' MATES

Australian Government
Department of Veterans' Affairs

12 November 2018

«Title» «First_Name» «Last_Name»
«Position»
«Organisation»
«Address_1»
«Address_2»
«Surburb» «State» «Postcode»

Dear «Title» «Last_Name»

It is my pleasure to share with you the 2018 Veterans' Medicines Advice and Therapeutics Education Services (MATES) report. The report provides a snapshot of the program's recent accomplishments and showcases the innovative work that has been carried out to support the health and wellbeing of the Australian veteran community. I also encourage you to view the full suite of Veterans' MATES resources and the program's substantial contribution to health services research on the MATES website at https://www.veteransmates.net.au/

Veterans' MATES is funded by the Australian Government Department of Veterans' Affairs.
I look forward to your ongoing support and interest in the Veterans' MATES program.

Yours sincerely

s22

s47E(d) MBBS MPH FAFOEM
Chief Health Officer / Principal Medical Adviser
Australian Government Department of Veterans' Affairs

This page and the following 11 pages are exempt under s22 of the Freedom of Information Act.

From: s47E(d) on behalf of ddvahrec
Sent: Tuesday, 13 November 2018 1:06 PM
To: s47F
Cc: s47F ddvahrec
Subject: 20181113 - ADRE - s47F - Approval of amendment - E016/007 Veterans' Medicines Advice and Therapeutics Education Services [SEC=UNCLASSIFIED]

UNCLASSIFIED

Dear s47F

The amendment to this project submitted on 12 November 2018 to include s47F as an s47F was approved out-of-session by myself on behalf of the Departments of Defence and Veterans' Affairs Human Research Ethics Committee (DDVA HREC) on 13 November 2018.

You must forward a copy of this email to all Principal Investigators and to your institution. Please note that all requirements of the original ethical approval for this project still apply.

Should you wish to discuss this matter, please contact the DDVA HREC Secretariat on s47E(d) or ddva.hrec@defence.gov.au.

The DDVA HREC wishes you every continued success in your research.

Yours sincerely

s47E(d)
Assistant Director Research Ethics

The Departments of Defence and Veterans' Affairs Human Research Ethics Committee is constituted and operates in accordance with the National Health and Medical Research Council's (NHMRC) *National Statement on Ethical Conduct in Human Research.*

From: s47F @unisa.edu.au>
Sent: Monday, 12 November 2018 12:19 PM
To: ddvahrec <ddva.hrec@defence.gov.au>
Cc: 'Ethics.Committee' <ETHCOM@dva.gov.au>; s47F @unisa.edu.au>; s47F s47F @unisa.edu.au>
Subject: DDVA HREC - Progress Report & Research Protocol Amendment form - E016/007 Veterans' MATES Program

Good morning,

Please find attached the following items for consideration at your next meeting:

- Bi-annual Progress Report E016/007 Veteran MATES Program
- Research Protocol Amendment Form along with CV
- 2018 Veterans' MATES Report & cover letter, referenced in the Research Progress Report

Kind regards,

s47F

s47F
Veterans' MATES Program
Quality Use of Medicines and Pharmacy Research Centre
Sansom Institute I School of Pharmacy and Medical Sciences I University of South Australia
GPO Box 2471 ADELAIDE SA 5001
Phone: s47F I Fax: s47F I Email: s47F @unisa.edu.au

CRICOS Provider No. 00121B

From: s47E(d) on behalf of ddvahrec
Sent: Monday, 4 March 2019 1:45 PM
To: s47F ddvahrec
Cc: ethics.committee@dva.gov.au; s47F
Subject: 20190304 (1344h) - 1044h) - DDVA HREC - Progress Report - E016/007 Veterans' MATES Program

Categories: File

UNCLASSIFIED

Thanks for providing this s47F here were no other concerns with the Progress Report.
The next Progress Report for this study is due by 19 February 2020.
Kind regards

s47E(d)
Assistant Director Research Ethics, Joint Health Command
s47E(d) Campbell Park Offices, PO Box 7911, Canberra BC ACT 2610
Phone: s47E(d)

From: s47F @unisa.edu.au>
Sent: Monday, 4 March 2019 1:39 PM
To: ddvahrec <ddva.hrec@defence.gov.au>
Cc: ethics.committee@dva.gov.au; s47F @unisa.edu.au>; s47F s47F @unisa.edu.au>; s47F @unisa.edu.au>
Subject: RE: 20190207 (1044h) - DDVA HREC - Progress Report - E016/007 Veterans' MATES Program [SEC=UNCLASSIFIED]

Hi s47E(d)

No problem at all. Please find attached the AIHW approval letter.

Kind regards,
s47F

From: s47E(d) @defence.gov.au> **On Behalf Of** ddvahrec
Sent: Monday, 4 March 2019 1:01 PM
To: s47F @unisa.edu.au>
Cc: ethics.committee@dva.gov.au; s47F unisa.edu.au>; s47F s47F @unisa.edu.au>; s47F @unisa.edu.au>; ddvahrec <ddva.hrec@defence.gov.au>
Subject: RE: 20190207 (1044h) - DDVA HREC - Progress Report - E016/007 Veterans' MATES Program [SEC=UNCLASSIFIED]

UNCLASSIFIED

Hi s47F

Thank you for contacting me about my request. Upon further review I have overlooked the amendment that was submitted and approved in August 2017. I apologise for the confusion.
Can you please send me though a copy of the AIHW approval letter for this for inclusion on our files.
Kind regards

s47E(d)
Assistant Director Research Ethics, Joint Health Command
s47E(d) Campbell Park Offices, PO Box 7911, Canberra BC ACT 2610
Phone: s47E(d)

From: s47E(d) @defence.gov.au> **On Behalf Of** ddvahrec
Sent: Friday, 1 March 2019 4:20 PM
To: s47F @unisa.edu.au>; ddvahrec <ddva.hrec@defence.gov.au>
Cc: ethics.committee@dva.gov.au; s47F @unisa.edu.au>; s47F s47F @unisa.edu.au>; s47F @unisa.edu.au>
Subject: RE: 20190207 (1044h) - DDVA HREC - Progress Report - E016/007 Veterans' MATES Program [SEC=UNCLASSIFIED]

UNCLASSIFIED

Good afternoon s47F
Thank you for submitting the progress report for the above mentioned study. I have reviewed the report and note that since the last report was tabled you received approval for the amendment relating the linkage to NDI data that was approved by the AIHW HREC. In reviewing our files, I have noticed that an amendment to reflect the additional data set has not been submitted to the DDVA HREC. Can you please submit a protocol amendment and include a copy of the AIHW ethical approval letter in support of the amendment.
Kind regards

s47E(d)
Assistant Director Research Ethics, Joint Health Command
s47E(d) Campbell Park Offices, PO Box 7911, Canberra BC ACT 2610
Phone: s47E(d)

From: s47F @unisa.edu.au>
Sent: Thursday, 7 February 2019 10:44 AM
To: ddvahrec <ddva.hrec@defence.gov.au>
Cc: ethics.committee@dva.gov.au; s47F @unisa.edu.au>; s47F s47F @unisa.edu.au>; s47F @unisa.edu.au>
Subject: 20190207 (1044h) - DDVA HREC - Progress Report - E016/007 Veterans' MATES Program

Good morning,

Please find attached the Bi-annual Progress Report E016/007 Veterans' MATES Program and Veterans' MATES 2018 Report & cover letter, referenced in the Progress Report, for consideration at your next meeting:

Kind regards,
s47F

s47F
Veterans' MATES Program
Quality Use of Medicines and Pharmacy Research Centre
Sansom Institute I School of Pharmacy and Medical Sciences I University of South Australia
GPO Box 2471 ADELAIDE SA 5001
Phone: s47F I Fax: s47F I Email: s47F @unisa.edu.au

CRICOS Provider No. 00121B

DEPARTMENTS OF DEFENCE AND VETERANS' AFFAIRS HUMAN RESEARCH ETHICS COMMITTEE
RESEARCH PROTOCOL AMENDMENT FORM

In the event that an approved research project requires amendment, this form must be submitted to the Departments of Defence and Veterans' Affairs Human Research Ethics Committee (DDVA HREC) by the Principal Investigator (PI).

An amendment **must not** be implemented until approval has been granted by the committee.

All completed forms are to be electronically submitted to ddva.hrec@defence.gov.au

Section 1: Project Details	
Protocol Number:	E016-007
Project Title:	Veterans MATES Program
Ethical approval date:	19 February 2016
Ethical approval expiration date:	30 May 2021
Date of amendment submission:	

Section 2: Investigator Details	
Name:	s47F
Organisation (command/division):	University of South Australia (UniSA)
Phone:	s47F
Email:	@unisa.edu.au

Section 3: Amendment Details

Explain the proposed/ intended changes *(may include changes in procedure, direction of project, source/manner of recruitment, number of participants or changes to research personnel)*

The Veterans' MATES program directly benefits the health of veterans. The program sends patient specific data provided by DVA to general practitioners to support appropriate care. The veteran's general practitioner also receives tailored evidence based educational materials designed to improve health outcomes. The program, up until now, has provided other health professionals and veterans with tailored educational materials only.
This amendment seeks to further enhance the program by providing, patient specific feedback, where appropriate, directly to veterans in addition to the educational information they already receive.

Reason for the changes *(include a comment on the impact on the research project and the participants at sites)*

The Veterans' MATES interventions target all veterans who meet the criteria for the condition of interest (e.g. musculoskeletal pain, diabetes) and materials are provided to the veteran and their health care team. The materials for each intervention are tailored to the behaviour change targeted in the intervention (e.g. reduction on inappropriate medicine use, increase in under-used services).
The educational material is delivered to veterans via the 'veteran brochure'. Where appropriate, additional materials providing follow up information and reinforcement messages may be provided to veterans who remain within the target groups. The

sequential delivery of these materials provide opportunity for reinforcement of key-messages and build veterans' health literacy over time. The additional materials for veterans take advantage of existing supporting technologies including podcasts, educational videos, infographics, health information animations or decision support tools, where available. We also develop veteran tools, including self-completed questionnaires, which veterans can complete prior to visiting their general practitioner or community pharmacist. All resources developed are designed to support and empower veterans to monitor their own health and engage confidently and proactively with their health professional. General practitioners and pharmacists are made aware of these resources via dissemination of the therapeutic material.

To further support veterans in the management of their health, tailored patient specific feedback would be provided directly to the veteran when relevant and appropriate (for example, notification of no testing for glycosylated haemoglobin for diabetes monitoring in the last six months despite claims for diabetes care). The patient specific feedback would include topic specific information and related claims history relevant to an individual veteran's care. The information provided will be identified from the DVA data. We may also identify and include in the patient-specific feedback, where appropriate, use or lack there of non-pharmacological services, e.g. allied health visits. The patient specific feedback to the veteran will be provided in a manner to enhance the patient-doctor conversation. It will aim to stimulate veteran engagement so that they become more active partners in their own care. It may also enable the veteran to drive improvements and changes in their healthcare. Veterans would be better informed about their own health and may be more likely to take-up medical advice.

Direct patient-related feedback on prescribing will still be relayed to the veterans' GPs. The program will continue to provide therapeutic information to GPs treating veterans which may include advice on prescribing or medical treatment. GPs will be made aware of the feedback provided to veterans they are treating. Any decision to initiate, change or cease medicines or health services will be at the discretion of the treating doctor in consultation with the veteran. No treatment will be administered or changed by the research team. Personal information will not be used for any other purpose.

UniSA discussed the concept of patient specific feedback to veterans as a means of empowered health care with Dr Paul Nicolarakis, Chief Data Officer, Assistant Secretary - Data, Informatics & Research, DVA. The concept was endorsed by the Veterans' MATES Editorial Committee on 1 February, 2019. Members of the committee were advised that an ethics amendment would be sought for patient specific feedback directly to veterans for use in future MATES topics.

Finally, the advent of national infrastructure, including My Health Record, means this information will be available to veterans via their My Health Record account. By proactively providing the same information accompanied by supporting educational material, Veterans' MATES will be assisting veterans to understand the data that are contained in each veterans' My Health Record.

Do these changes raise any ethical issues?	☐ Yes ☑ No

If yes, identify the ethical issues.

We don't believe this raises any ethical issues as the same information will be available to veterans' via their My Health Record account. The advantage of providing this information via the Veterans' MATES program means veterans will be educated to understand the information in My Health Record.

List all amended documents to be reviewed.

Document Title *(include version number, if applicable)* *Insert additional rows if required.*	**Version Date**
N/A	

Section 4: Participating Sites

Are all participating sites affected by this amendment? ☑ Yes ☐ No

If no, list all affected sites below. Insert additional rows if required.

Site *(Organisation)*	**State**

An amendment to an approved research protocol may also impact the individual research sites. The Commanding Officer (CO) at each affected site (named above) must be notified of the amendment by the PI to determine if the site is impacted. Final approval to implement an amendment at a site will be issued by that site's CO.

Section 5: Declaration

I confirm that this project is being conducted in keeping with the conditions of ethical approval. I confirm that the project is being conducted in compliance with the *National Statement on Ethical Conduct in Human Research*.

