



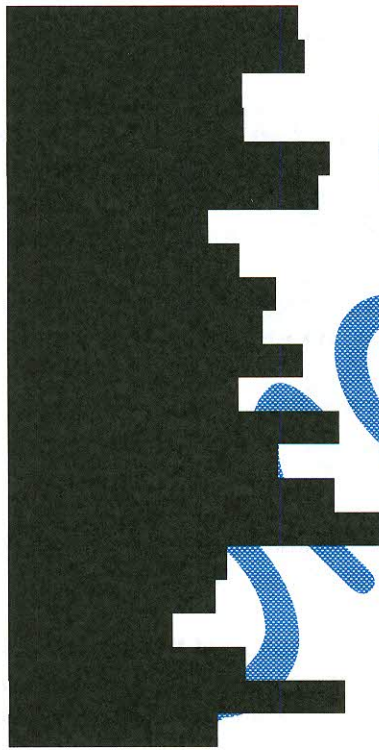
Ministry of Defence Research Ethics Committee

Minutes of 6th Meeting of the MoD Research Ethics Committee

Held at MoD Main Building, Whitehall
On Tuesday, 03 September 2013

Duration of Meeting :
Commenced at 0955 Hours
Closed at 1745 Hours

Participants :



Chairman
Vice-Chairman
Alternate Vice-Chairman

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



Chairman ASAC

Apologies :



Chairman RNSAC

MoDREC Protocol 465/MoDREC/13 : A Field-Based Thermal Burden Assessment of Operational Performance in a Hot Environment [REDACTED] and [REDACTED] [REDACTED] INM]

24. The following points were raised by the Committee prior to the arrival of the study investigators :

- [REDACTED] requested an opinion on this protocol from [REDACTED]. [REDACTED] informed the Committee that his personal view was that much of the information was already available and, therefore, he had to query

the need for the study. [REDACTED] clarified that a great deal of information was available on the temperature aspect and work had been conducted in hot dry environments.

- [REDACTED] highlighted to the Committee that within the MoD there were two funding routes, one of which was from CSA's research budget and then there was INM that was still funded 'on the vote'.
- [REDACTED] indicated that he believed that this study was to ensure that they can record body temperatures for future studies.
- [REDACTED] noted that this study was observational rather than monitoring and withdrawing at specific pre-set conditions, ie. 39.5 C.
- [REDACTED] queried whether there was the opportunity to control risk in the training environment.
- [REDACTED] drew the attention of the Committee to a previous study with divers in which the radio pill had been used to determine the lowest body temperatures and the duty of care aspect that had forced the withdrawal of individuals when their core temperatures reduced to potentially critical levels. It was also noted that the individuals had seen it as a challenge to achieve the lowest temperature.
- [REDACTED] noted that the pill would transmit the temperature in real time.
- [REDACTED] indicated that if the Committee did not approve the study, there would be no opportunity to understand what happens at 39.5 C.

[REDACTED] indicated that the recent events in the Brecon Beacons needed to be taken into account to determine whether or not reputationally it was the right time for the MoD to consider a study of this nature.

- [REDACTED] observed that the virtue of a real time study might be to obtain a real life view of what happens to the body in conditions over 39.5 C.
- [REDACTED] raised concerns over the perception of the responsibility of the MoD if the study is approved and an accident happens and it becomes known that the temperatures were being monitored but nothing was done once the recognised critical temperature was reached.
- [REDACTED] confirmed that the recognised critical core temperature for heat stroke is recognised as 39.5 C.
- [REDACTED] raised the aspect of the hormone level assessment and the arginine vasopressure impact which could result in severe dehydration. [REDACTED] queried whether the study was actually designed to identify these individuals and determine the impact in the protocol although it would be valuable information.
- [REDACTED] indicated that there was an argument that this study could provide valuable information for use in the ongoing investigation into the Brecon Beacons incident.
- [REDACTED] raised the similarities between this study and previous General Service Respirator (GSR) trials conducted in Australia, which had been approved by MoDREC(Gen). The Committee were reminded that this study had involved the trial

of the new GSR with chemical warfare suits in hot jungle conditions and that the training exercises had included every possible aspect which had resulted in several severe adverse events.

