Annex K.  Examples of the consent form, the lay statement and the compensation form, introduced into use in 1987.

The following pages are examples of the forms introduced by Porton in 1987 for signed informed consent.

They are:

- a blank copy of the consent form
- an example of the lay statement (the example given relates to a study of the interaction between different forms of therapy)
- an example of the terms relating to compensation.
PARTICIPATION AS A VOLUNTEER IN
RESEARCH AT CBD PORTON DOWN

FORM OF CONSENT

I agree to take part in:

'Title of Study'

at CBD Porton Down, the general nature, object and duration of which have been described to me by a Military Officer (or Business Group Manager), not himself involved in the investigations, who is named below. He has given me ample opportunity to ask questions and has explained to me that I may withdraw at any time without prejudice to myself in any way.

I understand that each test involved in the investigation will be described to me by the investigator before the procedure is carried out. I shall be forewarned if any discomfort is likely to be involved.

I understand that an appropriate entry will be made in my Service (or OHS) medical documents. The procedure for applying to claim compensation, in the unlikely event of an accident occurring as a result of these investigations at CBD Porton Down, has been fully explained to me and I have been given a written copy of the details. I have been told that, if I am in doubt, I should consult the immediate superior in my unit (or my Business Group Manager) or if I have left the Service (or DERA), the nearest military unit (or my GP).

Signed: ____________________________  Signed: ____________________________

Date: ______________________________  Date: ______________________________

Name of Volunteer: ____________________  Officer / BGM: ______________________

Service / Staff No.: ____________________  Service / Staff No.: ____________________
A study of Pharmacokinetic Interactions Between Repeated Doses of Ciprofloxacin and Pyridostigmine Bromide

LAY STATEMENT TO BE READ TO VOLUNTEERS

If the situation arose where it was possible that both chemical and biological agents could be used against UK forces, service personnel would need to take the Nerve Agent Pretreatment Set (NAPS) and the Biological Agent Treatment Set (BATS) simultaneously for protection against the combined threat. NAPS consists of pyridostigmine (30mg), which is taken three times a day; BATS consists of the antibiotic ciprofloxacin (500mg), which is taken twice a day.

A study of the effect of taking single doses of ciprofloxacin and pyridostigmine suggests that the protective effect of NAPS might be reduced if it was taken with ciprofloxacin. No studies on the interactions between repeated doses of pyridostigmine and ciprofloxacin have, however, been carried out. The aim of this study is to establish whether there are any significant interactions between repeated doses of pyridostigmine and ciprofloxacin, so that advice can be given regarding the appropriate dose of NAPS, when it is to be taken together with BATS.

If you take part in this study you will be one of eight male volunteers, either servicemen or CBD staff. On four occasions, separated by at least six days, you will be asked to take (1) a single dose of ciprofloxacin, (2) a single dose of ciprofloxacin followed two hours later by pyridostigmine, (3) a single dose of pyridostigmine followed two hours later by ciprofloxacin, and (4) pyridostigmine eight hourly, and ciprofloxacin twelve hourly, for two days.

On the first three occasions, blood samples will be taken from a cannula in one of the veins in your forearm, and urine will be collected for 24 hours after you have taken the tablets. On the fourth occasion blood and urine sample will be collected on the first and third days after you have started taking the tablets.

You will be asked to remain in the Clinical Research Unit (CRU) while blood samples are being collected, to refrain from drinking alcohol for the duration of each study day, and to fast from 2300 hr on the night before each study day. You will also be asked to consume no xanthine containing foods (eg chocolate) or drinks (eg tea, coffee, cola) from 2100 hr on the night before the study until 2000 hr on the day of the study.

You may experience some discomfort following the insertion of an intravenous cannula on two occasions. You will be asked to collect urine samples for 24 hours which may be inconvenient. Side effects reported to occur in some people after taking pyridostigmine include nausea, stomach cramps, excess flatus, diarrhoea, and occasionally increased production of saliva or muscle twiching. Ciprofloxacin has been reported to cause nausea, vomiting and diarrhoea, occasionally headaches and disordered sleep patterns, and rarely skin rashes. These symptoms are all unlikely to occur after taking these two drugs for only two days.