I confirm that I have not received any information in any form from anyone involved in the research to suggest this report does not accurately reflect the progress of the project.

s47F	s47F
PI Signature	**PI Printed Name**
Date: 12/03/2019	

Australian Government
Department of Defence
Department of Veterans' Affairs

Departments of Defence and Veterans' Affairs Human Research Ethics Committee
CP3-7-038 Campbell Park Offices, PO Box 7912, Canberra BC ACT 2610

DDVA HREC/OUT/2019/BN3900145

14 March 2019

s47F
University of South Australia

Dear s47F

E016/007 Veterans MATES Program

The amendment to this project submitted on 12 March 2019 was approved by the Chair of the Departments of Defence and Veterans' Affairs Human Research Ethics Committee (DDVA HREC) on 12 March 2019. The approval includes the addition of providing specific feedback to patients, where appropriate.

You must forward a copy of this letter to all Principal Investigators and to your institution. Please note that all requirements of the original ethical approval for this project still apply.

Should you wish to discuss this matter, please contact the DDVA HREC Secretariat on s47E(d) or ddva.hrec@defence.gov.au.

The DDVA HREC wishes you every continued success in your research.

Yours sincerely

s22

s47E(d)
Assistant Director Research Ethics

For
s47E(d)
Chair, Departments of Defence and Veterans' Affairs Human Research Ethics Committee

DEPARTMENTS OF DEFENCE AND VETERANS' AFFAIRS HUMAN RESEARCH ETHICS COMMITTEE
RESEARCH PROTOCOL AMENDMENT FORM

In the event that an approved research project requires amendment, this form must be submitted to the Departments of Defence and Veterans' Affairs Human Research Ethics Committee (DDVA HREC) by the Principal Investigator (PI).

An amendment **must not** be implemented until approval has been granted by the committee.

All completed forms are to be electronically submitted to ddva.hrec@defence.gov.au

Section 1: Project Details	
Protocol Number:	E016-007
Project Title:	Veterans MATES Program
Ethical approval date:	19 February 2016
Ethical approval expiration date:	30 May 2021
Date of amendment submission:	

Section 2: Investigator Details	
Name:	s47F
Organisation (command/division):	University of South Australia (UniSA)
Phone:	s47F
Email:	@unisa.edu.au

Section 3: Amendment Details		
Explain the proposed/ intended changes *(may include changes in procedure, direction of project, source/manner of recruitment, number of participants or changes to research personnel)*		
Two additional personnel with involvement in the service delivery or project administration of the program have been added. Two staff members, s47F s47F have left UniSA and are therefore are no longer involved in the Veterans MATES Program.		
Reason for the changes *(include a comment on the impact on the research project and the participants at sites)*		
The two new staff are engaged in the roles of s47F and s47F s47F s47F s47F		
Do these changes raise any ethical issues?	☐ Yes	☒ No
If yes, identify the ethical issues.		
List all amended documents to be reviewed.		
Document Title *(include version number, if applicable)* *Insert additional rows if required.*		**Version Date**
s47F CV		
s47F CV		

Section 4: Participating Sites

Are all participating sites affected by this amendment? *If no, list all affected sites below. Insert additional rows if required.*	☒ Yes	☐ No
Site *(Organisation)*	**State**	

An amendment to an approved research protocol may also impact the individual research sites. The Commanding Officer (CO) at each affected site (named above) must be notified of the amendment by the PI to determine if the site is impacted. Final approval to implement an amendment at a site will be issued by that site's CO.

Section 5: Declaration

I confirm that this project is being conducted in keeping with the conditions of ethical approval. I confirm that the project is being conducted in compliance with the *National Statement on Ethical Conduct in Human Research*.

I confirm that I have not received any information in any form from anyone involved in the research to suggest this report does not accurately reflect the progress of the project.

s47F	s47F
PI Signature	**PI Printed Name**
Date: 30 January, 2020	

<insert date>

<Name>
<Position>
<Organisation>
<Address 1>
<Address 2>
<Suburb> <State> <Postcode>

Dear <Title> <Last Name>

I am pleased to share with you the 2019 Veterans' Medicines Advice and Therapeutics Education Services (MATES) report. The report highlights the program's recent accomplishments in the area of mental health and chronic pain and provides a snapshot of the innovative work that has been carried out within the program to support the health and wellbeing of the Australian veteran community. The full suite of Veterans' MATES resources is available on the MATES website at https://www.veteransmates.net.au.

Veterans' MATES is funded by the Australian Government Department of Veterans' Affairs.

I look forward to your ongoing support and interest in the Veterans' MATES program.

Yours sincerely

s22

s47E(d)
Chief Health Officer
Australian Government of Department of Veterans' Affairs

DEPARTMENTS OF DEFENCE AND VETERANS' AFFAIRS HUMAN RESEARCH ETHICS COMMITTEE
RESEARCH PROJECT PROGRESS REPORT

The 'National Statement on Ethical Conduct in Human Research' section 5.5.5 requires researchers to provide progress reports to the relevant ethical review body/ies and institution/s.

Progress reports are to be submitted to Departments of Defence and Veterans' Affairs Human Research Ethics Committee at least annually. For clinical trials, progress reports are to be submitted six monthly. Due dates for submission of the reports will be stated on the Principal Investigators Assurance.

Reports are to be signed by the 1st listed Principal Investigator. Failure to submit a progress report may result in withdrawal of ethical approval.

Note: Failure to complete all relevant fields will result in the report being returned and the additional information being requested.

Completed reports are to be emailed to ddva.hrec@defence.gov.au

Section 1: Research Project Details

Protocol Number:	E016/007
Project Title:	Veterans' MATES Program
Ethical approval date:	19 February 2016
Ethical approval expiration date:	30 May 2021
Anticipated completion date:	30 June 2021
Is this student research?	☐ Yes ☒ No

Section 2: Investigator details

Principal Investigator

Name:	s47F
Organisation (command/division):	University of South Australia (UniSA)
Phone:	s47F
Email:	@unisa.edu.au

Student (where applicable)

Name:	
Organisation (command/division):	
Phone:	
Email:	

Additional Investigators				
List any investigators who have joined the research team since ethical approval was granted (for new research projects) or since the date of the previous Progress Report. Indicate whether each new investigator is listed on a Research Protocol Amendment Form. If an amendment form was not submitted a request for amendment form must be submitted and include an explanation as to why it was not submitted previously. *Insert additional rows as required.*				
Name		**Institution**	**Amendment Form**	
s47F		UniSA	☒ Yes	☐ No
		UniSA	☒ Yes	☐ No

Section 3: Research Project Progress Summary

Current status of research project

Has the study started?	☒ Yes	☐ No
If no, please provide an explanation: ***Note:*** *If a research project does not commence within 12 months of receiving ethical approval, the ethical approval will lapse unless there is a valid reason.*		
If yes, what was the actual start date?	The contract between Australian Government Department of Veterans' Affairs (DVA) and UniSA was fully executed on 23 December, 2015. Ethics was granted on 19 February, 2016 and the first intervention was disseminated in August 2016.	
Is the study ongoing and <u>open to enrolment?</u>	☐ Yes	☒ No
Ongoing but <u>closed to enrolment</u> *<u>(Choose one)</u>*	☐ Active follow-up continues ☐ Long-term follow-up continues ☒ Ongoing analysis only	
If no, do you plan to start this project? *Note: Submission of a Final Report form is also required if there is no intention to start the project.*	☐ Yes	☐ No
If yes, what is the expected start date?		

Provide a brief summary of the essential aspects of progress or results to date:

Our agreement with DVA, executed on the 23 Dec 2015, contracts us to deliver a minimum of four interventions per year. Each intervention is targeted to a specific health or medication-related problem. All veterans who meet the target criteria for the specific intervention are targeted, as are the health professionals who care for the targeted veterans.

DVA provides us with the DVA administrative claims data (DVA data) consistent with requirements that meets all physical, logical and personnel requirements laid down by the Australian Government (Department of Defence) Defence Signals Directorate (DSD) in line with current versions of the Protective Security Policy Framework (PSPF) and the Australian

Government Information Security Manual (ISM) relating to the security of any information that is stored, processed or transmitted in electronic form. Four security audits per annum by the State Security section of DVA are undertaken. The DVA data are updated monthly. We will continue to receive the DVA data into the future for the life of the program.
In addition to the summary below of progress to date, please also find attached our Veterans' MATES Report 2019 along with the cover letter.

2016 Topic 1 "Dementia and changes in behaviour" was distributed in August 2016. Evaluation of changes in medicine use as a result of the topic found the module to be successful in reducing the number of veterans using risperidone for dementia and the time for which they were taking it. In addition, the rate of initiation of this medication was reduced in the targeted population. There did not appear to be inappropriate therapeutic shift to other antipsychotics.

2016 Topic 2 "Reviewing the Medicine Routine" was distributed in November 2016. Evaluation revealed an increase in the rate of home medicine reviews as a result of the program.

2017 Topic 1 "Optimising management of chronic obstructive pulmonary disease" was distributed in March 2017 to general practitioners (GPs), residential aged-care facilities (RACF), pharmacies and accredited pharmacists, as well as to veterans. The topic aimed to improve use of pulmonary rehabilitation services amongst veterans with COPD. An increase in physiotherapy services for this cohort has been observed as well as increased visits to clinics where pulmonary rehabilitation is provided.

2017 Topic 2 "Wound management" was distributed in June 2017 GPs, residential aged-care facilities, pharmacies and accredited pharmacists, as well as to veterans in July 2017. Responses to this topic indicate the materials were well received and suggest actions were promoted by health professionals in relation to the appropriate use of moisturisers for skin tears and compression therapy for venous leg ulcers. The topic successfully promoted the DVA wound care module and the services and treatments available to veterans.

2017 Topic 3 "Reducing the burden of chronic pain" was distributed in September 2017 to GPs, pharmacists and psychologists. Veterans were sent educational material across two mailings in October and November, 2017. This was the first Veterans' MATES module that targeted psychologists working with veterans. The response rate from psychologists indicated that they thought the materials would be helpful in providing treatment for their veteran patients with chronic pain. They also reported that receiving future modules would be beneficial. The module provided new information to veterans and health professionals regarding the role of opioids in long-term treatment of pain and the therapeutic benefits of understanding pain.

2017 Topic 4 "Management of depression in veterans" was distributed to GPs and pharmacists in December 2017 and to veterans in January, 2018. The materials were well received with the majority of health professionals finding the materials helpful in understanding when it might be appropriate to review the duration of antidepressant therapy.

2018 Topic 1 "Medicines and falls" was distributed to GPs, pharmacists, RACFs and veterans in April 2018. The module highlighted to health professionals the benefits of using a multifactorial approach to prevent falls in their veteran patients and review medicines that may increase the patient's risk of falls.

2018 Topic 2 “Osteoporosis management” distributed to GPs and pharmacists in June 2018 and to veterans in July 2018. The majority of health professionals indicated that the materials encouraged them to recall patients who are at risk of osteoporosis and understand optimal diagnosis, prevention and treatment.

2018 Topic 3 “Proton pump inhibitors” (PPIs) was distributed to GPs, pharmacists and RACFs in August 2018 and to veterans in September 2018. Evaluation revealed the majority of GPs indicated at least one veteran listed in the prescriber feedback required a review of their PPI medicines. Veterans reported that they intended to make a specific appointment to speak with their doctor about taking a lower dose of their PPI or using the medicine only when symptoms appear.

2018 Topic 4 “Medicines and dry mouth” was distributed to GPs, pharmacists and dentists in November 2018 and to veterans in January 2019. This was the first Veterans’ MATES module to target dentists. The dentists indicated the materials would prompt them to ask if their patients were prescribed medicines that can cause dry mouth or have any symptoms of dry mouth. They also reported that receiving future modules related to dentistry would be beneficial. The module encouraged health professionals to talk to their patients about dry mouth and their medicines. Veterans with symptoms of dry mouth reported that they intended to make an appointment with their GP to discuss their symptoms.

2019 Topic 1 “Cognitive impairment” was distributed to GPs and pharmacists in March 2019 and to veterans in April 2019. Suggested actions were promoted by health professionals in relation to referring patients with cognitive impairment for an occupational therapy assessment, reviewing medication to see if any could be modified to improve cognitive function and considering the need for a dose administration aid. Veterans reported that they would make a specific appointment with their GP to discuss having an occupational therapist visit their home.

2019 Topic 2 “Insomnia management” was distributed to GPs, pharmacists and psychologists in June 2019 and to veterans in July 2019. The materials increased knowledge for health professionals about the treatment of insomnia and the DVA health services available to identify and help veterans with sleep difficulties. Veterans indicated that the materials provided new information about cognitive behavioural therapy for insomnia.

2019 Topic 3 “Renal impairment” was distributed to GPs, pharmacists and RACFs in September 2019 and to veterans in October 2019. Evaluation revealed the majority of GPs reported that a least one of their veterans listed required a review of their medicines that are renally cleared. Veterans indicated that they intended to talk to their GP about their kidney function at their next visit.

2019 Topic 4 “Empowering veterans to manage diabetes” was distributed to GPs, pharmacists in mid-November 2019 and to veterans in late November 2019. Evaluation will commence in 2020.

Is an extension to the period of ethical approval required?	☒ Yes ☐ No

If yes, please indicate when the extension is being requested until and include reasons for the request for extension. ***Note:*** *An extension in excess of three years will not be granted. Any studies that require extensions longer than that period will need to submit an additional request for extension closer to the period of expiration of the revised period of ethical approval.*

An extension of 1 month is requested through to 30 June 2021.The Agreement between DVA and UniSA for the provision of Veterans'MATES services, with an end date of 30 December 2018 included an option for a 3year extension. DVA exercised its option to extend the agreement by 30 months to 30 June 2021. DDVA HREC period of approval was granted until 30 May 2021 with advice to submit a subsequent extension closer to the date of expiration.

