



Australian Government

Department of Defence

Department of Veterans' Affairs

BN62959020

**MINUTES OF THE 58th MEETING OF THE DEPARTMENTS OF DEFENCE
AND VETERANS' AFFAIRS HUMAN RESEARCH ETHICS COMMITTEE**

(DDVA HREC) EC00460

HELD AT s47E(d)

CANBERRA ACT 2600

ON 16 OCTOBER 2023

Attendees:

Dr Tony Cotton, AM

Chair



Secretariat:

s47E(c)

Assistant Director Research Ethics
Research Ethics Officer

Observers:

Ms Nadine Clode

Assistant Secretary Community & Research Branch
(Department of Veterans' Affairs) [via teleconference]

ITEM 1 – OPENING

1.01– Opening & Acknowledgment of Country

1. The meeting opened at 1410 hours. The Chair welcomed members and noted apologies from those listed above.
2. The Chair acknowledged and paid respects to the Indigenous custodians of Country throughout Australia, their culture and Elders past, present and future.
3. Ms Clode introduced herself to members.

1.02 – Meeting Recorded

4. The meeting was recorded for the purpose of transcribing of the minutes, and the audio recording will be deleted once the minutes are finalised.

1.03 – Conflicts of Interest

5. Members are to advise any conflicts of interests in accordance with the ‘National Statement on Ethical Conduct in Human Research’ (National Statement) paragraphs 5.2.4 and 5.4.5 and the ‘DDVA HREC Researcher and Administrative Guidelines’.
6. s47E(d) declared an institutional involvement with the projects being discussed at agenda items s47E(d) and that in the event that s47E(d) the meeting for those items were considered by the Committee to be a conflict of interest, s47 could leave the meeting for the discussion of those items. The Committee determined that there was a conflict of interest and that s47E(d) would excuse s47E(d) for the discussion of agenda items s47E(d).
7. s47E(d) both advised that they knew the s47E(d) but had no relationship with or involvement in the research being proposed.
8. No other conflicts of interest were declared.

ITEM 2 – CONFIRMATION OF THE PREVIOUS MEETING’S MINUTES

9. The Minutes of the previous meeting, that was held on 11 September 2023 were accepted by members upon motion by

ITEM 3 – MATTERS ARISING FROM PREVIOUS MINUTES

10. The Committee noted the Matters Arising from the previous meetings. Since the papers were circulated, the Defence sponsor have initiated contact with DDVA HREC and the researchers are liaising with them.
11. The Committee discussed processes for withdrawing ethics approval where ethics approval has expired and whether participants were advised of the withdrawal of ethical approval. It was noted that in instances where ethics approval has expired, multiple attempts are made to contact the researchers prior to closing the file. Moreover, as the DDVA HREC was not aware of who had actually participated in research, it is not feasible for the Committee to advise participants of the closure of the file and the implications for the research.

