TEXAS DEPARTMENT OF CORRECTIONS
Huntsville, Texas

AGENDA FOR REGULAR MEETING

OF THE

TEXAS BOARD OF CORRECTIONS

McAllen, Texas

354th Meeting

May 16, 1977

TEXAS BOARD OF CORRECTIONS

May 16, 1977

ORDER OF BUSINESS

Call to Order

Invocation

Approval of Minutes

I. INMATE AFFAIRS - Mr. Windham

A. Activity Summary

1. Educational Programs
2. Agency Reports
3. Chaplaincy Program
4. Medical Reports
5. Release Programs

B. Deaths

C. Statistical Reports

1. Disciplinary
2. Inmate Strength
3. Received-Released

D. Escapes

E. Interviews with Inmates

F. Multi-Purpose Building at Retrieve

G. Expenditure from E & R Funds for Folding Chairs at Coffield

H. Medical Research and Experimentation and Pharmaceutical Testing Protocols from Baylor College of Medicine

1. Comparison of Resistance to Wild-type Influenza A/Victoria Virus Following Vaccination with a Live-Attenuated Vaccine Candidate

(Cold-Adapted Recombinant) and
That Following Natural Infection

2. Development of Rhinovirus Type 3
Challenge System for Normal Volunteers

I. Amendment to Inmate Rules and Regulations

II. PERSONNEL - Mr. Boyd

A. Out-of-State Travel

B. Promotion Board

C. Training Academy

III. BUSINESS AND BUDGET - Mr. Montemayor

A. Selected Budget Records

B. Industrial Budget Report

C. Food Service Reports

D. Inmate Cost Per Day Report

E. Livestock Report

IV. LEGISLATION - Mr. McLaughlin

V. AGRICULTURE - Mr. LaMantia

Agricultural Report

VI. CONSTRUCTION - Mr. Shield

A. Progress Report

B. Authorization for Construction and/or
Renovation

VII. INDUSTRIES - Mr. Austin

Progress Report

VIII. LEGAL - Mr. McLaughlin

A. Tanya Tucker

B. Phillips Petroleum Company

TEXAS
DEPARTMENT OF CORRECTIONS

W. J. Estelle, Jr.
Director
Huntsville, Texas 77340

A. P. MANNING
ASSISTANT DIRECTOR
IN CHARGE OF TREATMENT

April 25, 1977

Mr. James M. Windham
Texas Board of Corrections
P. O. Box 1272
Livingston, Texas 77351

Dear Mr. Windham:

Enclosed is the Activity Summary for Inmate Affairs for the months of February and March, 1977. Would you please present this report at the next Board of Corrections meeting?

Board approval is requested for the following items:

- Funds remaining from the Retrieve Multi-Purpose Building to be diverted as follows:

  $17,500 Enlarge visiting room area at Retrieve Unit

  $5,000 Wynne Unit Band Building (additional $14,000 required is donated funds)

- Expenditure of $6,000 out of E & R Funds to be used for folding chairs on the Coffield Unit.

10753

- Medical Research and Experimentation and Pharmaceutical Testing Protocols from Baylor College of Medicine:

  1. Comparison of Resistance to Wild-Type Influenza A/Victoria Virus Following Vaccination with a Live-Attenuated Vaccine Candidate (Cold-Adapted Recombinant) and That Following Natural Infection.

  2. Development of Rhinovirus Type 3 Challenge System for Normal Volunteers.

Very truly yours,

A. P. Manning

mwk

Enclosures

State Commission for the Blind

Inmates Receiving Services	366
Monies Expended	$583.30
Local Funds (Non-client Services)	$595.40

Social Security Administration

Inmates Receiving Services	109

Texas Veterans Affairs Commission

Inmates Receiving Services	141

CHAPLAINCY

Number of Church Services	653
Inmate Attendance-Church Services	43,020
Counseling Interviews	11,224
Death Messages Delivered	230
Inmate Letters Written	1,402

MEDICAL REPORTS

General Hospital Report

Patients Admitted	409
Patients Discharged	404
Out-Patients Treated	2,067
Current Census	102

Unit Hospital Report
(All Units)

Medication Line	413,560
Sick Call with Physician	4,776
Sick Call with Medical Assistant	80,968
Routine Transfers for Medical Attention	1,547
Emergency Transfers for Medical Attention	138
Emergency Transfers to Civilian Hospital	60
New Inmates Processed	2,03[illegible]

Treatment Center

Treatment in First Aid	0
Sick Call with Medical Assistant	59
Sick Call with Physician	3
Interviews with Psychiatrist	281
Current Census	293

Operating Room Census

General Surgery	30
Local Surgery	43
Oral Surgery	7
Ophthalmolic Surgery	0
ENT Clinic	21
Plastic Procedures	30
Podiatry Clinic	32
Anesthetics	0
Procedures - John Sealy Hospital	49
Blood Transfusions	0
Procedures - Huntsville Unit Hospital	141

Laboratory Reports

Hemotology	2,430
Blood Chemistry	3,604
Bacteriology	426
Parasitology	12
Urinalysis	2,602
Serology	810
Blood Bank	8
Cerebrospinal Fluids	0
Total Laboratory Reports (All Units)	9,892

Roentgenologist Reports

General	1,154
Head	199
Extremities	518
Electrocardiograms	166
Electroencephalographs	22
Total Reports	6,803

Special Clinics Report

Ophthalmology Out-Patients	2,092
Optometrist-Refractions Completed	607
Total Reports	2,699

Oral Surgery Reports

Total	136

Dental Procedures
(All Units)