Are records being maintained in accordance with the approved protocol?	☒ Yes ☐ No
If no, please provide details:	
Is the research project being conducted according to the protocol?	☒ Yes ☐ No
If no, please provide details:	
Are all conditions of ethical approval being met?	☒ Yes ☐ No
If no, please provide details:	

Section 4: Participant Summary	
Participant recruitment target:	N/A
Recruitment to date:	
Is recruitment on target:	☐ Yes ☐ No
If recruitment is not on target, provide an explanation:	
Withdrawn to date:	
Provide reason(s) for withdrawal:	
Advise participant numbers if multiple reasons apply:	
Do you plan to increase the planned recruitment of participants into the study? *Note: Any increase in planned recruitment should be notified to the Committee as a substantial amendment for ethical review*	☐ Yes ☐ No

Section 5: Site Information	
Do you plan to increase the total number of sites proposed for the study? *Note: A request for amendment will be required.*	☐ Yes ☒ No
Has research been discontinued from any site?	☐ Yes ☒ No
If yes, please provide details:	

Section 6: Adverse Events	
Have there been Adverse Events or Serious Adverse Events occur since the last report?	☐ Yes ☒ No
If yes, please summarise:	
If yes, has formal notification been submitted to the Departments of Defence and Veterans' Affairs HREC? *If no, you will need to submit and Adverse Event/Serious Adverse Event Form.*	☐ Yes ☐ No

Section 7: Complaints	
Have any participants, researchers or others expressed any complaint about the project?	☐ Yes ☒ No
If yes, please summarise:	

Have any participants claimed to have suffered harm or injury?	☐ Yes ☒ No
If yes, please summarise:	

Section 8: Clinical Trials		
Is the study a clinical trial? *If no, go to Section 9*		☐ Yes ☒ No
Is the study registered on a publicly accessible register?		☐ Yes ☐ No
If yes, provide the name of the register and the registration number.		
If no:		
a.	What is the reason for non-registration?	
b.	What are you intentions for registration?	

Section 9: Other Issues	
Are there any other developments in the project that you wish to report to the Committee?	☐ Yes ☒ No
If yes, please provide details:	
Are there any ethical issues on which further advice is required?	☐ Yes ☒ No
If yes, please provide details:	

Section 10: Declaration	
I confirm that this project is being conducted in keeping with the conditions of ethical approval, and accurately reflects the status of the above research project. I confirm that the project is being conducted in compliance with the *National Statement on Ethical Conduct in Human Research*. I confirm that I have not received any information in any form from anyone involved in the project to suggest this report does not accurately reflect the progress of the project to date.	
s47F	s47F
PI Signature	**PI Printed Name**
Date:	**30 January, 2020**

This page and the following 12 pages are exempt under s22 of the Freedom of Information Act.

From: s47E(d) on behalf of ddvahrec
Sent: Thursday, 27 February 2020 3:53 PM
To: s47F ddvahrec
Cc: ethics.committee@dva.gov.au; s47F
Subject: 20200227 (1553h) - 1315h) - DDVA HREC - Progress Report - E016/007 Veterans' MATES Program
Attachments: E016-007 Extension approval - 20200227.pdf

Categories: Reciept for next agenda

UNCLASSIFIED

Hi s47F

I'm so very sorry for the delay in getting a response to you. Our team has been understaffed and swamped with work and as such, while the DDVA HREC Chair actually approved your requests very quickly, unfortunately getting a response back to you slipped under our radar.

The Progress Report, extension request and amendment request submitted on 30 January 2020 for the above mentioned project were all approved by the DDVA HREC Chair out-of-session on behalf of Departments of Defence and Veterans' Affairs Human Research Ethics Committee (DDVA HREC) on 31 January 2020.

Attached is the letter approving the extension request until **30 June 2021**. Your next progress report is due **19 February 2021.**

The approved amendment includes the addition of s47F as a s47F and s47F as a s47F

The approved requests also include:

- Veterans' MATES Report 2019_WEB-double-page (ID 29390)
- CoverLetter for Veterans MATES Report 2019_template APPROVED (ID 30115)
- s47F CV
- CV

You must forward a copy of this email to all Principal Investigators and to your institution. Please note that all requirements of the original ethical approval for this project still apply.

Should you wish to discuss this matter, please contact the DDVA HREC Secretariat on s47E(d) or ddva.hrec@defence.gov.au.

The DDVA HREC wishes you every continued success in your research.

Kind regards

s47E(d)
Senior Research Ethics Officer
Joint Health Command | Department of Defence
s47E(d) Campbell Park Offices, PO Box 7911, Canberra BC ACT 2610
E: ddva.hrec@defence.gov.au
Ph: s47E(d)

From s47F @unisa.edu.au>
Sent: Thursday, 30 January 2020 1:13 PM
To: ddvahrec <ddva.hrec@defence.gov.au>
Cc: ethics.committee@dva.gov.au; s47F @unisa.edu.au>; s47F s47F @unisa.edu.au>; s47F @unisa.edu.au>
Subject: 20200130 (1315h) - DDVA HREC - Progress Report - E016/007 Veterans' MATES Program

Good morning,

Please find attached the attached documents for consideration at your next meeting:

- Bi-annual Progress Report E016/007 Veterans' MATES Program and Veterans' MATES 2019 Report & cover letter, referenced in the Progress Report
- Research Protocol Amendment Form along with CVs

Kind regards,
s47F

s47F
Veterans' MATES Program
Quality Use of Medicines and Pharmacy Research Centre
School of Pharmacy and Medical Sciences I University of South Australia
GPO Box 2471 ADELAIDE SA 5001
Phone: s47F I Fax: s47F I Email: s47F @unisa.edu.au

CRICOS Provider No. 00121B

Australian Government
Department of Defence
Department of Veterans' Affairs

Departments of Defence and Veterans' Affairs Human Research Ethics Committee
CP3-7-038, Campbell Park Offices, PO Box 7912, Canberra BC ACT 2610

DDVA HREC/OUT/2020/BN13985025

27 February 2020

s47F
University of South Australia

Dear s47F

E016-007 – Veterans' Medicines Advice and Therapeutics Education Services (Veterans' MATES Program)

Thank you for submitting a request to extend the period of ethical approval for the above research project. Your request to extend the period of ethical approval until 30 June 2021 was reviewed and approved on 31 January 2020 by the Chair of the Departments of Defence and Veterans' Affairs Human Research Ethics Committee (DDVA HREC) on the following conditions:

- The research is to be conducted in accordance with the approved protocol.
- The Principal Investigator will immediately report anything that might warrant review of ethical approval of the project.
- The Principal Investigator will notify the DDVA HREC of any event that requires an amendment/modification to the protocol or other project documents.
- The Principal Investigator will submit any necessary reports related to the safety of research participants.
- The Principal Investigator will submit progress reports to the DDVA HREC annually and notify DDVA HREC when the project is completed at all sites. The next progress report for this study is due by **19 February 2021.**
- The Principal Investigator will notify the DDVA HREC if the project is discontinued at a participating site before the expected completion date, with reasons provided.
- The Principal Investigator will notify the DDVA HREC of any plan to extend the duration of the project past the approval period listed above and will submit any associated required documentation.
- The Principal Investigator will notify the DDVA HREC of their inability to continue and indicate the name of and contact information for a replacement.

If you have any queries please feel free to contact the DDVA HREC Secretariat on s47E(d) or ddva.hrec@defence.gov.au.

The DDVA HREC wishes you every success in your research.

Yours sincerely

s22

s47E(d)
Assistant Director Research Ethics

For
s47E(d)
Chair, Departments of Defence and Veterans' Affairs Human Research Ethics Committee

The Departments of Defence and Veterans' Affairs Human Research Ethics Committee is constituted and operates in accordance with the National Health and Medical Research Council's (NHMRC) *National Statement on Ethical Conduct in Human Research.*

DEPARTMENTS OF DEFENCE AND VETERANS' AFFAIRS HUMAN RESEARCH ETHICS COMMITTEE
RESEARCH PROTOCOL AMENDMENT FORM

In the event that an approved research project requires amendment, this form must be submitted to the Departments of Defence and Veterans' Affairs Human Research Ethics Committee (DDVA HREC) by the Principal Investigator (PI).

An amendment **must not** be implemented until approval has been granted by the committee.

All completed forms are to be electronically submitted to ddva.hrec@defence.gov.au

Section 1: Project Details	
Protocol Number:	E016-007
Project Title:	Veterans MATES Program
Ethical approval date:	19 February 2016
Ethical approval expiration date:	30June 2021
Date of amendment submission:	

Section 2: Investigator Details	
Name:	s47F
Organisation (command/division):	University of South Australia (UniSA)
Phone:	s47F
Email:	@unisa.edu.au

Section 3: Amendment Details

Explain the proposed/ intended changes *(may include changes in procedure, direction of project, source/manner of recruitment, number of participants or changes to research personnel)*

One additional person with involvement in the service delivery of the program has been added. Three staff members have resigned from UniSA and are therefore are no longer involved in the Veterans MATES Program. s47F
s47F

Reason for the changes *(include a comment on the impact on the research project and the participants at sites)*

The new staff member is fulfilling a key role in program deliverables under Deed of Agreement with Department of Veterans' Affairs.
s47F

Do these changes raise any ethical issues?	☐ Yes ☒ No

If yes, identify the ethical issues.

List all amended documents to be reviewed.

Document Title *(include version number, if applicable)* *Insert additional rows if required.*	**Version Date**
s47F _CV	

Section 4: Participating Sites		
Are all participating sites affected by this amendment? *If no, list all affected sites below. Insert additional rows if required.*	☒ Yes	☐ No
Site *(Organisation)*	**State**	
An amendment to an approved research protocol may also impact the individual research sites. The Commanding Officer (CO) at each affected site (named above) must be notified of the amendment by the PI to determine if the site is impacted. Final approval to implement an amendment at a site will be issued by that site's CO.		

Section 5: Declaration

I confirm that this project is being conducted in keeping with the conditions of ethical approval. I confirm that the project is being conducted in compliance with the *National Statement on Ethical Conduct in Human Research*.

I confirm that I have not received any information in any form from anyone involved in the research to suggest this report does not accurately reflect the progress of the project.

s47F **PI Signature**	s47F **PI Printed Name**
Date: 03/02/2021	

<insert date>

Dear Friends of Veterans' MATES,

I am pleased to share with you the 2020 Veterans' Medicines Advice and Therapeutics Education Services (MATES) report. This year has required individuals, communities and organisations to adapt to a rapidly changing and challenging environment. This report highlights the program's activities to support the veteran community during the COVID-19 pandemic. The full suite of Veterans' MATES resources is available on the MATES website at https://www.veteransmates.net.au.

Veterans' MATES is funded by the Australian Government Department of Veterans' Affairs.

I look forward to your ongoing support and interest in the Veterans' MATES program.

Yours sincerely

s22

s47E(d)

Chief Health Officer
Australian Government of Department of Veterans' Affairs

DEPARTMENTS OF DEFENCE AND VETERANS' AFFAIRS HUMAN RESEARCH ETHICS COMMITTEE
RESEARCH PROJECT PROGRESS REPORT

The 'National Statement on Ethical Conduct in Human Research' section 5.5.5 requires researchers to provide progress reports to the relevant ethical review body/ies and institution/s.

Progress reports are to be submitted to Departments of Defence and Veterans' Affairs Human Research Ethics Committee at least annually. For clinical trials, progress reports are to be submitted six monthly. Due dates for submission of the reports will be stated on the Principal Investigators Assurance.

Reports are to be signed by the 1st listed Principal Investigator. Failure to submit a progress report may result in withdrawal of ethical approval.

Note: Failure to complete all relevant fields will result in the report being returned and the additional information being requested.

Completed reports are to be emailed to ddva.hrec@defence.gov.au

Section 1: Research Project Details

Protocol Number:	E016/007
Project Title:	Veterans' MATES Program
Ethical approval date:	19 February 2016
Ethical approval expiration date:	30 June 2021
Anticipated completion date:	31 December 2021
Is this student research?	☐ Yes ☒ No

Section 2: Investigator details

Principal Investigator

Name:	s47F
Organisation (command/division):	University of South Australia (UniSA)
Phone:	s47F
Email:	@unisa.edu.au

Student (where applicable)

Name:	
Organisation (command/division):	
Phone:	
Email:	

Additional Investigators			
List any investigators who have joined the research team since ethical approval was granted (for new research projects) or since the date of the previous Progress Report. Indicate whether each new investigator is listed on a Research Protocol Amendment Form. If an amendment form was not submitted a request for amendment form must be submitted and include an explanation as to why it was not submitted previously. *Insert additional rows as required.*			
Name	**Institution**	**Amendment Form**	
s47F	UniSA	☒ Yes	☐ No
		☐ Yes	☐ No

Section 3: Research Project Progress Summary

Current status of research project		
Has the study started?	☒ Yes	☐ No
If no, please provide an explanation: ***Note:*** *If a research project does not commence within 12 months of receiving ethical approval, the ethical approval will lapse unless there is a valid reason.*		
If yes, what was the actual start date?	The contract between Australian Government Department of Veterans' Affairs (DVA) and UniSA was fully executed on 23 December, 2015. Ethics was granted on 19 February, 2016 and the first intervention was disseminated in August 2016.	
Is the study ongoing and open to enrolment?	☐ Yes	☒ No
Ongoing but closed to enrolment *(Choose one)*	☐ Active follow-up continues ☐ Long-term follow-up continues ☒ Ongoing analysis only	
If no, do you plan to start this project? *Note: Submission of a Final Report form is also required if there is no intention to start the project.*	☐ Yes	☐ No
If yes, what is the expected start date?		

