



# Ministry of Defence Research Ethics Committee

## Minutes of 15<sup>th</sup> Meeting of the MoD Research Ethics Committee

Held at MoD Main Building, Whitehall  
On Tuesday, 03 June 2014

**Duration of Meeting:**  
Commenced at 0940 Hours  
Closed at 1615 Hours

**Participants:**

[REDACTED]

Chairman  
Vice-Chairman  
Alternate Vice-Chairman

[REDACTED]

MoD Science and Technology Adviser  
Military Advisor  
Military Medical Advisor  
MoDREC Secretary (Dstl)

**Apologies:**

[REDACTED]

**Attendees:**

[REDACTED]

Chair RNSAC

**MoDREC Protocol 552/MoDREC/14: Study into Team Dynamics in Increasingly Demanding Environments Based on Exercise Antarctic Endurance 2016.** [REDACTED]

33. The following points were raised by the Committee and [REDACTED] prior to the arrival of the researchers:

- [REDACTED] informed the Members that he had asked [REDACTED] to join the Committee for their pre-review as he had been put under impossible pressure to



review this protocol and ensure that it was of an appropriate standard to warrant a review.

- [REDACTED] acknowledged that the first version received had been somewhat lacking in scientific rigour but he believed that following a great deal of interaction and hard work it was no an actual protocol.
- [REDACTED] indicated that the protocol gave the impression the team were going to Antarctica for 30 months, in reality this was six months, so a realistic timeline would be helpful to demonstrate that the voyage at the end was a small part of the overall study.
- Concerns were raised by various members of the Committee that the impression was that if you signed up for the expedition you were also signing up for the study and it was agreed that these two issues needed to be clearly separated.
- [REDACTED] queried the actual nature of the research, questioning whether it was the tests at the beginning, middle and end or the training. Noting that there was complete confusion in the protocol.
- [REDACTED] reminded the Committee that this Exercise would go ahead regardless and that this was an opportunity to assess whether expeditions involving extreme conditions actually improved character in the way they were perceived to.
- [REDACTED] highlighted the necessity to separate out the training and the research and the requirement to be able to withdraw from the research aspect.
- It was acknowledged that the individuals were volunteering, and paying to go on the expedition and that this was not being used to select the participants for the Exercise.
- [REDACTED] highlighted that there were two parts to the study. The initial screening i.e. when send someone on adventure training were these the most individuals and whether these could be used to predict if these are the most resilient. [REDACTED] noted that [REDACTED] used stress questionnaires GHQ12 and/or CFQ to measure mental robustness
- [REDACTED] noted that if the individuals had signed up to the Exercise they would need to be involved in the training however from an NRES perspective this could be viewed as Service Evaluation rather than research and therefore would not require ethical approval.
- [REDACTED] highlighted that the PI had not been able to disarticulate the expedition from the research which resulted in it appearing to be coercive, the voluntary participation in the research needed to be up front.
- [REDACTED] raised concerns about the ability of the individuals to withdraw from the research study.
- [REDACTED] informed the Committee that he had spoken to [REDACTED] and believed that he did understand the issues and the requirement for separation but had been unable to articulate this. [REDACTED] also noted that this was a great opportunity to assess the success of this type of exercise in developing individuals.



- [REDACTED] highlighted that there was some urgency to be able to start this assessment study at the beginning of the selection process to access all of the potential participants at the start of the process.
- [REDACTED] indicated that he was struggling with the expedition and/or the research study to understand how many individuals would be involved. If n=50 for the research study then there is a reliance on everyone involved in the expedition being involved in the research study, but only 10-15 would be involved in the final leg.
- [REDACTED] indicated that he believed that there would be 11 individuals on the yacht but two of them would be investigators.
- [REDACTED] questioned whether in reality the success of the expedition would really be dependent on the leadership shown.
- [REDACTED] acknowledged that this was version 6 of the protocol and requested clarification of the changes. [REDACTED] confirmed that the changes from the study team were in blue and his were in red.
- [REDACTED] indicated that there was a requirement to state at the beginning that one aspect of the expedition related to training and another separate aspect to a research study which individuals could withdraw at any time. It was recognised that many of the individuals would probably wish to volunteer for the research study but that it needed to be made clear that there was an option and they could withdraw.
- [REDACTED] queried the key outcomes and questioned as a non-interventional study what the objective or hypothesis to be tested was. [REDACTED] indicated that there were some points on page 9 that could be utilised as null hypotheses.
- [REDACTED] questioned the statistical analysis and factor scores indicating that with over 70 results expected the factors were inadequate.
- The use of a control group was questioned and the need to test this group against time, in parallel to the test group was discussed to ensure there was a measure against time. [REDACTED] indicated that the protocol did not include any detail regarding the control group.
- [REDACTED] raised a concern regarding the ability of the investigators as listed to actually do the study. [REDACTED] indicated that he had had similar concerns but believed that the MOD staff had the grit to carry out the training and actual expedition and that they had the services of [REDACTED] to administer and review the questionnaires.
- [REDACTED] indicated that he had reviewed the website and accepted that many of the individuals involved would be highly motivated and were actually paying to go on the exercise but for the study n=50 so would there be any information gained if n =25. [REDACTED] stated that he did not believe that they would get a 50% drop out from the training.
- [REDACTED] highlighted that for the last leg of the exercise n=9 and queried what type of power calculation could be derived from this number.
- It was queried what would happen if the result was in the negative, i.e. the exercise had a detrimental effect on individuals.