- ██████████ stressed that the study needed to be constrained to normal training conditions, ██████████ indicated that there was no set 'normal' training activity.
- ██████████ highlighted the requirement for clarification of the actual research question. ██████████ noted that there were five hypotheses for this study and ██████████ noted that none of these detailed the correlation of the peptides.
- ██████████ raised concerns that the study did not include real time sight of the data being monitored and that the safety issues were not clearly addressed in the protocol.
- ██████████ queried the pre-existing data from results in theatre and the recognition of individual variability.
- ██████████ observed that the PIS was all very vague and needed to be rewritten.
- ██████████ questioned whether the limitation of the availability of equipment was appropriate justification for the number of participants.
- ██████████ indicated that there were issues with the sample size and questioned the provenance of the paragraph in red regarding the multivariate analysis.
- ██████████ stated that if the study was observational on a routine training exercise then the individuals would be undertaking the exercise only and this was taking measurements for later analysis. However, it was a different prospect if the involvement of the study was likely to change the exercise, if this was the case it was proposed that the information was reviewed after two participants.
- ██████████ confirmed that the key was real soldiers in the real world situations doing what they would normally do with no changes.
- ██████████ highlighted the question of observation versus intervention and whether this was simply collecting scientific information.
- ██████████ clarified that the decision to remove any individuals from the exercise would be an operational decision.
- ██████████ observed that given the time period in which this was proposed it was likely that the results could be requested by the Coroner in relation to the ongoing investigation.
- ██████████ noted that the protocol was unclear as to the primary purpose as it was trying to do too many things, but if the primary objective was to assess maximum core temperatures then the numbers were too small to account for the individual variations.
- ██████████ queried whether there was any data on fatalities due to heat stress from theatre and the numbers of individuals experiencing this condition. ██████████ indicated that heat related illnesses were specifically defined but the numbers were unknown. ██████████ questioned the information from real life theatre experiences.

- [REDACTED] reviewed the normal processes of medical aid in the field, ie. first aid followed by a medic and questioned whether the presence of six individuals from INM labelled as medics would impact on action in the field.

25. The Research Team were requested to join the meeting to enable the Committee to review the information provided and the following points were raised during the discussion :

- [REDACTED] informed the Research Team that the Committee had had a lengthy pre-discussion on the protocol and had some questions including the primary purpose of the study. [REDACTED] informed the Committee that INM undertook a great deal of heat stress work via UORs. However, now the chassis and load carriage was changing over the next few years and there was a requirement to understand the actual core body temperatures and measure energy expenditure to set past and future research in context by understanding where it sits on the temperature continuum.
- [REDACTED] highlighted the incidents over the summer and indicated that these were the first time that these two aspects had come together.
- [REDACTED] pushed the study team to confirm the primary objective and it was confirmed that this was the observation of core temperatures and the endocrine aspect. [REDACTED] confirmed the interest in the impact of external aspects, particularly hot dry environments on the mechanistic aspects of endocrinology. It was clarified that this would generate novel data in hot environments.
- [REDACTED] noted the requirement to understand the consequences of the thermal load to provide a baseline to reduce the temperature and hormone impact.
- [REDACTED] observed that they were not actually monitoring the temperatures in real time but the PIS seemed to imply that this was the case. [REDACTED] queried the rationale for this approach.
- [REDACTED] indicated that to do so would interfere with the exercise. It was highlighted that in a previous study in Cyprus the exercise had been halted but the aim was to monitor the actual temperatures achieved, but if there was an incident the temperature data would be available.
- [REDACTED] informed the Committee that there was a technology issue as the transmitters were short range and that the data loggers were actually on the man with the team being removed by a set distance due to the nature of the exercise.
- [REDACTED] indicated that he would be additional medical support on the study.
- [REDACTED] questioned whether it would be obvious who was involved in the study and if the Platoon Cmdr was aware. [REDACTED] indicated that the whole platoon would be aware of the study and that some members would have volunteered. [REDACTED] indicated that there would be no obvious signs and that all of the platoon would look the same.
- The question of the possibility of increasing the activity of the exercise was queried. [REDACTED] indicated that these were elite Infantry and were possibly more cautious

following the events of the summer. [REDACTED] informed the Committee that the kit had been minimised and was designed not to have an impact.