Provide a brief summary of the essential aspects of progress or results to date:
Our agreement with DVA, executed on the 23 Dec 2015, contracts us to deliver a minimum of four interventions per year. Each intervention is targeted to a specific health or medication-related problem. All veterans who meet the target criteria for the specific intervention are targeted, as are the health professionals who care for the targeted veterans.
DVA provides us with the DVA administrative claims data (DVA data) consistent with requirements that meets all physical, logical and personnel requirements laid down by the Australian Government (Department of Defence) Defence Signals Directorate (DSD) in line with current versions of the Protective Security Policy Framework (PSPF) and the Australian

Government Information Security Manual (ISM) relating to the security of any information that is stored, processed or transmitted in electronic form. Four security audits per annum by the State Security section of DVA are undertaken. The DVA data are updated monthly. We will continue to receive the DVA data into the future for the life of the program.
In addition to the summary below of progress to date, please also find attached our Veterans' MATES Report 2020 along with the cover letter.

2016 Topic 1 "Dementia and changes in behaviour" was distributed in August 2016. Evaluation of changes in medicine use as a result of the topic found the module to be successful in reducing the number of veterans using risperidone for dementia and the time for which they were taking it. In addition, the rate of initiation of this medication was reduced in the targeted population. There did not appear to be inappropriate therapeutic shift to other antipsychotics.

2016 Topic 2 "Reviewing the Medicine Routine" was distributed in November 2016. Evaluation revealed an increase in the rate of home medicine reviews as a result of the program.

2017 Topic 1 "Optimising management of chronic obstructive pulmonary disease" was distributed in March 2017 to general practitioners (GPs), residential aged-care facilities (RACF), pharmacies and accredited pharmacists, as well as to veterans. The topic aimed to improve use of pulmonary rehabilitation services amongst veterans with COPD. An increase in physiotherapy services for this cohort has been observed as well as increased visits to clinics where pulmonary rehabilitation is provided.

2017 Topic 2 "Wound management" was distributed in June 2017 GPs, residential aged-care facilities, pharmacies and accredited pharmacists, as well as to veterans in July 2017. Responses to this topic indicate the materials were well received and suggest actions were promoted by health professionals in relation to the appropriate use of moisturisers for skin tears and compression therapy for venous leg ulcers. The topic successfully promoted the DVA wound care module and the services and treatments available to veterans.

2017 Topic 3 "Reducing the burden of chronic pain" was distributed in September 2017 to GPs, pharmacists and psychologists. Veterans were sent educational material across two mailings in October and November, 2017. This was the first Veterans' MATES module that targeted psychologists working with veterans. The response rate from psychologists indicated that they thought the materials would be helpful in providing treatment for their veteran patients with chronic pain. They also reported that receiving future modules would be beneficial. The module provided new information to veterans and health professionals regarding the role of opioids in long-term treatment of pain and the therapeutic benefits of understanding pain.

2017 Topic 4 "Management of depression in veterans" was distributed to GPs and pharmacists in December 2017 and to veterans in January, 2018. The materials were well received with the majority of health professionals finding the materials helpful in understanding when it might be appropriate to review the duration of antidepressant therapy.

2018 Topic 1 "Medicines and falls" was distributed to GPs, pharmacists, RACFs and veterans in April 2018. The module highlighted to health professionals the benefits of using a multifactorial approach to prevent falls in their veteran patients and review medicines that may increase the patient's risk of falls.

2018 Topic 2 “Osteoporosis management” distributed to GPs and pharmacists in June 2018 and to veterans in July 2018. The majority of health professionals indicated that the materials encouraged them to recall patients who are at risk of osteoporosis and understand optimal diagnosis, prevention and treatment.

2018 Topic 3 “Proton pump inhibitors” (PPIs) was distributed to GPs, pharmacists and RACFs in August 2018 and to veterans in September 2018. Evaluation revealed the majority of GPs indicated at least one veteran listed in the prescriber feedback required a review of their PPI medicines. Veterans reported that they intended to make a specific appointment to speak with their doctor about taking a lower dose of their PPI or using the medicine only when symptoms appear.

2018 Topic 4 “Medicines and dry mouth” was distributed to GPs, pharmacists and dentists in November 2018 and to veterans in January 2019. This was the first Veterans’ MATES module to target dentists. The dentists indicated the materials would prompt them to ask if their patients were prescribed medicines that can cause dry mouth or have any symptoms of dry mouth. They also reported that receiving future modules related to dentistry would be beneficial. The module encouraged health professionals to talk to their patients about dry mouth and their medicines. Veterans with symptoms of dry mouth reported that they intended to make an appointment with their GP to discuss their symptoms.

2019 Topic 1 “Cognitive impairment” was distributed to GPs and pharmacists in March 2019 and to veterans in April 2019. Suggested actions were promoted by health professionals in relation to referring patients with cognitive impairment for an occupational therapy assessment, reviewing medication to see if any could be modified to improve cognitive function and considering the need for a dose administration aid. Veterans reported that they would make a specific appointment with their GP to discuss having an occupational therapist visit their home.

2019 Topic 2 “Insomnia management” was distributed to GPs, pharmacists and psychologists in June 2019 and to veterans in July 2019. The materials increased knowledge for health professionals about the treatment of insomnia and the DVA health services available to identify and help veterans with sleep difficulties. Veterans indicated that the materials provided new information about cognitive behavioural therapy for insomnia.

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2019 Topic 4 “Empowering veterans to manage diabetes” was distributed to GPs, pharmacists in mid-November 2019 and to veterans in late November 2019. The intervention was well targeted with the majority of GPs estimating that at least one of their veterans required a review of their diabetes tests and services. Veterans reported the information in the brochure will help them to remember the tests and health checks needed to manage their diabetes.

2020 Topic 1 “Reviewing your patients on gabapentinoids” was mailed to GPs, pharmacists, psychologists and veterans in March 2020. The topic was useful to health professionals who work with veterans with chronic pain. GPs reported that it would assist them in reviewing gabapentinoid use in their patients and they would explain how cognitive and emotional factors can influence pain to their veterans.

Through the current MATES contract arrangements UniSA can propose additional releases of educational material, where there is an identified need. The Program Management Plan, the overarching master planning document for the program, includes the scope for development and delivery of innovative program proposals. As a result of the Coronavirus (COVID-19) pandemic, Veterans' MATES was able to provide an agile response by reorientating the program to develop and deliver modules regarding the COVID-19 outbreak. Two business cases were presented and approved by DVA to adjust the forward 2020 year's program to provide *Rapid Response (RR) modules* to identified DVA clients and general practitioners (GPs). Veterans' MATES will continue to adapt future interventions of the program for the duration of the epidemic to address issues relevant to DVA clients as they arise.

2020 Topic 2 "*COVID-19 Rapid Response: Comorbidities*" materials were disseminated at the end of April 2020 to GPs, RACFs and veterans. The materials provided information to identified DVA clients on how to access health services, including telehealth and home medicines delivery services, as well as to GPs by identifying their DVA clients who have increased risk of poor outcomes if they contract COVID-19 due to the DVA client's age and comorbidity profile.

2020 Topic 3 "*COVID-19 Rapid Response: Mental Health*". The materials advised the identified DVA clients on simple measures they can try at home to reduce distress, including mindfulness exercises. The materials provided information to GPs identifying their DVA clients who have increased risk of mental distress due to the client's mental health profile. Materials were disseminated to GPs, pharmacists and veterans in July 2020.

2020 Topic 4 "Helping older patients to be physically and socially active" was provided to GPs, pharmacist, RACFs and veterans in August 2020. GPs reported that the materials helped them understand a patient's overall sedative load and RACF Directors noted that the materials would assist their staff understand how medicines with sedative effects can affect a patient's functional ability.

2020 Topic 5 "Reviewing veterans with heart failure" materials were disseminated in November 2020 to GPs, pharmacists and veterans. Evaluation will commence in 2021.

Is an extension to the period of ethical approval required?	☒ Yes ☐ No

If yes, please indicate when the extension is being requested until and include reasons for the request for extension. ***Note:*** *An extension in excess of three years will not be granted. Any studies that require extensions longer than that period will need to submit an additional request for extension closer to the period of expiration of the revised period of ethical approval.*

An extension of 6 months is requested through to 31 December 2021.The Agreement between DVA and UniSA for the provision of Veterans'MATES services, with an end date of 30 December 2018 included an option for a 3year extension. DVA exercised its option to extend the agreement by 30 months to 30 June 2021 and have now further extended by 6 months through to the end of 2021.

Are records being maintained in accordance with the approved protocol?	☒ Yes ☐ No
If no, please provide details:	
Is the research project being conducted according to the protocol?	☒ Yes ☐ No
If no, please provide details:	
Are all conditions of ethical approval being met?	☒ Yes ☐ No

If no, please provide details:

Section 4: Participant Summary	
Participant recruitment target:	N/A
Recruitment to date:	
Is recruitment on target:	☐ Yes ☐ No
If recruitment is not on target, provide an explanation:	
Withdrawn to date:	
Provide reason(s) for withdrawal:	
Advise participant numbers if multiple reasons apply:	
Do you plan to increase the planned recruitment of participants into the study? *Note: Any increase in planned recruitment should be notified to the Committee as a substantial amendment for ethical review*	☐ Yes ☐ No

Section 5: Site Information	
Do you plan to increase the total number of sites proposed for the study? *Note: A request for amendment will be required.*	☐ Yes ☒ No
Has research been discontinued from any site?	☐ Yes ☒ No
If yes, please provide details:	

Section 6: Adverse Events	
Have there been Adverse Events or Serious Adverse Events occur since the last report?	☐ Yes ☒ No
If yes, please summarise:	
If yes, has formal notification been submitted to the Departments of Defence and Veterans' Affairs HREC? *If no, you will need to submit and Adverse Event/Serious Adverse Event Form.*	☐ Yes ☐ No

Section 7: Complaints	
Have any participants, researchers or others expressed any complaint about the project?	☐ Yes ☒ No
If yes, please summarise:	
Have any participants claimed to have suffered harm or injury?	☐ Yes ☒ No
If yes, please summarise:	

Section 8: Clinical Trials		
Is the study a clinical trial? *If no, go to Section 9*		☐ Yes ☒ No
Is the study registered on a publicly accessible register?		☐ Yes ☐ No
If yes, provide the name of the register and the registration number.		
If no:		
a.	What is the reason for non-registration?	
b.	What are you intentions for registration?	

Section 9: Other Issues	
Are there any other developments in the project that you wish to report to the Committee?	☐ Yes ☒ No
If yes, please provide details:	
Are there any ethical issues on which further advice is required?	☐ Yes ☒ No
If yes, please provide details:	

Section 10: Declaration	
I confirm that this project is being conducted in keeping with the conditions of ethical approval, and accurately reflects the status of the above research project. I confirm that the project is being conducted in compliance with the *National Statement on Ethical Conduct in Human Research*. I confirm that I have not received any information in any form from anyone involved in the project to suggest this report does not accurately reflect the progress of the project to date.	
s47F	s47F
PI Signature	**PI Printed Name**
Date:	**03/02/2021**

This page and the following 27 pages are exempt under s22 of the Freedom of Information Act.

From: s47E(d) on behalf of ddvahrec
Sent: Friday, 5 February 2021 8:33 AM
To: s47F
Cc: s47F ddvahrec; ETHICS.POC
Subject: 20210205 (0832h) - ADRE - s47F - Approval of amendment - E016/007 Veterans' MATES Program

OFFICIAL

Dear s47F

E016/007 VETERANS MATES PROGRAM

The amendment to this project submitted on 3 February 2021 was approved by myself on behalf of the Departments of Defence and Veterans' Affairs Human Research Ethics Committee (DDVA HREC). The approved amendment includes:

a. addition of s47F
b. s47F from the research team.

You must forward a copy of this email to all Principal Investigators and to your institution. Please note that all requirements of the original ethical approval for this project still apply.

Should you wish to discuss this matter, please contact the DDVA HREC Secretariat on s47E(d) or ddva.hrec@defence.gov.au.

The DDVA HREC wishes you every continued success in your research.

Yours sincerely

s47E(d)

Assistant Director Research Ethics

On behalf of the

Departments of Defence and Veterans' Affairs Human Research Ethics Committee

PO Box 7911, Canberra BC ACT 2610

The Departments of Defence and Veterans' Affairs Human Research Ethics Committee is constituted and operates in accordance with the *National Statement on Ethical Conduct in Human Research.*

From: s47F
Sent: Wednesday, 3 February 2021 12:41 PM
To: ddvahrec
Cc: ethics.committee@dva.gov.au; s47F
Subject: DDVA HREC - Progress Report & Amendment Form- E016/007 Veterans' MATES Program

Good morning,

Please find attached the attached documents for consideration at your next meeting:

- Bi-annual Progress Report E016/007 Veterans' MATES Program, along with Veterans' MATES 2020 Report & cover letter, (referenced in the Progress Report) and
- Research Protocol Amendment Form along with CV.