If you agree to take part in this study you will be asked to sign a consent form stating that you understand that you are a volunteer and that you have been given details of how to apply to claim compensation in the very unlikely event of an accident. If you agree to take part and then decide not to, you may withdraw from the study at any time. You do not have to give a reason if you do not want to, and it will not be held against you in any way. You may be withdrawn from the study if you fail it or if you do not follow the study requirements.

It is CBD Sector policy to call back some of the volunteer subjects from time to time to ensure that the techniques we use give reproducible results, and to confirm that no significant changes have occurred with time.
PARTICIPATION AS A VOLUNTEER IN DERA RESEARCH

ARRANGEMENTS FOR COMPENSATION FOR
PERSONAL INJURY, DISABILITY OR DEATH

This document must be brought to the attention of all volunteers intending to participate in research approved by the relevant Ethics Committee and conducted by DERA staff before they volunteer to participate in each research project. Prior to participating, volunteers are required to sign to indicate that they have read and understand these arrangements. This signature is to be witnessed by one of the investigators.

Introduction.
This document sets out the arrangements for claiming compensation in the unlikely event of your suffering injury, disability or death as a result of participating as a volunteer in research approved by the relevant Ethics Committee and conducted by DERA staff (“DERA Research”). It has been approved by all DERA Ethics Committees.

Claiming No-Fault Compensation.
In the event of your suffering injury, disability or death as a result of participating as a volunteer in DERA research, DERA, without admission of liability, will offer you or your personal representatives a no-fault compensation payment. On behalf of DERA, the Ministry of Defence (DC&L(F&S)Claims) will assess the level of the compensation to be offered which will be determined by taking account of the level of compensation that a court would have awarded for the same injury, disability or death had it resulted from negligence. This no-fault compensation will be paid without the need to demonstrate negligence by DERA or to take legal action and does not in any way undermine the right to proceed via the courts if preferred. Further details of the no-fault compensation arrangements are at Annex A.

Service Personnel Only.

Pension.
In the event of your suffering injury or disability as a result of your participation in DERA research sufficiently serious for you subsequently to be medically discharged from the services, your medical records will automatically be forwarded to the Department of Social Security (DSS) War Pensions Agency for consideration of a war disablement pension in addition to whatever MOD pension/ gratuity you will be entitled to by virtue of your service. Similarly, in the event of death as a result of your participation in DERA research, your dependants may be entitled to receive a pension. If you or your dependants receive payment under the DERA no-fault compensation arrangements (or as a result of a common law compensation claim) for the same condition as that for which you or your dependants receive a pension, any pension entitlement may be reduced. Such payment may be taken into account because of the principle that someone should not be compensated twice for the same injury, disability or death.

If after you have left the service, other than for medical reasons, you consider that you are suffering some disability as a result of participating in DERA research, you should write direct to the DSS War Pensions Agency yourself, asking them to consider payment of a war pension or gratuity in respect of your disability. You should send full details of your disability and how it arose, to:

War Pensions Agency,
Norcross,
Blackpool,
FY6 3WP.
Common Law Compensation.
If you or your personal representatives believe that your injury, disability or death was caused by the negligence of DERA or its staff, and do not wish to pursue the possibility of a no-fault compensation payment, a common law claim for compensation may be submitted in accordance with DCI JS 126/97.

Civilian Staff Only.

Pension.
In the event of your suffering injury or disability as a result of your participation in DERA research sufficiently serious for you subsequently to suffer a loss in earnings capacity, you may be eligible for benefits under Section 11 of the Principal Civil Service Pension Scheme (PCSPS). Further details are available in the PCSPS booklet Injury at Work. Similarly, in the event of death as a result of your participation in DERA research, your dependants may be entitled to receive benefits.

Common Law Compensation.
If you or your personal representatives believe that your injury, disability or death was caused by the negligence of DERA or its staff, and do not wish to pursue the possibility of a no-fault compensation payment, a common law claim for compensation should be submitted in accordance with DCI GEN 178/97.

Non-MOD Personnel.

Common Law Compensation.
If you or your personal representatives believe that your injury, disability or death was caused by the negligence of DERA or its staff, and do not wish to pursue the possibility of a no-fault compensation payment, you or your representatives should write to DC8L(F&S)Claims 3 (at the address given in Annex A) setting out the full facts of the claim and stating that common law compensation is being sought.