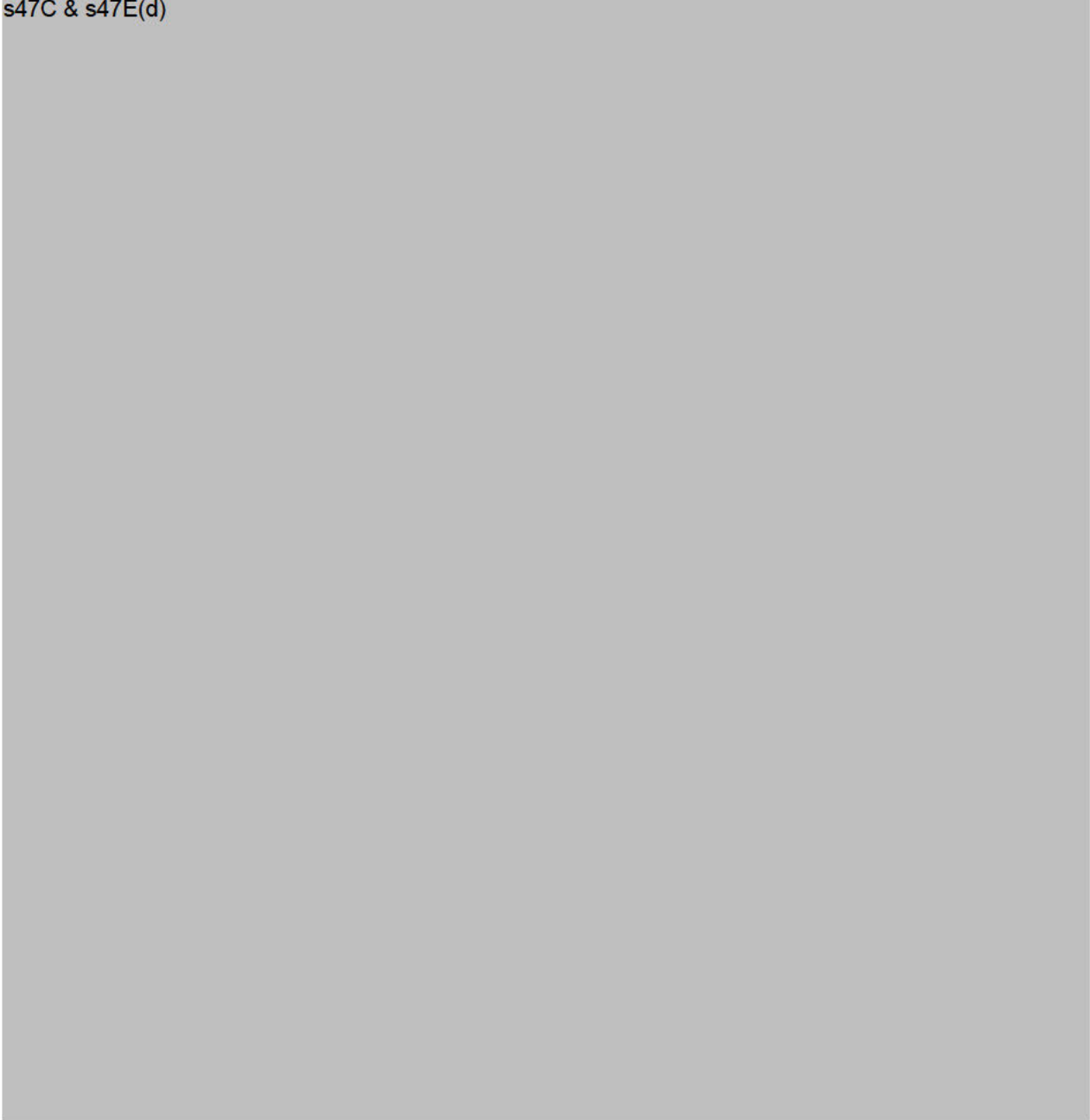
12. The Committee noted that where research is abandoned and recruitment had commenced, researchers are told that they should contact participants (where they are known to the researcher) to advise them of the abandonment of the research to uphold the principles of respect under the National Statement.

13. It was agreed that it would be beneficial to include further guidance within the policy regarding communication with research participants and sponsors where ethics approval expires, is withdrawn, or the research is abandoned.

Action: Secretariat to ensure that further guidance on implications of expired ethics approval, withdrawal of ethics approval and abandonment of research are included in the revisions to the DDVA HREC policy.

ITEM 4 – NEW APPLICATIONS (3)

s47C & s47E(d)



ITEM 5 – COMPLAINTS (1)

s47E(d)

s47E(d)

22. The Committee noted that an additional complaint has been received from the complainant that raised concerns about the s47E(d)

Some of the concerns raised are identical to what was raised by the complainant s47E(d).

23. The Chair and the s47E(d) met with the investigators and a representative from the s47E(d) to discuss the concerns and determine an appropriate course of action.

24. The Committee noted that response to the complainant from the Chair. The complainant has not responded to the DDVA HREC correspondence 47E(d)

ITEM 6 – PROGRESS AND FINAL REPORTS

25. The Committee noted the following:

- a. Fifteen Progress Reports were approved. A progress report was received for s47E(d) post circulation of the meeting papers, and has been approved.
- b. Two Final Reports were approved.
- c. Nine reports are being reviewed or further information has been requested.

s47E(d)

ITEM 7 – MATTERS FOR NOTING

27. The Committee noted the following:

- a. Six new applications were reviewed out-of-session under non-HREC pathways. Two other new applications were received but were deemed to be invalid.
- b. Four resubmissions were reviewed out-of-session. Ten resubmissions are pending.
- c. Two application were withdrawn by the researchers.

- d. Ten amendments were considered out-of-session.
- e. Five extensions to the period of ethical approval were considered out-of-session.
- f. Four desktop audits were conducted.
- g. No adverse or serious adverse event reports were received.
- h. No deviations were reported.