Kind regards,
s47F

s47F
Veterans' MATES Program
Quality Use of Medicines and Pharmacy Research Centre (QUMPRC)
Clinical and Health Sciences I University of South Australia
GPO Box 2471 ADELAIDE SA 5001
Phone: s47F I Email: s47F@unisa.edu.au

CRICOS Provider No: 00121B

From: s47E(d) on behalf of ddvahrec
Sent: Monday, 15 March 2021 12:56 PM
To: ddvahrec s47F
Cc: ethics.committee@dva.gov.au; s47F
Subject: 20210315 (1256h) - ADRE - s47F approval of Progress Report & extension to ethical approval - E016/007 Veterans' MATES Program

OFFICIAL

Dear s47F

E016/007 Veterans' MATES Program

Thank you for submitting the progress report and a request to extend the period of ethical approval for the above research project. The Secretariat have reviewed the report on behalf of the DDVA HREC and have no concerns.

I have reviewed the request to extend the period of ethical approval until 31 December 2021 and approved it on the following conditions:

- The research is to be conducted in accordance with the approved protocol.
- The Principal Investigator will immediately report anything that might warrant review of ethical approval of the project.
- The Principal Investigator will notify the DDVA HREC of any event that requires an amendment/modification to the protocol or other project documents.
- The Principal Investigator will submit any necessary reports related to the safety of research participants.
- The Principal Investigator will submit progress reports to the DDVA HREC annually and notify DDVA HREC when the project is completed at all sites. The study is due to be completed by the time the next progress report is due. We therefore request submission of a Final Report by 31 December 2021. If the study is to extend beyond this period, please submit a request for amendment.
- The Principal Investigator will notify the DDVA HREC if the project is discontinued at a participating site before the expected completion date, with reasons provided.
- The Principal Investigator will notify the DDVA HREC of any plan to extend the duration of the project past the approval period listed above and will submit any associated required documentation.
- The Principal Investigator will notify the DDVA HREC of their inability to continue and indicate the name of and contact information for a replacement.

If you have any queries please feel free to contact the DDVA HREC Secretariat on (02) 6212 1431 or ddva.hrec@defence.gov.au.

The DDVA HREC wishes you every success in your research.

Yours sincerely

s47E(d)

Assistant Director Research Ethics

On behalf of

Departments of Defence and Veterans' Affairs Human Research Ethics Committee

PO Box 7912

CANBERRA BC ACT 2610

The Departments of Defence and Veterans' Affairs Human Research Ethics Committee is constituted and operates in accordance with the National Health and Medical Research Council's (NHMRC) *National Statement on Ethical Conduct in Human Research.*

From: s47F
Sent: Wednesday, 3 February 2021 12:41 PM
To: ddvahrec
Cc: ethics.committee@dva.gov.au; s47F
Subject: 20210203 (1242h) - DDVA HREC - Progress Report & Amendment Form- E016/007 Veterans' MATES Program

Good morning,

Please find attached the attached documents for consideration at your next meeting:

- Bi-annual Progress Report E016/007 Veterans' MATES Program, along with Veterans' MATES 2020 Report & cover letter, (referenced in the Progress Report) and
- Research Protocol Amendment Form along with CV.

Kind regards,
s47F

s47F
Veterans' MATES Program
Quality Use of Medicines and Pharmacy Research Centre (QUMPRC)
Clinical and Health Sciences I University of South Australia
GPO Box 2471 ADELAIDE SA 5001

Phone: s47F | Email: s47F @unisa.edu.au

CRICOS Provider No: 00121B

DEPARTMENTS OF DEFENCE AND VETERANS' AFFAIRS HUMAN RESEARCH ETHICS COMMITTEE
RESEARCH PROJECT PROGRESS REPORT

The 'National Statement on Ethical Conduct in Human Research' section 5.5.5 requires researchers to provide progress reports to the relevant ethical review body/ies and institution/s.

Progress reports are to be submitted to Departments of Defence and Veterans' Affairs Human Research Ethics Committee at least annually. For clinical trials, progress reports are to be submitted six monthly. Due dates for submission of the reports will be stated on the Principal Investigators Assurance.

Reports are to be signed by the 1st listed Principal Investigator. Failure to submit a progress report may result in withdrawal of ethical approval.

Note: Failure to complete all relevant fields will result in the report being returned and the additional information being requested.

Completed reports are to be emailed to ddva.hrec@defence.gov.au

Section 1: Research Project Details

Protocol Number:	E016/007
Project Title:	Veterans' MATES Program
Ethical approval date:	19 February 2016
Ethical approval expiration date:	31 December 2021
Anticipated completion date:	31 December 2022
Is this student research?	☐ Yes ☒ No

Section 2: Investigator details

Principal Investigator	
Name:	s47F
Organisation (command/division):	University of South Australia (UniSA)
Phone:	s47F
Email:	@unisa.edu.au

Student (where applicable)	
Name:	
Organisation (command/division):	
Phone:	
Email:	

Additional Investigators				
List any investigators who have joined the research team since ethical approval was granted (for new research projects) or since the date of the previous Progress Report. Indicate whether each new investigator is listed on a Research Protocol Amendment Form. If an amendment form was not submitted a request for amendment form must be submitted and include an explanation as to why it was not submitted previously. *Insert additional rows as required.*				
Name		**Institution**	**Amendment Form**	
s47F		UniSA	☒ Yes	☐ No
		UniSA	☒ Yes	☐ No
		UniSA	☒ Yes	☐ No
		UniSA	☒ Yes	☐ No

Section 3: Research Project Progress Summary		
Current status of research project		
Has the study started?	☒ Yes	☐ No
If no, please provide an explanation: ***Note:*** *If a research project does not commence within 12 months of receiving ethical approval, the ethical approval will lapse unless there is a valid reason.*		
If yes, what was the actual start date?	The contract between Australian Government Department of Veterans' Affairs (DVA) and UniSA was fully executed on 23 December, 2015. Ethics was granted on 19 February, 2016 and the first intervention was disseminated in August 2016.	
Is the study ongoing and <u>open to enrolment?</u>	☐ Yes	☒ No
Ongoing but <u>closed to enrolment</u> *<u>(Choose one)</u>*	☐ Active follow-up continues ☐ Long-term follow-up continues ☒ Ongoing analysis only	
If no, do you plan to start this project? *Note: Submission of a Final Report form is also required if there is no intention to start the project.*	☐ Yes	☐ No
If yes, what is the expected start date?		
Provide a brief summary of the essential aspects of progress or results to date: Our agreement with DVA, executed on the 23 Dec 2015, contracts us to deliver a minimum of four interventions per year. Each intervention is targeted to a specific health or medication-related problem. All veterans who meet the target criteria for the specific intervention are targeted, as are the health professionals who care for the targeted veterans.		

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work with veterans with chronic pain. GPs reported that it would assist them in reviewing gabapentinoid use in their patients and they would explain how cognitive and emotional factors can influence pain to their veterans.
Through the current MATES contract arrangements UniSA can propose additional releases of educational material, where there is an identified need. The Program Management Plan, the overarching master planning document for the program, includes the scope for development and delivery of innovative program proposals. As a result of the Coronavirus (COVID-19) pandemic, Veterans' MATES was able to provide an agile response by reorientating the program to develop and deliver modules regarding the COVID-19 outbreak. Two business cases were presented and approved by DVA to adjust the forward 2020 year's program to provide *Rapid Response (RR) modules* to identified DVA clients and general practitioners (GPs). Veterans' MATES will continue to adapt future interventions of the program for the duration of the epidemic to address issues relevant to DVA clients as they arise.

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2020 Topic 5 "Reviewing veterans with heart failure" materials were disseminated in November 2020 to GPs, pharmacists and veterans. GPs reported the materials encouraged them to setup a CVC program and refer patients for a medicines review. GPs and pharmacists indicated that the veteran brochure would help them educate their veterans with heart failure about how to watch for symptoms that may indicate a worsening of heart failure.

2021 Topic 1 "Optimising the management of chronic obstructive pulmonary disease" materials were sent to GPs, pharmacists, physiotherapists, exercise physiologists and veterans. GPs reported that they were encouraged to refer their veteran patients with COPD to a pulmonary rehabilitation program and then refer their patients to an exercise physiologist or physiotherapist for pulmonary rehabilitation. Physiotherapists or exercise physiologists reported that they were likely to use the information sheet provided to guide them in setting up a pulmonary rehabilitation program. Most veterans said that they would talk with their GP about reviewing their medicines and inhaler technique, followed by discussing appropriate exercises, participation in pulmonary rehabilitation and use of their COPD action plan.

2021 Topic 2 "Management of tinnitus" module was disseminated to GPs, pharmacists and veterans in June 2021. GPs reported they would refer their veteran patients with tinnitus to an audiologist for an assessment or review. GPs estimated that one or more of their veteran

patients with tinnitus may benefit from referral to a psychologist. Pharmacists had improved their understanding of the benefits of a multi-faceted approach to managing tinnitus.

2021 Topic 3 "Optimal use of diuretics in the elderly" materials were mailed to GPs, pharmacists, RACFs and veterans in September 2021. Evaluation of this topic is in progress.

2021 Topic 4 "Optimising emotional and mental wellbeing" scheduled for dissemination in the last week of November 2021 to GPs, pharmacists, psychologists, occupational therapists, social workers and veterans. Evaluation will commence in 2022.

Is an extension to the period of ethical approval required?	☒ Yes	☐ No

If yes, please indicate when the extension is being requested until and include reasons for the request for extension. ***Note:*** *An extension in excess of three years will not be granted. Any studies that require extensions longer than that period will need to submit an additional request for extension closer to the period of expiration of the revised period of ethical approval.*

An extension of 12 months is requested through to 31 December 2022.The Agreement between DVA and UniSA for the provision of Veterans'MATES services, with an end date of 30 December 2018, included an option for a 3 year extension. DVA exercised its option to extend the agreement by 30 months to 30 June 2021. This was followed by an extension of 6 months to 31 December 2021 and DVA have now further extended by 12 months through to the end of 2022.

Are records being maintained in accordance with the approved protocol?	☒ Yes	☐ No
If no, please provide details:		
Is the research project being conducted according to the protocol?	☒ Yes	☐ No
If no, please provide details:		
Are all conditions of ethical approval being met?	☒ Yes	☐ No
If no, please provide details:		

Section 4: Participant Summary

Participant recruitment target:	N/A	
Recruitment to date:		
Is recruitment on target:	☐ Yes	☐ No
If recruitment is not on target, provide an explanation:		
Withdrawn to date:		
Provide reason(s) for withdrawal:		
Advise participant numbers if multiple reasons apply:		
Do you plan to increase the planned recruitment of participants into the study? *Note: Any increase in planned recruitment should be notified to the Committee as a substantial amendment for ethical review*	☐ Yes	☐ No

Section 5: Site Information		
Do you plan to increase the total number of sites proposed for the study? *Note: A request for amendment will be required.*	☐ Yes	☒ No
Has research been discontinued from any site?	☐ Yes	☒ No
If yes, please provide details:		

Section 6: Adverse Events		
Have there been Adverse Events or Serious Adverse Events occur since the last report?	☐ Yes	☒ No
If yes, please summarise:		
If yes, has formal notification been submitted to the Departments of Defence and Veterans' Affairs HREC? *If no, you will need to submit and Adverse Event/Serious Adverse Event Form.*	☐ Yes	☐ No

Section 7: Complaints		
Have any participants, researchers or others expressed any complaint about the project?	☐ Yes	☒ No
If yes, please summarise:		
Have any participants claimed to have suffered harm or injury?	☐ Yes	☒ No
If yes, please summarise:		

Section 8: Clinical Trials		
Is the study a clinical trial? *If no, go to Section 9*	☐ Yes	☒ No
Is the study registered on a publicly accessible register?	☐ Yes	☐ No
If yes, provide the name of the register and the registration number.		
If no:		
a. What is the reason for non-registration?		
b. What are you intentions for registration?		

Section 9: Other Issues		
Are there any other developments in the project that you wish to report to the Committee?	☐ Yes	☒ No
If yes, please provide details:		
Are there any ethical issues on which further advice is required?	☐ Yes	☒ No
If yes, please provide details:		

Section 10: Declaration	
I confirm that this project is being conducted in keeping with the conditions of ethical approval, and accurately reflects the status of the above research project. I confirm that the project is being conducted in compliance with the *National Statement on Ethical Conduct in Human Research*. I confirm that I have not received any information in any form from anyone involved in the project to suggest this report does not accurately reflect the progress of the project to date.	
s47F	s47F
PI Signature	**PI Printed Name**
Date: 22/11/2021	

DEPARTMENTS OF DEFENCE AND VETERANS' AFFAIRS HUMAN RESEARCH ETHICS COMMITTEE
RESEARCH PROTOCOL AMENDMENT FORM

In the event that an approved research project requires amendment, this form must be submitted to the Departments of Defence and Veterans' Affairs Human Research Ethics Committee (DDVA HREC) by the Principal Investigator (PI).

An amendment **must not** be implemented until approval has been granted by the committee.

All completed forms are to be electronically submitted to ddva.hrec@defence.gov.au

Section 1: Project Details	
Protocol Number:	E016-007
Project Title:	Veterans' MATES Program
Ethical approval date:	19 February 2016
Ethical approval expiration date:	31 December 2022
Date of amendment submission:	

Section 2: Investigator Details	
Name:	s47F
Organisation (command/division):	University of South Australia (UniSA)
Phone:	s47F
Email:	@unisa.edu.au

Section 3: Amendment Details

Explain the proposed/ intended changes *(may include changes in procedure, direction of project, source/manner of recruitment, number of participants or changes to research personnel)*

Four additional staff members with involvement in the service delivery of the program have been added, details provided below.
Three staff members have resigned from UniSA and are therefore are no longer involved in the Veterans MATES Program. s47F
s47F

Reason for the changes *(include a comment on the impact on the research project and the participants at sites)*

The new staff members are fulfilling key roles in program deliverables under Deed of Agreement with Department of Veterans' Affairs.
s47F

Do these changes raise any ethical issues?	☐ Yes ☒ No

If yes, identify the ethical issues.

