



Medical Research Council

Medical Research Organisation
Common Cold Centre for
Virus Production and Research

MRC Common Cold Unit
Harvard Hospital
Coombe Road
Salisbury, Wilts
SP2 8BW

telegrams Harvard, Salisbury
telephone Salisbury (0722) 22485

our reference

Our reference C.1 (a)

PLEASE READ THIS BEFORE COMPLETING THE APPLICATION FORM

Dear Volunteer,

Thank you for your enquiry indicating that you may be willing to come here as a volunteer. I enclose an application form and a list of dates of future trials from which I hope you will find a suitable time.

When completing the form answer ALL questions fully and carefully, especially the section relating to your medical history. It is important to record details of previous illnesses or operations, and of any pills or medicines which you have taken in the recent past or at present. It is essential to ensure that volunteers are fit and are not taking medicines which might affect the results of the trials or, more importantly, might be harmful if taken with any of the trial materials which we may use here. In particular, individuals taking sleeping tablets, tranquillisers or anti-depressant medicines are not suitable for this type of research. Women should not volunteer if they are pregnant.

For information concerning the organisation of the Common Cold Unit, and procedures used during the trials, please read the attached Form C.1 carefully. It is necessary to point out that unmarried couples cannot be accommodated together.

Please note that volunteers have to give a blood specimen on arrival, and often another towards the end of the trial. A further specimen is collected by the volunteer's general practitioner or at a local hospital 10 days after departure, and sent by post in a specially provided pack to this Unit. Testing of these blood specimens measures the resistance of the volunteer to the particular virus before and after the trial.

Pets are not allowed.

Yours sincerely,

DR. JOHN S. WILLMAN M.B., B.Ch., D.P.H.
CLINICAL ADMINISTRATOR

Encs.

MEDICAL RESEARCH COUNCIL

Clinical Research Centre

MRC COMMON COLD UNIT*Postal Address:***HARVARD HOSPITAL,
COOMBE ROAD,
SALISBURY, WILTS
SP2 8BW****Telephone: SALISBURY (0722) 22485
Telegraphic Address: HARVARD, SALISBURY**

Introduction

The common cold is one of the primary causes of absenteeism from work, and of frequent visits to the doctor. It can also be a serious problem for old people and for those with chronic respiratory disease. So, for many years the Medical Research Council has supported the Common Cold Unit, where the problems of colds and influenza are studied. Many of the viruses which cause these diseases have been found, and at present the main object is to find ways of prevention, or even cures. Human volunteers are needed for this work, as convenient laboratory animals are not susceptible to the viruses.

Nearly 18,000 people have volunteered since the Unit was founded and nearly all of them have enjoyed their stay. Many have made repeated visits to the Unit.

Conditions for Volunteers

Healthy people aged 18-50 years are required to live here for periods of 10 days. Thirty volunteers can be accommodated for each period and board and lodgings are free. Pocket money of £1.75 per day is provided. Volunteers normally live in pairs (married couples or pairs of one sex) or in threes. Unmarried couples cannot be accommodated together. Although it may be possible for volunteers to live entirely on their own, we cannot guarantee this.

Each flat is centrally heated and has a sitting room, kitchenette, bathroom and either two or three individual bedrooms so that each volunteer has his or her own bedroom. Some volunteers like to come with a friend but many enjoy sharing with someone with common interests, and we can usually arrange this.

Free return travel warrants are issued for points of departure as far north as Glasgow and Edinburgh. Volunteers living further north will have to pay the excess fare. Volunteers from overseas and from Ireland will receive free travel from their port of entry subject to the same distance limitation as mentioned. Those planning to come by car or coach should contact the Unit before making final arrangements.

Facilities at the Unit

The Unit is sited on the southern boundary of the City of Salisbury, so there are good opportunities for country walks. However, volunteers must keep 30 feet away from anyone they may meet, including other volunteer groups. They may not go into the City, to any residential area, visit shops or pubs, or use public transport. Amenities provided include indoor and outdoor games involving not more than two or three persons (such as snooker, table tennis and badminton), a radio and colour T.V. in each sitting room, postal facilities and internal telephones for use during office hours. There is also a coin box telephone which may be used for outgoing calls only, provided the simple instructions concerning prevention of cross infection are observed. Urgent incoming messages for volunteers after office hours will, however, be passed on.

Library books and newspapers are provided free, though there is no restriction on the number of books which volunteers may wish to bring with them. There is ample opportunity for study, and this is particularly useful for students preparing for examinations.

Cooked meals are brought three times daily to the volunteer flats, and there are also facilities for making toast, tea, coffee, etc. In order to maintain isolation, domestic staff may not enter the volunteers' flats while trials are in progress. Volunteers are therefore asked to keep the flats clean and tidy and to make their own beds. The success of each trial depends on the willingness of volunteers to maintain strict discipline in essential matters affecting the experiment. Those unwilling to do so should not apply. Volunteers who break isolation will be sent home, and their pocket money withheld.