- ██████████ indicated that it was very straightforward to split the two aspects of the training and research study.
  - ██████████ highlighted the requirement to improve the use of controls and ensure that there was a measure of variance over time.
34. ██████████, representing the research team was requested to join the meeting to enable the Committee to review the information provided and the following points were raised during the discussion:
- ██████████ stated that the Committee appreciated that although ██████████ was involved in the expedition he was not necessarily a member of the actual research team.
  - ██████████ indicated that there were two issues with the statistics which could be simplified by have an opt in option at each stage and questioned the use of factor analysis and whether this related to the raw data from each questionnaire or all of the questionnaires. ██████████ agreed to ask the research team to revisit the statistical analysis.
  - The issue of the control group was raised and it was indicated that if it was chosen to use a control group then this could be a straight forward study to measure change over time but there was a requirement to make it clear that the participants were opting in and what change was being measured.
  - ██████████ indicated that a high take up rate was expected for the research as these were highly motivated individuals but participation would not be enforced. It was noted that it was an interesting study and many of the individuals would be very interested in participating.
  - ██████████ again queried the use of a control group; ██████████ indicated that as the study was based around proven questionnaires it would not be onerous to bring in controls to complete the questionnaires.
  - ██████████ requested further clarification of the overall aims of the study. ██████████ reiterated that the aim of the study was to determine whether the adventure training was delivering against the premise. ██████████ suggested that the series of questions on page nine could be used as the hypotheses to tighten the experimental design. It was also noted that the outcomes detailed were in reality the outputs of the study.
  - ██████████ requested that more effort be put into clearly separating out the two aspects of training and research including detailing the benefits of the research, the time required for the research and their ability to withdraw their consent at any point.
  - It was highlighted that the questionnaires were part of the research study and that this aspect of the expedition was voluntary.
  - It was clarified that the training was not research and that the research was about the impact of the training.
  - ██████████ highlighted that if the PIS was reviewed it appeared to be recruitment for the expedition and not the research study. The MODREC application should relate

only to the research study and the reason the potential participants have been chosen to participate is because they have been selected for the expedition.

- [REDACTED] suggested that the consent to participate in the research study was removed from the overall consent to participate in the expedition and dealt with separately using the normal MODREC consent proforma.
  - [REDACTED] requested some context to the actual expedition. [REDACTED] informed the Committee that this was a six week long expedition in January – February 2016 which was comprised of a team of 11 servicemen and that half of the team would be within their first five years of Service. The Committee was also informed that this was being supported by the Royal Navy Leadership Academy.
35. [REDACTED] highlighted that the Committee had detailed the requirement to separate out the training and research aspects of the study and that it was important to ensure that the science was right to enable there to be a possibility of actually answering the questions.
36. [REDACTED] accepted the points made and stressed that there was a very tight deadline as the expedition and research study were scheduled to start the last weekend in June.
37. The Committee noted the ambitious deadline and accepted that it would be helpful to start the use of the questionnaires at the very beginning but stressed that more thought needed to go into the control group, including their recruitment.

**Action: Secretary to forward the revised version of protocol 552/MoDREC/14 to the Officers for review for approval ex-committee.**

**Action: The Officers to review and approve the revised version of protocol 552/MoDREC/14 ex-committee.**

*[The Committee spent 1 hour and 30 minutes reviewing the protocol]*

Secretary,  
MoDREC  
Date : 06 June 2014

Chairman,  
MoDREC  
Date :

Distribution: MoDREC Members  
Surgeon General  
Chief Technical Officer  
Senior Military Advisor Maritime  
MoDREC Secretary  
Chairs of the MoDSACs



**Annex A : MoDREC Actions**

<b>Serial</b>	<b>Date</b>	<b>Detail</b>	<b>Action</b>	<b>Status</b>	<b>Completion Date</b>
06/14-15	03 June 14	Secretary to forward the revised version of 552/MoDREC/14 to the Chairman to review and approve ex-committee	Secretary	New	01 July 14
06/14-16	03 June 14	Chairman to review and approve the revised version of protocol 552/MoDREC/14 ex-committee	Chairman	New	01 July 14

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