List all amended documents to be reviewed.	
Document Title *(include version number, if applicable)* *Insert additional rows if required.*	**Version Date**
s47F CV	
s47F CV	
s47F _CV	
s47F _CV	

Section 4: Participating Sites

Are all participating sites affected by this amendment? *If no, list all affected sites below. Insert additional rows if required.*	☒ Yes	☐ No
Site *(Organisation)*	**State**	

An amendment to an approved research protocol may also impact the individual research sites. The Commanding Officer (CO) at each affected site (named above) must be notified of the amendment by the PI to determine if the site is impacted. Final approval to implement an amendment at a site will be issued by that site's CO.

Section 5: Declaration

I confirm that this project is being conducted in keeping with the conditions of ethical approval. I confirm that the project is being conducted in compliance with the *National Statement on Ethical Conduct in Human Research*.

I confirm that I have not received any information in any form from anyone involved in the research to suggest this report does not accurately reflect the progress of the project.

s47F	s47F
PI Signature	**PI Printed Name**
Date: 22/11/2021	

From: s47E(d) on behalf of ddvahrec
Sent: Monday, 29 November 2021 10:58 AM
To: ddvahrec; s47F
Cc: s47F
Subject: 20211129 (1057h) - Approval of amendment - E016/007 Veterans Medicines Advice and Therapeutics Education Services

OFFICIAL

Dear s47F

The amendment to this project submitted on 22 November 2021 was approved out of-session by myself on behalf of the Departments of Defence and Veterans' Affairs Human Research Ethics Committee (DDVA HREC).

The approved amendment includes:

a. addition of s47F to the research team

b. removal of s47F from the research team.

You must forward a copy of this letter/email to all Principal Investigators and to your institution. Please note that all requirements of the original ethical approval for this project still apply.

Should you wish to discuss this matter, please contact the DDVA HREC Secretariat on s47E(d) or ddva.hrec@defence.gov.au. The DDVA HREC wishes you every continued success in your research.

Yours sincerely

s47E(d)

Assistant Director Research Ethics

On behalf of
Departments of Defence and Veterans' Affairs Human Research Ethics Committee

Campbell Park Offices

PO Box 7911, Canberra BC ACT 2610

The Departments of Defence and Veterans' Affairs Human Research Ethics Committee is constituted and operates in accordance with the *National Statement on Ethical Conduct in Human Research.*

From: s47F @unisa.edu.au>
Sent: Monday, 22 November 2021 1:23 PM
To: ddvahrec <ddva.hrec@defence.gov.au>
Cc: ethics.committee@dva.gov.au; s47F @unisa.edu.au>; s47F

s47F @unisa.edu.au>; s47F @unisa.edu.au>

Subject: 20211122 (1324h) - DDVA HREC - Progress Report & Amendment Form- E016/007 Veterans Medicines Advice and Therapeutics Education Services

Good morning,

The period of ethical approval for this study is due to expire on 31/12/2021. Please find attached our request to extend the period of ethical approval via submission of:

- Bi-annual Progress Report E016/007 Veterans' MATES Program and
- Research Protocol Amendment Form along with CVs.

Kind regards,

s47F

s47F Veterans' MATES Program
Quality Use of Medicines and Pharmacy Research Centre (QUMPRC)
Clinical and Health Sciences I University of South Australia
GPO Box 2471 ADELAIDE SA 5001
Phone: s47F I Email: s47F @unisa.edu.au

CRICOS Provider No: 00121B

From: s47E(d) on behalf of ddvahrec
Sent: Tuesday, 21 December 2021 4:05 PM
To: s47F ddvahrec; s47F
Cc: ethics.committee@dva.gov.au; s47F
Subject: 20211221 (1604h) - DDVA HREC - Progress Report & Amendment Form- E016/007 Veterans Medicines Advice and Therapeutics Education Services [SEC=OFFICIAL]

OFFICIAL

Thanks s47F

This completes the desktop audit.

I have accepted the progress report. The next report will be due by 31 December 2022 and will be a final report.

I have updated our records with the extension to the period of ethical approval and your formal notice of extension will follow this email.

Please let me know if there is anything else I can do for your team.

Kind regards

s47E(d)
Executive Officer, Joint Health Command
s47E(d) Campbell Park Offices, PO Box 7911, Canberra BC ACT 2610
Phone: s47E(d)
DDVA HREC website: https://www.defence.gov.au/health/hrec/

From: s47F @unisa.edu.au>
Sent: Monday, 20 December 2021 2:17 PM
To: ddvahrec <ddva.hrec@defence.gov.au>; s47F @unisa.edu.au>
Cc: ethics.committee@dva.gov.au; s47F @unisa.edu.au>; s47F s47F @unisa.edu.au>
Subject: RE: 20211220 (1347h) - DDVA HREC - Progress Report & Amendment Form- E016/007 Veterans Medicines Advice and Therapeutics Education Services [SEC=OFFICIAL]

Dear s47E(d)

I can confirm that our protocol was reviewed and most recently approved by University of South Australia Human Research Ethics Committee on the 5th October 2021. Ethics approval from the University of South Australia Human Research Ethics Committee is currently in place and valid until 27th October 2022 (Protocol No P203/04).

Kind regards

s47F
s47F Veterans' MATES Program | Quality Use of Medicines and Pharmacy Research Centre
UniSA: Clinical and Health Sciences | University of South Australia | P6-32 City East Campus
Phone: s47F | Mobile: s47F
s47F | Email: s47F @unisa.edu.au
CRICOS Provider Number: 00121B

CRICOS Provider No: 00121B

From s47E(d) @defence.gov.au> **On Behalf Of** ddvahrec
Sent: Monday, 20 December 2021 1:17 PM
To: s47F @unisa.edu.au>; ddvahrec <ddva.hrec@defence.gov.au>
Cc: ethics.committee@dva.gov.au; s47F @unisa.edu.au>; s47F s47F @unisa.edu.au>; s47F @unisa.edu.au>
Subject: 20211220 (1347h) - DDVA HREC - Progress Report & Amendment Form- E016/007 Veterans Medicines Advice and Therapeutics Education Services [SEC=OFFICIAL]

OFFICIAL

Dear s47F

I am finalising our files for the year and note that the progress report and extension to the period of ethical approval are still outstanding.

The request for extension to the period of ethical approval is a cause for the DDVA HREC secretariat to conduct a desktop audit on the protocol file and ensure it is complete.

The desktop audit on your file raised a question as to whether your protocol is also approved by University of South Australia HREC. Can you please confirm whether the project has been ethically reviewed by any other ethical review bodies, the outcome of review and any reference or identification number that may have been provided.

Once this is complete I will facilitate the review of the extension.

Kind regards

s47E(d)
Executive Officer, Joint Health Command
s47E(d) Campbell Park Offices, PO Box 7911, Canberra BC ACT 2610
Phone: s47E(d)
DDVA HREC website: https://www.defence.gov.au/health/hrec/

From: s47F @unisa.edu.au>
Sent: Monday, 22 November 2021 1:23 PM
To: ddvahrec <ddva.hrec@defence.gov.au>
Cc: ethics.committee@dva.gov.au; s47F @unisa.edu.au>; s47F s47F @unisa.edu.au>;s47F @unisa.edu.au>
Subject: 20211122 (1324h) - DDVA HREC - Progress Report & Amendment Form- E016/007 Veterans Medicines Advice and Therapeutics Education Services

Good morning,

The period of ethical approval for this study is due to expire on 31/12/2021. Please find attached our request to extend the period of ethical approval via submission of:

- Bi-annual Progress Report E016/007 Veterans' MATES Program and
- Research Protocol Amendment Form along with CVs.

Kind regards,

s47F

s47F
Veterans' MATES Program
Quality Use of Medicines and Pharmacy Research Centre (QUMPRC)
Clinical and Health Sciences I University of South Australia
GPO Box 2471 ADELAIDE SA 5001
Phone: s47F I Email:s47F @unisa.edu.au

From: s47E(d) on behalf of ddvahrec
Sent: Tuesday, 21 December 2021 4:09 PM
To: s47F
Cc: ddvahrec; s47F ethics.committee@dva.gov.au; s47F s47F
Subject: 20211221 (1608h) - EO - s47F Extension to the period of ethical approval - E016/007 [SEC=OFFICIAL]

OFFICIAL

s47F
University of South Australia

Dear s47F

E016/007 VETERANS MEDICINES ADVICE AND THERAPEUTICS EDUCATION SERVICES

Thank you for submitting a request to extend the period of ethical approval for the above research project. Your request to extend the period of ethical approval until 31 December 2022 was reviewed and approved by the Acting Chair of the Departments of Defence and Veterans' Affairs Human Research Ethics Committee (DDVA HREC) on the following conditions:

- The research is to be conducted in accordance with the approved protocol.
- The Principal Investigator will immediately report anything that might warrant review of ethical approval of the project.
- The Principal Investigator will notify the DDVA HREC of any event that requires an amendment/modification to the protocol or other project documents.
- The Principal Investigator will submit any necessary reports related to the safety of research participants.
- The Principal Investigator will submit progress reports to the DDVA HREC annually and notify DDVA HREC when the project is completed at all sites. The next progress report for this study is due by 31 December 2022.
- The Principal Investigator will notify the DDVA HREC if the project is discontinued at a participating site before the expected completion date, with reasons provided.
- The Principal Investigator will notify the DDVA HREC of any plan to extend the duration of the project past the approval period listed above and will submit any associated required documentation.
- The Principal Investigator will notify the DDVA HREC of their inability to continue and indicate the name of and contact information for a replacement.

If you have any queries please feel free to contact the DDVA HREC Secretariat on s47E(d) or ddva.hrec@defence.gov.au.

The DDVA HREC wishes you every success in your research.

Yours sincerely

s22

s47E(d)
Assistant Director Research Ethics

For
s47E(d)
Acting Chair, Departments of Defence and Veterans' Affairs Human Research Ethics Committee

Campbell Park Offices
PO Box 7911
CANBERRA BC ACT 2610

21 December 2021

The Departments of Defence and Veterans' Affairs Human Research Ethics Committee is constituted and operates in accordance with the National Health and Medical Research Council's (NHMRC) *National Statement on Ethical Conduct in Human Research.*

Australian Government
Department of Defence
Department of Veterans' Affairs

DEPARTMENTS OF DEFENCE AND VETERANS' AFFAIRS HUMAN RESEARCH ETHICS COMMITTEE

PROGRESS REPORT

The 'National Statement on Ethical Conduct in Human Research' section 5.5.5 requires researchers to provide progress reports to the relevant ethical review body/ies and institution/s.

Progress reports are to be submitted to Departments of Defence and Veterans' Affairs Human Research Ethics Committee at least annually. For clinical trials, progress reports are to be submitted six monthly. Due dates for submission of the reports will be stated on the outcome letter advising that ethical approval has been granted.

Reports are to be signed by the 1st listed Principal Investigator. Failure to submit a progress report may result in withdrawal of ethical approval.

Failure to complete all relevant fields will result in the report being returned and the additional information being requested.

Completed reports are to be emailed to ddva.hrec@defence.gov.au

SECTION 1: PROJECT DETAILS	
Protocol Number:	E016/007
Project Title:	Veterans' MATES Program
Anticipated completion date:	31/12/2023
Is this student research?	☐ Yes ☒ No

SECTION 2: INVESTIGATOR DETAILS	
Principal Investigator	
Name:	s47F
Organisation (command/division):	University of South Australia (UniSA)
Phone:	s47F
Email:	@unisa.edu.au
Student (where applicable)	
Name:	
Organisation (command/division):	
Phone:	
Email:	

Additional Investigators

List any investigators who have joined the research team since ethical approval was granted (for new research projects) or since the date of the previous Progress Report. Indicate whether each new investigator is listed on a Research Protocol Amendment Form.

If an amendment form was not submitted a request for amendment form must be submitted and include an explanation as to why it was not submitted previously.

Insert additional rows as required.

Name	**Institution**	**Amendment Form**	
s47F	UniSA	☒ Yes	☐ No

SECTION 3: SUMMARY OF PROGRESS

Current status of research project

Has the study started?	☒ Yes ☐ No
If no, do you plan to start this project? Note: Submission of a Final Report form is also required if there is no intention to start the project.	☐ Yes ☐ No
If you intend to commence the study at a future date, what is the anticipated start date?	

If you don't intend to start the study, please provide an explanation: **Note:** If a research project does not commence within 12 months of receiving ethical approval, the ethical approval will lapse unless there is a valid reason.

If the study has started, what was the actual start date?	The contract between Australian Government Department of Veterans' Affairs (DVA) and UniSA was fully executed on 23 December 2015. Ethics was granted on 19 February 2016 and the first intervention was disseminated in August 2016.
If the study has started, is it ongoing and <u>open to enrolment?</u>	☐ Yes ☒ No
Ongoing but <u>closed to enrolment</u> *(Choose one)*	☐ Active follow-up continues ☐ Long-term follow-up continues ☒ Ongoing analysis only

Provide a brief summary of the essential aspects of progress or results to date:

Our agreement with DVA, executed on the 23 Dec 2015, contracts us to deliver a minimum of four interventions per year. Each intervention is targeted to a specific health or medication-related problem. All veterans who meet the target criteria for the specific intervention are targeted, as are the health professionals who care for the targeted veterans.