Research Procedures Undertaken

The work of the Unit started in 1946, and the early years were spent in discovering laboratory techniques which could identify Common Cold viruses. In the years up to 1965, workers at Salisbury discovered how to grow two new types of cold virus in cultures of living tissue, and to measure their activity by the changes produced in those cultures. Thus the rhinoviruses and coronaviruses were discovered.

The nature of our research is now changed and volunteers are required to take part in a variety of different types of experiments involving the common cold or influenza. For example, the mechanism of transmission of colds from one person to another is still not clear, and volunteers can help us with this sort of study. We also want to know why some people get colds and others do not.

We have recently shown that psychological factors and antibodies are important. Thus volunteers are asked to complete a short confidential psychological questionnaire at the start of each trial and to give a sample of blood. The results of these tests are later used to assess the individual's response to a virus. Our main work at present consists of testing a number of different preparations (interferon is one example) for their ability to prevent or cure colds. In order to monitor the progress of a trial, volunteers are seen by a doctor and nurse each day and we usually collect several samples of nasal secretion - a simple and painless procedure - and sometimes one or two blood samples. Volunteers may be asked to take part in any of these investigations, be it common cold trial, an influenza trial or a medicinal drug trial. Anyone not willing to do so should not apply. We shall only use experimental medicines after the trial has been approved by the Committee on Safety of Medicines.

Experimental Methods and Isolation Precautions

Our trials are based on the double-blind system, in which some volunteers are given a virus, and others what is called 'control' material - i.e. not containing a virus. Neither the volunteer, nor the doctor who visits each day will know who gets infective - and who gets non-infective - material. If the trial is concerned with testing a new drug, about half the volunteers are given the drug and the others an inert material similar in appearance to the drug. As with the virus, neither the volunteers nor the doctor will know what has been administered. At the end of the trial, all the information is put together and only then will the volunteers be told which material was given. This double-blind system ensures that we interpret correctly any symptoms which may develop, and that we do not imagine that we see signs and symptoms of an infection that are not really there. Also, the volunteer should not think that he is bound to develop symptoms after being given nose drops. Indeed there is a good chance that he may not. Some volunteers prove resistant to the virus inoculum anyway. By and large, only about one third of all volunteers actually develop symptoms.

Before the above procedures actually take place, volunteers are kept under surveillance for two or three days after arrival, so as to ensure that they have not brought a respiratory infection with them. Isolation continues throughout the trial, and volunteers must keep away from everybody apart from flatmates (the doctors, nurses and laboratory staff who visit the flats wear gowns and masks). Because cross infection may also occur by breathing air in a room in which other people have recently been, short intervals must be allowed between the use of games rooms by volunteers.

It is emphasised that our experiments will succeed and give accurate results only if volunteers strictly observe these simple isolation rules.

DAVID A.J. TYRRELL
DIRECTOR

JOHN S. WILLMAN
CLINICAL ADMINISTRATOR

M R C C O M M O N C O L D U N I T

Dear Volunteer,

Please note the following additional information concerning your visit to this Unit.

TRAVEL ARRANGEMENTS

You should arrive at the station or at this address by 11am on Tuesday. If you are too far away to do this, I suggest that you plan to arrive on Monday afternoon before 5pm. Accommodation will be ready and so will provision for hot drinks and snacks, but no cooked meal will be available before Tuesday lunch. If you are coming by rail or 'bus and fill in your expected time of arrival on the enclosed form we will meet you at the rail or coach station in Salisbury with transport marked 'Harvard Hospital'. If you are coming by car, we will arrange parking (if possible under cover) in the Unit grounds, if you let us know your estimated time of arrival. If you are coming by rail you will be sent a free travel warrant two weeks before the Trial. You should exchange this at your local railway station for a return ticket to Salisbury by the most direct route. If you are coming by road, the cost of the second class return fare may be claimed at the end of the Trial. Only one fare may be claimed irrespective of the number of volunteers travelling in the car. If you travel by coach, you may claim the cost of the return fare.

ARRANGEMENTS FOR YOUR STAY AT HARVARD

Isolation starts on Tuesday after lunch and ends on the following Thursday at 11am. After lunch on the Thursday, some volunteers wish to leave, but others prefer to explore Salisbury before leaving on Friday. Volunteers must vacate their flats by 9am on the Friday.

You will not be able to use your own or any other transport (including bicycles), during the isolation period of the Trial, but there is plenty of parking space available. It may even be possible for us to garage your car, but we cannot allow access to it until isolation is over, unless the permission of Matron or Clinical Administrator has been obtained.