- [REDACTED] questioned whether individuals would still be doing the same thing regardless of whether or not MoDREC approved the study. [REDACTED] confirmed that was the case.
- [REDACTED] queried the consent process and indicated that it was unclear, especially the time period between the PIS and taking consent. [REDACTED] clarified that the requirement was for genuine volunteers and that the whole Battalion was invited via daily orders to a series of presentations over a number of weeks, following this there were question and answer opportunities in either small groups or individually. She confirmed that they would have received a lot of information prior to consent and the interval would be at least 24 hours.
- [REDACTED] raised the issue that Part 1 Orders are mandatory. [REDACTED] confirmed that during the face to face briefings it was made clear that participation in the studies was voluntary.
- [REDACTED] requested that this detail be included in the sections 14a and 14b.
- [REDACTED] requested that on page 6 the hormone aspect was introduced and detailed properly.
- [REDACTED] queried whether there was any existing data relating to heat illness incidents during training exercises in Kenya. The Committee were informed that the reports were in single figures and probably unrealistic. Therefore, there was a requirement to assess them whilst doing normal jobs to understand the thermal stress.
- [REDACTED] stressed that all of the kit to be worn was normal for the exercise and the previous studies were those undertaken in the chamber.
- It was queried whether 24 individuals were too few to be able to assess the hormone levels due to normal individual variations. It was agreed that this was a possible issue but that this would be the first time these had been assessed out of the lab in real time situations.
- [REDACTED] informed the Committee that from taking previous work from the lab to the field it had become apparent that an exaggerated response was seen in the lab. Hence the requirement to do this study in real life where normal behavioural responses come into play. It was confirmed that this would provide a baseline for further studies in Kenya.
- [REDACTED] queried whether this was actually a pilot study. [REDACTED] confirmed that it was the first of a series of studies over the next few years as part of [REDACTED].
- [REDACTED] queried the power proposed and cautioned against generalisation.
- [REDACTED] questioned the provenance of the paragraph in red, [REDACTED] indicated that this had been added following advice from RNSAC. [REDACTED] requested the removal of the paragraph as he was satisfied with the explanation within the protocol.

- ██████ requested clarification in the protocol regarding the data analysis.
 - ██████ queried the timing of the blood samples. ██████ indicated that these would be at sunrise and as soon as possible post the live firing exercise.
 - ██████ queried whether any analysis would be undertaken in Kenya. ██████ clarified that all samples would be centrifuged on site prior to cold chain transportation back to INM. Analysis would be undertaken at either INM or Newcastle.
 - ██████ requested whether the study could be stopped if issues occurred during the exercise. It was confirmed that the study could be halted but the exercise couldn't. It was requested that this information be included in the protocol and the PIS.
 - ██████ whether there were any issues during the previous study the team had run in Cyprus. ██████ indicated that there were no issues, which was qualified by ██████ who informed the Committee that there were a couple of minor adverse heat illness issues which were dealt with immediately in accordance with the pre-set heat illness extraction process. The Committee were reassured that the pre-set heat illness extraction process had operated well.
 - ██████ highlighted that the exercise in Kenya had good medical support and that this would be present in a no play capacity ready to intervene if required.
 - ██████ queried the phrase small blood sample and requested that additional detail was provided in relation to the volume being taken.
 - ██████ questioned the inconvenience payment.
 - ██████ raised the issue of the transmission of the data logger and questioned whether it could transmit to base. ██████ reiterated that they did not have that technology, ██████ pointed out that Dstl did have the technology. ██████ indicated that in addition they did not want to use one in theatre that transmits.
 - It was requested that details relating to swallowing of the radio pill were included in the protocol together with the restrictions to be employed prior to its excretion. It was confirmed that the pill was a single use variety and that there was no requirement to collect and return it.
- ██████ highlighted that this specific tasking was from the Heat Illness Working Group, HIWG, under ██████.
- ██████ noted that this was an observational study but that there was also a requirement to be mindful of the external environmental conditions.
 - ██████ requested that the details of the anthropological measurements were included in the protocol and the PIS.

26. The researchers were requested to leave the meeting to enable the Committee to review the information provided during the discussion.

27. [REDACTED] clarified that the Committee was willing to support the protocol subject to clarification of :

- The recruitment process.
- The statistics to be utilised and the analysis process.
- The inclusion of the timing of the samples.
- The inclusion of an explanation of the peptidases.
- The inclusion of the safety data regarding the radio pill.
- The inclusion of the ability to halt the study.

Action : Secretary to forward the revised protocol to the Chairman for review and approval ex-Committee.

Action : Chairman to review and approve the revised protocol ex-Committee.

(The Committee spent 1 hours and 45 minutes reviewing the protocol)

Secretary,
MoDREC
Date : 05 September 2013

Chairman,
MoDREC
Date :

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

Annex A : MoDREC Actions

Serial	Date	Detail	Action	Status	Completion Date
06/13-06	03 Sept 13	Secretary to forward the revised protocol 465/MoDREC/13 to the Chairman for review and approval ex-Committee.	Secretary	New	08 Oct 13
06/13-07	03 Sept 13	Chairman to review and approve the revised protocol 465/MoDREC/13 ex-Committee.	Chairman	New	08 Oct 13

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