DVA provides us with the DVA administrative claims data (DVA data) consistent with requirements that meets all physical, logical and personnel requirements laid down by the Australian Government (Department of Defence) Defence Signals Directorate (DSD) in line with current versions of the Protective Security Policy Framework (PSPF) and the Australian Government Information Security Manual (ISM) relating to the security of any information that is stored, processed or transmitted in electronic form. Four security audits per annum by the State Security section of DVA are undertaken. The DVA data is updated weekly. We will continue to receive the DVA data into the future for the life of the program.

2016 Topic 1 "Dementia and changes in behaviour" was distributed in August 2016. Evaluation of changes in medicine use as a result of the topic found the module to be successful in reducing the number of veterans using risperidone for dementia and the time for which they were taking it. In addition, the rate of initiation of this medication was reduced in the targeted population. There did not appear to be inappropriate therapeutic shift to other antipsychotics.

2016 Topic 2 "Reviewing the Medicine Routine" was distributed in November 2016. Evaluation revealed an increase in the rate of home medicine reviews as a result of the program.

2017 Topic 1 “Optimising management of chronic obstructive pulmonary disease” was distributed in March 2017 to general practitioners (GPs), residential aged-care facilities (RACF), pharmacies and accredited pharmacists, as well as to veterans. The topic aimed to improve use of pulmonary rehabilitation services amongst veterans with COPD. An increase in physiotherapy services for this cohort has been observed as well as increased visits to clinics where pulmonary rehabilitation is provided.

2017 Topic 2 “Wound management” was distributed in June 2017 GPs, residential aged-care facilities, pharmacies and accredited pharmacists, as well as to veterans in July 2017. Responses to this topic indicate the materials were well received and suggest actions were promoted by health professionals in relation to the appropriate use of moisturisers for skin tears and compression therapy for venous leg ulcers. The topic successfully promoted the DVA wound care module and the services and treatments available to veterans.

2017 Topic 3 “Reducing the burden of chronic pain” was distributed in September 2017 to GPs, pharmacists and psychologists. Veterans were sent educational material across two mailings in October and November, 2017. This was the first Veterans’ MATES module that targeted psychologists working with veterans. The response rate from psychologists indicated that they thought the materials would be helpful in providing treatment for their veteran patients with chronic pain. They also reported that receiving future modules would be beneficial. The module provided new information to veterans and health professionals regarding the role of opioids in long-term treatment of pain and the therapeutic benefits of understanding pain.

2017 Topic 4 “Management of depression in veterans” was distributed to GPs and pharmacists in December 2017 and to veterans in January, 2018. The materials were well received with the majority of health professionals finding the materials helpful in understanding when it might be appropriate to review the duration of antidepressant therapy.

2018 Topic 1 “Medicines and falls” was distributed to GPs, pharmacists, RACFs and veterans in April 2018. The module highlighted to health professionals the benefits of using a multifactorial approach to prevent falls in their veteran patients and review medicines that may increase the patient’s risk of falls.

2018 Topic 2 “Osteoporosis management” distributed to GPs and pharmacists in June 2018 and to veterans in July 2018. The majority of health professionals indicated that the materials encouraged them to recall patients who are at risk of osteoporosis and understand optimal diagnosis, prevention and treatment.

2018 Topic 3 “Proton pump inhibitors” (PPIs) was distributed to GPs, pharmacists and RACFs in August 2018 and to veterans in September 2018. Evaluation revealed the majority of GPs indicated at least one veteran listed in the prescriber feedback required a review of their PPI medicines. Veterans reported that they intended to make a specific appointment to speak with their doctor about taking a lower dose of their PPI or using the medicine only when symptoms appear.

2018 Topic 4 “Medicines and dry mouth” was distributed to GPs, pharmacists and dentists in November 2018 and to veterans in January 2019. This was the first Veterans’ MATES module to target dentists. The dentists indicated the materials would prompt them to ask if their patients were prescribed medicines that can cause dry mouth or have any symptoms of dry mouth. They also reported that receiving future modules related to dentistry would be beneficial. The module encouraged health professionals to talk to their patients about dry

mouth and their medicines. Veterans with symptoms of dry mouth reported that they intended to make an appointment with their GP to discuss their symptoms.

2019 Topic 1 "Cognitive impairment" was distributed to GPs and pharmacists in March 2019 and to veterans in April 2019. Suggested actions were promoted by health professionals in relation to referring patients with cognitive impairment for an occupational therapy assessment, reviewing medication to see if any could be modified to improve cognitive function and considering the need for a dose administration aid. Veterans reported that they would make a specific appointment with their GP to discuss having an occupational therapist visit their home.

2019 Topic 2 "Insomnia management" was distributed to GPs, pharmacists and psychologists in June 2019 and to veterans in July 2019. The materials increased knowledge for health professionals about the treatment of insomnia and the DVA health services available to identify and help veterans with sleep difficulties. Veterans indicated that the materials provided new information about cognitive behavioural therapy for insomnia.

2019 Topic 3 "Renal impairment" was distributed to GPs, pharmacists and RACFs in September 2019 and to veterans in October 2019. Evaluation revealed the majority of GPs reported that a least one of their veterans listed required a review of their medicines that are renally cleared. Veterans indicated that they intended to talk to their GP about their kidney function at their next visit.

2019 Topic 4 "Empowering veterans to manage diabetes" was distributed to GPs, pharmacists in mid-November 2019 and to veterans in late November 2019. The intervention was well targeted with the majority of GPs estimating that at least one of their veterans required a review of their diabetes tests and services. Veterans reported the information in the brochure will help them to remember the tests and health checks needed to manage their diabetes.

2020 Topic 1 "Reviewing your patients on gabapentinoids" was mailed to GPs, pharmacists, psychologists and veterans in March 2020. The topic was useful to health professionals who work with veterans with chronic pain. GPs reported that it would assist them in reviewing gabapentinoid use in their patients and they would explain how cognitive and emotional factors can influence pain to their veterans.
Through the current MATES contract arrangements UniSA can propose additional releases of educational material, where there is an identified need. The Program Management Plan, the overarching master planning document for the program, includes the scope for development and delivery of innovative program proposals. As a result of the Coronavirus (COVID-19) pandemic, Veterans' MATES was able to provide an agile response by reorientating the program to develop and deliver modules regarding the COVID-19 outbreak. Two business cases were presented and approved by DVA to adjust the forward 2020 year's program to provide *Rapid Response (RR) modules* to identified DVA clients and general practitioners (GPs). Veterans' MATES will continue to adapt future interventions of the program for the duration of the epidemic to address issues relevant to DVA clients as they arise.

2020 Topic 2 "*COVID-19 Rapid Response: Comorbidities*" materials were disseminated at the end of April 2020 to GPs, RACFs and veterans. The materials provided information to identified DVA clients on how to access health services, including telehealth and home medicines delivery services, as well as to GPs by identifying their DVA clients who have increased risk of poor outcomes if they contract COVID-19 due to the DVA client's age and comorbidity profile.

2020 Topic 3 "*COVID-19 Rapid Response: Mental Health*". The materials advised the identified DVA clients on simple measures they can try at home to reduce distress, including mindfulness exercises. The materials provided information to GPs identifying their DVA clients who have increased risk of mental distress due to the client's mental health profile. Materials were disseminated to GPs, pharmacists and veterans in July 2020.

2020 Topic 4 "Helping older patients to be physically and socially active" was provided to GPs, pharmacist, RACFs and veterans in August 2020. GPs reported that the materials helped them understand a patient's overall sedative load and RACF Directors noted that the materials would assist their staff understand how medicines with sedative effects can affect a patient's functional ability.

2020 Topic 5 "Reviewing veterans with heart failure" materials were disseminated in November 2020 to GPs, pharmacists and veterans. GPs reported the materials encouraged them to setup a CVC program and refer patients for a medicines review. GPs and pharmacists indicated that the veteran brochure would help them educate their veterans with heart failure about how to watch for symptoms that may indicate a worsening of heart failure.

2021 Topic 1 "Optimising the management of chronic obstructive pulmonary disease" materials were sent to GPs, pharmacists, physiotherapists, exercise physiologists and veterans. GPs reported that they were encouraged to refer their veteran patients with COPD to a pulmonary rehabilitation program and then refer their patients to an exercise physiologist or physiotherapist for pulmonary rehabilitation. Physiotherapists or exercise physiologists reported that they were likely to use the information sheet provided to guide them in setting up a pulmonary rehabilitation program. Most veterans said that they would talk with their GP about reviewing their medicines and inhaler technique, followed by discussing appropriate exercises, participation in pulmonary rehabilitation and use of their COPD action plan.

2021 Topic 2 "Management of tinnitus" module was disseminated to GPs, pharmacists and veterans in June 2021. GPs reported they would refer their veteran patients with tinnitus to an audiologist for an assessment or review. GPs estimated that one or more of their veteran patients with tinnitus may benefit from referral to a psychologist. Pharmacists had improved their understanding of the benefits of a multi-faceted approach to managing tinnitus.

2021 Topic 3 "Optimal use of diuretics in the elderly" materials were mailed to GPs, pharmacists, RACFs and veterans in September 2021. The intervention helped to increase awareness among health professionals about how often to monitor fluid status, electrolytes and renal function when prescribing a diuretic medicine, and diuretic induced adverse effects.

2021 Topic 4 "Optimising emotional and mental wellbeing" scheduled for dissemination in the last week of November 2021 to GPs, pharmacists, psychologists, occupational therapists, social workers and veterans. This module was important in providing health professionals with different strategies to support DVA clients who were struggling with their mental wellbeing, which will lead to a more collaborated model of care. Health professionals reported that they would utilise the recommended DVA High Res SMART tools.

2022 Topic 1 "Persistent Pain" materials were mailed to GPs, pharmacists, psychologists, physiotherapists, exercise physiologists and veterans at the end of April 2022. Health professionals reported that they would utilise the pain neuroscience education or brain retraining tools for treating pain.

2022 Stage 1: Topic 2 "COVID-19 Rapid Response (Antivirals)" education materials were rolled out in June 2022 about the availability of COVID-19 treatments for veterans at high risk

of poor outcomes from COVID-19 infection and to provide information to assist doctors to use medicines safely in the high-risk population.

2022 Stage 2: Topic 2 "COVID-19 Rapid Response (Antivirals)". From 1 July 2022 the PBS eligibility criteria for COVID-19 oral antiviral treatments was expanded. Analysis of the DVA claims data showed an additional 75,000 members of the DVA community were likely to meet the new criteria. Based on this information, Stage 2 of the COVID Rapid Response materials were disseminated at the end of July 2022 to GPs and veterans.

2022 Topic 3 "Complex Medicines" materials were mailed to GPs, pharmacists, RACFs and veterans in August 2022. Evaluation of this topic is in progress.

Was ethical approval required from another ethical review body for this study?	☒ Yes ☐ No
If additional ethical approval was required, has evidence of their approval been provided to the Secretariat for inclusion on your file? If no, please provide a copy of the outcome letter in support of this report.	☒ Yes ☐ No
Is an extension to the period of ethical approval required?	☒ Yes ☐ No

If yes, please indicate when the extension is being requested until and include reasons for the request for extension. **Note:** An extension in excess of three years will not be granted. Any studies that require extensions longer than that period will need to submit an additional request for extension closer to the period of expiration of the revised period of ethical approval.

An extension of 12 months is requested through to 31 December 2023.The Agreement between DVA and UniSA for the provision of Veterans'MATES services, with an end date of 30 December 2018, included an option for a 3 year extension. DVA exercised its option to extend the agreement by 30 months to 30 June 2021. This was followed by an extension of 6 months to 31 December 2021 with a further extension of 12 months through to the end of 2022. UniSA submitted a tender response to the AusTender *ATM ID: MATES-21 Provision of the Veterans'MATES Program* beyond 31 December 2022. The outcome of the tender is pending.

Are records being maintained in accordance with the approved protocol?	☒ Yes ☐ No
If no, please provide details:	
Is the research project being conducted according to the protocol?	☒ Yes ☐ No
If no, please provide details:	
Are all conditions of ethical approval being met?	☒ Yes ☐ No
If no, please provide details:	

SECTION 4: PARTICIPANTS	
Does the study involve active recruitment of participants? If no, go to section 5.	☐ Yes ☒ No
Participant recruitment target:	
Recruitment to date:	
Is recruitment on target:	☐ Yes ☐ No
If recruitment is not on target, provide an explanation:	
Withdrawn to date:	
Provide reason(s) for withdrawal:	
Advise participant numbers if multiple reasons apply:	

Do you plan to increase the planned recruitment of participants into the study? Note: Any increase in planned recruitment should be notified to the Committee as a substantial amendment for ethical review.	☐ Yes ☐ No

SECTION 5: USE OF EXISTING DATA	
Does the study involve use of existing data? If no, go to section 6.	☒ Yes ☐ No
Describe the data transfer process: Data are transferred by secure file transfer between Services Australia and UniSA	
Description of data: DVA Health claims data	
Number of records: 250,000 persons	
Has the data custodian released the data?	Yes

SECTION 6: SITE INFORMATION	
Do you plan to increase the total number of sites proposed for the study? Note: A request for amendment will be required.	☐ Yes ☒ No
Has research been discontinued from any site?	☐ Yes ☒ No
If yes, please provide details:	

SECTION 7: ADVERSE EVENTS	
Have there been Adverse Events or Serious Adverse Events occur since the last report?	☐ Yes ☒ No
If yes, please summarise:	
If yes, has formal notification been submitted to the Departments of Defence and Veterans' Affairs HREC? If no, you will need to submit and Adverse Event/Serious Adverse Event Form.	☐ Yes ☐ No

SECTION 8: COMPLAINTS	
Have any participants, researchers or others expressed any complaint about the project?	☐ Yes ☒ No
If yes, please summarise:	
Have any participants claimed to have suffered harm or injury?	☐ Yes ☒ No
If yes, please summarise:	

SECTION 9: CLINICAL TRIALS		
Is the study a clinical trial? If no, go to Section 10		☐ Yes ☒ No
Is the study registered on a publicly accessible register?		☐ Yes ☐ No
If yes, provide the name of the register and the registration number.		
If no:		
a.	What is the reason for non-registration?	
b.	What are you intentions for registration?	