Statement by volunteer
I, ........................................... (print initials and surname) have read and understand these arrangements.

........................................... (signature) ........................................ (date)

Witnessed by,

........................................... (print initials and surname)

........................................... (signature) ........................................ (date)
Annex A

PARTICIPATION AS A VOLUNTEER IN DERA RESEARCH
ARRangements FOR COMPENSATION FOR
PERSONAL INJURY, DISABILITY OR DEATH

The purpose of this Annex is to set out the arrangements for the payment of no-fault compensation in respect of volunteers who suffer injury, disability or death as a result of participating as a human volunteer in research conducted by DERA staff ("DERA research"). These arrangements are administered and financed by DERA and only cover DERA research. The no-fault compensation arrangements only apply to volunteers (service, civilian, or non-MOD) who participate in DERA research which has been approved by the relevant Ethics Committee.

A volunteer or his / her personal representatives ("the claimant") wishing to seek no-fault compensation under these arrangements should contact DC&L(F&S)Claims 3, Room 811, Ministry of Defence, Northumberland House, Northumberland Avenue, London WC2N 5BP using the form at Appendix 1. In the case of injury or disability, DC&L(F&S)Claims 3 may need to ask the volunteer to be seen by a MOD medical adviser.

DC&L(F&S)Claims 3 will consider reasonable requests for reimbursement of legal or other expenses incurred in relation to pursuing a claim (eg. private medical advice, clinical tests, legal advice on the level of compensation offered) provided that they have been notified by the claimant of the intention to make such a claim.

If an incident is sufficiently serious to warrant an internal DERA enquiry, any settlement will be delayed until the outcome is known and made available to the claimant in order to inform his or her decision about whether to accept no-fault compensation or to proceed with a common law claim.

Conditions of Receipt for No-Fault Compensation.
In order to claim compensation under these no-fault arrangements, a volunteer must have sustained injury, disability or death as a result of participation in DERA research. A claim must be submitted within three years of when the incident concerned occurred or, if symptoms develop at a later stage, within three years of such symptoms being medically documented.

On behalf of DERA, the Ministry of Defence (DC&L(F&S)Claims) confirms that a defence based on the Limitation Act will not be raised in relation to claims for no-fault compensation unless settlement negotiations fail and the claimant is given 28 days notice to issue and serve legal proceedings and fails to do so. The fact that a volunteer has been formally warned by DERA of possible injurious effects of the trial upon which a claim is subsequently based does not abrogate DERA's responsibility for payment of no-fault compensation.

In assessing the level of compensation in any case, DC&L(F&S)Claims 3, in line with common law principles, will take into account the degree to which the volunteer may have been responsible for his or her injury, disability or death and a deduction may be made accordingly. It is the volunteer's responsibility to do all that he or she can to mitigate his or her loss.

In the event of DC&L(F&S)Claims 3 and the claimant being unable to reach a mutually acceptable decision about compensation, the claim will be presented to a QC nominated by DC&L(F&S) for arbitration. This does not affect in any way the rights of the claimant to withdraw from the negotiation and pursue his or her case through the Courts. DC&L(F&S)Claims 3 will, however, undertake to accept the outcome of any such arbitration.

Footnote 4 Currently Sir David Calcutt QC, nominated for 5 years from 4 January 1999.
Appendix 1

DERA NO-FAULT COMPENSATION ARRANGEMENTS - CLAIM FORM

Please complete this form and then send it to: DC&S(L)(F&S)Claims 3, Room 811, Northumberland House, Northumberland Avenue, London WC2N 5BP

Full Name :

.................................................................

Rank/Title : ........................................ Date of Birth :

.................................................................

Unit/Establishment Address : .................................................................

.................................................................

Staff/Service No : ................................. N.I. No :

.................................................................

Name of DERA Establishment where injury was sustained :

.................................................................

Details of DERA research participating in at the time of the incident :

.................................................................

Incident :

.................................................................

Date of Incident :

.................................................................

Details of Incident :

.................................................................

Injury Sustained :

.................................................................

Any Additional Information :

.................................................................

.................................................................

STATEMENT : I am content for the Ministry of Defence, its agents and its medical advisers to have access to my Service / Medical records for the purposes of dealing with the claim for compensation.