ITEM 8 – OTHER BUSINESS

8.01 – Veterans’ MATES Program

s47E(d)

29. The Committee noted that due to recent media coverage and multiple emails from individuals regarding the release of personal data to third parties, a review of the project file was undertaken by the Secretariat. s47C & s47E(d)

s47C & s47E(d)

30. As a result of the findings, the Chair wrote to the researchers and DVA, and requested further information regarding what data fields are being provided by DVA (including a description of the fields), copies of updated surveys and further information regarding the complaint that was referred to in the media article. They were also advised that no further data transfer was to occur until the matters identified above were resolved.

31. The University of South Australia and DVA have both provided a response

s47C & s47E(d)

32. Members were advised that 33 individuals have contacted the HREC and have raised concerns about the release of their personal information to the University of South Australia. Another individual has contacted the HREC following receipt of the DVA response to the Freedom of Information request. The response shows that in addition to personal health information, the personal details of the individual including name, date of birth, gender and address are provided to the University of South Australia.

33. Members noted that the complaint that was submitted to the Office of the Australian Information Commissioner (OAIC) related to an individual who opted out of participation in the program and DVA do not fully implement the request. s47

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s47C & s47E(d)

Note: the OIAC report is available at [Department of Veterans' Affairs final report – handling of personal information | OIAC](#).

34. Members discussed the matter at length and agreed on the following:

s47C & s47E(d)

35. Prior to sending the letter to the Principal Investigator and DVA, the draft correspondence is to be provided to members for review

Action: Secretariat to draft outcome letter and send to members for review prior to dissemination.

8.02 – Review of Standard Operating Procedures, Terms of Reference and ancillary documents

36. Members noted that policy, Terms of Reference and ancillary documents have been reviewed to ensure compliance with the updated National Statement (that comes into effect 1 January 2024). Members noted that the policy and Terms of Reference have been circulated twice for review and minimal feedback has been provided. If members wish to provide feedback on the proposed changes, they should do so by COB 23 October 2023.

37. Members noted the following:

- a. The layout has changed significantly from the current policy however much of the content remains unchanged
- b. Additional detail has been added where necessary to provide clearer guidance for stakeholders on what is required
- c. It is proposed to increase the period of ethical approval from three to five years. This would be consistent with the period of ethical approval allowed for unregistered therapeutic goods and devices and decrease the administrative workload for the Secretariat.
- d. It is proposed to remove the requirement for a signed Principal Investigators Assurance prior to the commencement of the research. The Project Description template amendments mean that Principal Investigators are required to sign something very similar prior to ethical review being conducted. Removal of the need to sign an assurance will ensure alignment with the practices for the low risk ethics panels and decrease the administrative workload of the Secretariat (less follow up of outstanding documents).
- e. It is proposed to remove the need for the Guidelines for Volunteers to be provided to research participants. The information contained within Participant Information Sheets has improved and negates the need for the provision of this document to participants. A link to the DDVA HREC

website for individuals who are wanting more information could be provided (website content will need to be updated).

38. There is no hard cap on the number of meetings to be held each year. Each year, approximately eight or nine meetings are scheduled for the year and the additional meetings provide contingency if an extraordinary meeting needs to be held. If additional meetings need to be held, approval will be sought.

39. As part of the discussion of agenda item 4.02, it was agreed that points of contact for the research should be members of the research team. This guidance should be added into the revisions to the DDVA HREC policy.

8.03 – Senior s47E(c)

40. Members noted that the APS6 s47E(c) role is currently being advertised and applications close this week.

8.04 – Resignation of s47F

41. Members noted that s47F has resigned and that in addition to the email that was sent to members (including s47F); the Chair has sent s47F a formal letter recognising the significant contribution s47F has made in s47F tenure on both the DDVA HREC and the Australian Defence Human Research Ethics Committee.

8.05 – Updated National Statement

42. Members noted that it is anticipated that further changes to the National Statement Section 4 will be made prior to the end of the year (following on from the public consultation earlier this year). Once the updates have been made, bound hard copies of the documents will be provided to members.

ITEM 9 – NEXT MEETING

43. The next DDVA HREC meeting is scheduled for 20 November 2023 at 1400 hours, s47E(d) in Canberra. The following members are rostered to attend:

[illegible]

44. The meeting closed at 1645 hours.

s22

Dr Tony Cotton, AM
Chair
18 October 2023

s22

s47E(c) [REDACTED]
Meeting Secretary
18 October 2023

Distribution list:

DDVA HREC

For information:

Director General, Health Business & Plans (Defence)

Executive Director, Strategic Policy (DVA)

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