SECTION 10: OTHER ISSUES	
Are there any other developments in the project that you wish to report to the Committee?	☐ Yes ☒ No
If yes, please provide details:	
Are there any ethical issues on which further advice is required?	☐ Yes ☒ No
If yes, please provide details:	

SECTION 11: PRINCIPAL INVESTIGATOR DECLARATION	
I confirm that this project is being conducted in keeping with the conditions of ethical approval, and accurately reflects the status of the above research project. I confirm that the project is being conducted in compliance with the *National Statement on Ethical Conduct in Human Research*. I confirm that I have not received any information in any form from anyone involved in the project to suggest this report does not accurately reflect the progress of the project to date.	
s47F	s47F
Name	**Signature**
Date:	**14/11/22**

Australian Government
Department of Defence
Department of Veterans' Affairs

DEPARTMENTS OF DEFENCE AND VETERANS' AFFAIRS HUMAN RESEARCH ETHICS COMMITTEE

AMENDMENT FORM

In the event that an approved research project requires amendment, this form must be submitted to the Departments of Defence and Veterans' Affairs Human Research Ethics Committee (DDVA HREC) by the Principal Investigator (PI).

An amendment **must not** be implemented until approval has been granted by the committee.

All completed forms are to be electronically submitted to ddva.hrec@defence.gov.au

SECTION 1: PROJECT DETAILS	
Protocol Number:	E016-007
Project Title:	Veterans' MATES Program
Date of amendment submission:	14/11/2022

SECTION 2: PRINCIPAL INVESTIGATOR DETAILS	
Name:	s47F
Organisation (command/division):	University of South Australia (UniSA)
Phone:	s47F
Email:	@unisa.edu.au

SECTION 3: AMENDMENT DETAILS

Proposed/ intended changes - select all that apply

☒ research personnel [include name, contact details, conflict of interest declaration, role of project, brief CV not exceeding five pages]

☐ eligibility criteria/ research cohort [updated recruitment and consent materials may need to be provided. Ensure that for research that involves active recruitment of Defence personnel, that Command Approvals are relevant to the cohort and current. Additional approvals may be required]

☐ advertising/ recruitment [attach relevant documentation]

☐ survey/interview questions/ focus group [attach revised survey, interview focus group questions]

☐ site/s

☐ data

☒ extension to period of ethical approval

☐ other (please specify)

Reason for the changes *(include a comment on the impact on the research project and the participants at sites)*

Research personnel:

A new staff member fulfilling key role in program deliverables under Deed of Agreement with Department of Veterans' Affairs.

s47F

Extension to period of ethical approval:

An extension of 12 months is requested through to 31 December 2023.The Agreement between DVA and UniSA for the provision of Veterans'MATES services, with an end date of 30 December 2018, included an option for a 3 year extension. DVA exercised its option to extend the agreement by 30 months to 30 June 2021. This was followed by an extension of 6 months to 31 December 2021 with a further extension by 12 months through to the end of 2022. UniSA submitted a tender response to the AusTender *ATM ID: MATES-21 Provision of the Veterans'MATES Program* beyond 31 December 2022. The outcome of the tender is pending.

Do these changes raise any ethical issues?	☐ Yes ☒ No

If yes, identify the ethical issues.

List all amended documents to be reviewed.

Document Title - Insert additional rows if required.	**Version & Date**
s47F CV	

SECTION 4: PARTICIPATING SITES

Are all participating sites affected by this amendment? If no, list all affected sites below. Insert additional rows if required.	☐ Yes	☒ No

Site *(Organisation)*	**State**

An amendment to an approved research protocol may also impact the individual research sites. The Commanding Officer (CO) at each affected site (named above) must be notified of the amendment by the PI to determine if the site is impacted. Final approval to implement an amendment at a site will be issued by that site's CO.

SECTION 5: PRINCIPAL INVESTIGATOR DECLARATION

I confirm that this project is being conducted in keeping with the conditions of ethical approval. I confirm that the project is being conducted in compliance with the *National Statement on Ethical Conduct in Human Research*.

I confirm that I have not received any information in any form from anyone involved in the research to suggest this report does not accurately reflect the progress of the project.

s47F **Name**	s47F **Signature**
Date: 14/11/22	

From: s47E(d)
Sent: Friday, 18 November 2022 6:44 AM
To: s47F
Cc:
Subject: - E016/007 Veterans' Medicines Advice and Therapeutics Education Services [SEC=OFFICIAL]

OFFICIAL

Australian Government
Department of Defence
Department of Veterans' Affairs

Dear s47F

The amendment to this project to include s47F on the research team that was submitted on 14 November 2022 was approved out-of-session by the Chair of the Departments of Defence and Veterans' Affairs Human Research Ethics Committee (DDVA HREC).

You must forward a copy of this email to all Principal Investigators and to your institution. Please note that all requirements of the original ethical approval for this project still apply.

Should you wish to discuss this matter, please contact the DDVA HREC Secretariat on s47E(d) or ddva.hrec@defence.gov.au. The DDVA HREC wishes you every continued success in your research.

Yours sincerely

s47E(d)
Assistant Director Research Ethics

For
s47E(d)
Chair, Departments of Defence and Veterans' Affairs Human Research Ethics Committee

Campbell Park Offices
PO Box 7911, Canberra BC ACT 2610

The Departments of Defence and Veterans' Affairs Human Research Ethics Committee is constituted and operates in accordance with the *National Statement on Ethical Conduct in Human Research.*

From: s47E(d)
Sent: Friday, 18 November 2022 6:53 AM
To: s47F
Cc: s47F ddvahrec; s47F
Subject: Approval of extension of ethical approval - E016/007 Veterans' Medicines Advice and Therapeutics Education Services [SEC=OFFICIAL]

OFFICIAL

Australian Government
Department of Defence
Department of Veterans' Affairs

Dea s47F

Thank you for submitting a request to extend the period of ethical approval for the above research project. I have approved the request to extend the period of ethical approval until 31 December 2023 on the following conditions:

- The research is to be conducted in accordance with the approved protocol.
- The Principal Investigator will immediately report anything that might warrant review of ethical approval of the project.
- The Principal Investigator will notify the DDVA HREC of any event that requires an amendment/modification to the protocol or other project documents.
- The Principal Investigator will submit any necessary reports related to the safety of research participants.
- The Principal Investigator will submit progress reports to the DDVA HREC and notify DDVA HREC when the project is completed at all sites. The next progress report for this study is due by **14 November 2023**.
- The Principal Investigator will notify the DDVA HREC if the project is discontinued at a participating site before the expected completion date, with reasons provided.
- The Principal Investigator will notify the DDVA HREC of any plan to extend the duration of the project past the approval period listed above and will submit any associated required documentation.
- The Principal Investigator will notify the DDVA HREC of their inability to continue and indicate the name of and contact information for a replacement.

If you have any queries please feel free to contact the DDVA HREC Secretariat on s47E(d) or ddva.hrec@defence.gov.au.

The DDVA HREC wishes you every success in your research.

Yours sincerely

s47E(d)
Assistant Director Research Ethics

For
s47E(d)
Chair, Departments of Defence and Veterans' Affairs Human Research Ethics Committee

Campbell Park Offices
PO Box 7911
CANBERRA BC ACT 2610

DD Month 2022

The Departments of Defence and Veterans' Affairs Human Research Ethics Committee is constituted and operates in accordance with the National Health and Medical Research Council's (NHMRC) *National Statement on Ethical Conduct in Human Research.*

Australian Government
Department of Defence
Department of Veterans' Affairs

DEPARTMENTS OF DEFENCE AND VETERANS' AFFAIRS HUMAN RESEARCH ETHICS COMMITTEE

AMENDMENT FORM

In the event that an approved research project requires amendment, this form must be submitted to the Departments of Defence and Veterans' Affairs Human Research Ethics Committee (DDVA HREC) by the Principal Investigator (PI).

An amendment **must not** be implemented until approval has been granted by the committee.

All completed forms are to be electronically submitted to ddva.hrec@defence.gov.au

SECTION 1: PROJECT DETAILS	
Protocol Number:	E016-007
Project Title:	Veterans' MATES Program
Date of amendment submission:	15/05/2023

SECTION 2: PRINCIPAL INVESTIGATOR DETAILS	
Name:	s47F
Organisation (command/division):	University of South Australia (UniSA)
Phone:	s47F
Email:	@unisa.edu.au

SECTION 3: AMENDMENT DETAILS

Proposed/ intended changes - select all that apply

☐ research personnel [include name, contact details, conflict of interest declaration, role of project, brief CV not exceeding five pages]

☐ eligibility criteria/ research cohort [updated recruitment and consent materials may need to be provided. Ensure that for research that involves active recruitment of Defence personnel, that Command Approvals are relevant to the cohort and current. Additional approvals may be required]

☐ advertising/ recruitment [attach relevant documentation]

☐ survey/interview questions/ focus group [attach revised survey, interview focus group questions]

☐ site/s

☐ data

☒ extension to period of ethical approval

☐ other (please specify)

Reason for the changes *(include a comment on the impact on the research project and the participants at sites)*

Extension to period of ethical approval

New completion date requested: 30 June 2027.

In 2023, in response to the *AusTender ATM ID: MATES-21 Provision of the Veterans'MATES Program*, the University of South Australia was awarded the contract to deliver the Veterans' MATES Program and entered in to a new Deed of Agreement for the provision of the services with an initial deed period from 10 March 2023 to 30 June 2027 with two (2) option periods each with a duration of three (3) years.

Do these changes raise any ethical issues?	☐ Yes ☒ No
If yes, identify the ethical issues.	
List all amended documents to be reviewed.	

Document Title - Insert additional rows if required.	**Version & Date**

SECTION 4: PARTICIPATING SITES

Are all participating sites affected by this amendment? If no, list all affected sites below. Insert additional rows if required.	☒ Yes	☐ No

Site *(Organisation)*	**State**

An amendment to an approved research protocol may also impact the individual research sites. The Commanding Officer (CO) at each affected site (named above) must be notified of the amendment by the PI to determine if the site is impacted. Final approval to implement an amendment at a site will be issued by that site's CO.

SECTION 5: PRINCIPAL INVESTIGATOR DECLARATION

I confirm that this project is being conducted in keeping with the conditions of ethical approval. I confirm that the project is being conducted in compliance with the *National Statement on Ethical Conduct in Human Research*.

I confirm that I have not received any information in any form from anyone involved in the research to suggest this report does not accurately reflect the progress of the project.

s47F **Name**	s47F **Signature**
Date: 29/05/23	

Australian Government
Department of Defence
Department of Veterans' Affairs

2023/BN65423872

s47F
University of South Australia

Copy: s47F

Dear s47F

E016/007 VETERANS' MEDICINES ADVICE AND THERAPEUTICS EDUCATION SERVICES PROGRAM

Thank you for submitting a request to extend the period of ethical approval for the above research project. I have approved an extension to the period of ethical approval until 30 May 2026 on the following conditions:

- The research is to be conducted in accordance with the approved protocol.
- The Principal Investigator will immediately report anything that might warrant review of ethical approval of the project.
- The Principal Investigator will notify the DDVA HREC of any event that requires an amendment/modification to the protocol or other project documents.
- The Principal Investigator will submit any necessary reports related to the safety of research participants.
- The Principal Investigator will submit progress reports to the DDVA HREC and notify DDVA HREC when the project is completed at all sites. The next progress report for this study is due by 14 November 2023.
- The Principal Investigator will notify the DDVA HREC if the project is discontinued at a participating site before the expected completion date, with reasons provided.
- The Principal Investigator will notify the DDVA HREC of any plan to extend the duration of the project past the approval period listed above and will submit any associated required documentation.
- The Principal Investigator will notify the DDVA HREC of their inability to continue and indicate the name of and contact information for a replacement.

If you have any queries please feel free to contact the DDVA HREC Secretariat on s47E(d) s47E or ddva.hrec@defence.gov.au.

The DDVA HREC wishes you every success in your research.

Yours sincerely

s22

s47E(d)

Assistant Director Research Ethics

On behalf of
Departments of Defence and Veterans' Affairs Human Research Ethics Committee

Campbell Park Offices
PO Box 7911
CANBERRA BC ACT 2610

30 May 2023

The Departments of Defence and Veterans' Affairs Human Research Ethics Committee is constituted and operates in accordance with the National Health and Medical Research Council's (NHMRC) *National Statement on Ethical Conduct in Human Research*.