If you like walking, bring heavy shoes or boots. Wellingtons can be supplied on request. An anorak or short coat which is wet and wind resistant is strongly advised, for although we usually enjoy good weather, it can be wet or windy at times. Rubber soled shoes or plimsolls will come in useful for games, etc. You need not bring games or books unless you wish.

Towels are provided, but you should bring personal toilet articles, including soap. You need only bring a few handkerchiefs as you will use our disposable ones during the Trial.

Free fishing on the Avon is available, but you must bring your own equipment. You can obtain full details and a Wessex River Authority licence when you arrive.

Please note that only basic provisions can be made for vegetarians or vegans, as there is no special dietary department at the Unit.

When you are in residence, personal calls can be made or received through the office switchboard during office hours 9am to 5pm, Monday to Friday, and 9am to 11.30am on Saturday. However, outgoing calls made during working hours will be charged for and deducted from pocket money. Outside office hours you cannot be telephoned, but an emergency message could be taken by Matron and delivered to you. A telephone box adjacent to the volunteer flats is also available for making outside calls, but incoming calls cannot be received on it.

We look forward to welcoming you to Harvard.

Yours sincerely,



JOHN S. WILLMAN M.B., B.Ch., D.P.H.

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VOLUNTEER'S APPLICATION FORM

Home Telephone Number:

Sex (M or F):

Date of Birth:

Age:

Occupation:

Number of previous visits (if any):

Date of last visit:

Trial number(s) you wish to attend:
*(If you are giving more than one Trial,
give the trial numbers in order of preference.
Put an R against the trial number if you are
prepared to be a reserve should that trial be
fully booked.)*

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Name of Partner(s) (who must apply separately)
(If coming with friends or relatives)

PLEASE GIVE FULL NAME AND ADDRESS BELOW, INCLUDING FIRST NAME.
(if details above are not correct)

MEDICAL HISTORY

Have you ever suffered from any of the following:
(If the answer is 'yes' give details with dates)

Asthma	Yes/No
Hay Fever	Yes/No
Chronic Nasal Catarrh	Yes/No
Sinusitis	Yes/No
Middle Ear Disease	Yes/No
Tuberculosis	Yes/No
Any other serious illness	Yes/No
Have you ever been in hospital (Include out-patients)	Yes/No
Are you taking any medicines or tablets prescribed by a doctor	Yes/No
N.B. No medication apart from oral contraception can be taken during a trial or for two weeks before.	
Height:	Weight:
Name and Address of Family Doctor	

I (Name) _____ of (Address) _____
 have read Form C.1 and understand the nature of the investigations proposed which are described therein.
 I offer my services as a volunteer and confirm my willingness to take part in any trials described, be it a
 common cold trial, an influenza vaccine trial, or a medicinal drug trial. I agree to fill in a psychological test
 questionnaire to be used solely for the analysis of my cold symptoms.

Signed _____

Date _____

MRC COMMON COLD UNIT

Medical Examination Record

MEDICAL HISTORY Present Condition	MEDICAL EXAMINATION			
U.R.T:	Height:		Weight:	
Abdominal:	Ears:			
C.N.S:	Nose:			
Other:	Throat:			
	Heart:		B.P:	
	Lungs:			
Previous Illnesses	Chest X-ray (if done):			
Asthma: Hay Fever:	Other systems:			
Sinusitis: Otitis Media:				
Tonsillitis: Influenza:				
Other Illnesses or Surgery:				
	Urine: Protein:			
	Sugar:			
	Pregnancy:			
	Blood Tests Abnormalities			
	Haematology		Biochemistry	
L.M.P: Last chest X-ray:	Pre-Trial	Post-Trial	Pre-Trial	Post-Trial
Allergies: Food: Drug:				
Others:				
Smoking History:				
Alcohol Usage:				
Medicaments:				
	Action taken:			
Common Cold Experience	<u>Post-Trial Observations</u>			
No./year (average):				
No. in past year:				
Last cold: Date:				
Duration:				

DAILY OBSERVATIONS

Day	0	1	2	3	4	5	6	7	8	9						
Sneezing																
Nasal Stuffiness																
Eyes																
Sore Throat																
Post-Nasal Disch.																
Hoarseness																
Cough																
Sputum																
Face/Ear Ache																
Headache																
Malaise																
Myalgia																
Chill																
Extra Bed (Hrs)																
Tissue Count																
Mucopurulence																
Temp a.m.																
Temp p.m.																
Nasal Obstruction																
Cervical Adenitis																
DAILY SCORE											TOTAL SCORE:					
Secretion Wts. (g)																
Virus Shedding																
Inoculum											O.	S.	I.	E.		
Medication																
ANTIBODY TITRE											COLD (significance of clinical response) 1 = not significant <input type="checkbox"/> 2 = significant <input type="checkbox"/>					
Test																
Pre-Trial																
Post-Trial																
Included in Trial:				Excluded:												

ASSESSMENT