Total	10,964

Medical Reprieves

Total	98

RELEASE PROGRAMS

Pre-Release Programs

Inmates Completing Programs	345
General Sessions	136
Group Counseling Sessions	8
Individual Counseling Sessions	50
Outside Activities	10
Speakers Participating	126
Present Enrollment	161

Work Release Programs
(See Exhibit A)

Inmates Employed	38
Inmates Removed	8
Inmates Currently Employed	30

Post-Release Program

Inmates Enrolled	229
Job Resources Developed	62
Enrolled Inmates Released	22
Positive Terminations	178

1. Title: Comparison of Resistance to Wild-Type Influenza A/Victoria Virus Following Vaccination with a Live-Attenuated Vaccine Candidate (Cold-Adapted Recombinant) and That Following Natural Infection

2. Principal Investigator and Associates: Thomas R. Cate, M. D.
Robert B. Couch, M. D.
Julius A. Kasel, Ph. D.
Howard R. Six; Ph. D.
W. Paul Glezen, M. D.
Vernon Knight, M. D.

3. Department Involved: Microbiology and Immunology

4. Granting Agency: NIH Contract AI 42528

5. Period of Grant: June 26, 1974 - June 25, 1979

6. Location of Study: Baylor College of Medicine
Ramsey Unit of the Texas Department of Corrections

7. Outline of Study:

Background Information. Parenteral vaccination with currently available inactivated influenza A virus vaccines provides 50-90% protection against infection with homologous virus (1). Estimates of the duration of protection against closely related influenza viruses have ranged from 3 years to more than 15 but less than 27 months (2). An additional problem is frequent antigenic variation of influenza A viruses necessitating yearly review and frequent updating of the vaccines. As a consequence, annual revaccination is recommended in order to obtain the greatest possible protection with inactivated influenza vaccines.

Occasionally troublesome but rarely serious reactions to inactivated influenza vaccines, such as headache, malaise and fever, have been reduced to an apparent minimum consistent with retention of antigenicity by current methods of manufacture. However, a much less frequent but more serious concomitant to vaccination with inactivated influenza vaccines came to light during the 1976 National Influenza Immunization Program, namely, the Guillain-Barre syndrome (3). This syndrome of uncertain pathogenesis is characterized by ascending paralysis and frequently follows mild respiratory illnesses by 2-3 weeks. It normally occurs at a monthly incidence of about 0.6 per million persons and carries a 5-10% mortality. Recipients of influenza vaccine in the fall of 1976 had a definitely increased incidence of Guillain-Barre syndrome, approximately 12-fold, with the increase being greatest 2-3 weeks after vaccination and not persisting longer than 2 months after vaccination (4).

Because of the association of inactivated influenza vaccine administration with Guillain-Barre syndrome, all human studies involving influenza vaccination were suspended. This suspension includes trials that we and others (Drs. Brian Murphy, Myron Levine, and Gordon Douglas) have been performing with live-attenuated influenza virus vaccine candidate strains administered intranasally. No complications have occurred during the latter trials, but the number of participants is low enough that it is still possible that an attenuated influenza virus infection could be associated with Guillain-Barre syndrome if the monthly incidence is as low as the approximately one case per 140,000 observed following receipt of inactivated influenza vaccine. However, when one examines the question of whether Guillain-Barre syndrome occurs following natural influenza virus infection, the seasonal patterns of occurrence of the two do not overlap, suggesting that there is no association (5, 6). A study comparing serological evidence of recent influenza infection in patients with Guillain-Barre syndrome and control subjects failed to find any difference in the two populations (7), and there is no correlation of deaths from Guillain-Barre syndrome with influenza-pneumonia deaths over the past 10 years (see attached figure and reference 8). Therefore, if attenuated influenza virus infections behave like natural infections appear to do in causing little predisposition to Guillain-Barre syndrome, it could be argued that the increased incidence of the syndrome after receipt of inactivated influenza vaccines should provide added impetus to the development of live attenuated vaccines. Moreover, it is hoped that respiratory infection with the latter vaccines will induce a more effective and durable immunity than that following receipt of inactivated vaccine.

The protocol under which we were performing trials with live attenuated influenza viruses, "Evaluation of Recombinant ts-mutant Vaccines for Influenza A/Victoria Virus," was approved by Baylor College of Medicine (6/22/76), the Texas Board of Corrections (7/12/76), and the National Institutes of Health (6/22/76) committees for review of human research. Studies performed under this protocol prior to the suspension involved a total of 55 volunteers and are summarized below.

Thirty-two men were inoculated intranasally with 8×10^4 $TCID_{50}$ of influenza vaccine candidate, A/Victoria/75-ts-1[E], on 7/25/76. Two of those 32 men had high titers of naturally acquired antibody and have been excluded from further analysis. Of the remaining 30 men with both hemagglutination inhibiting (HAI) and antineuraminidase serum antibody titers of $\leq$1:20 before inoculation, 15 shed ts-virus in their nasal secretions, 18 developed an $\geq$4-fold rise in serum antibody titer (HAI and/or neutralizing) against influenza A/Victoria, and a total of 23 were infected based on one or both of these criteria. However, 10 of 30 men inoculated with the candidate vaccine virus also developed a respiratory illness, 4 with fever ($\geq$ 100°F).

On 9/19/76, 14 of the men who had received influenza A/Victoria-ts-1[E] eight weeks previously were challenged intranasally with 8×10^5 $TCID_{50}$ of wild-type influenza A/Victoria virus. Two of these men had had no evidence of infection with the ts-virus; both were infected by the wild-type virus

(no virus shedding, but ≥4-fold rises in serum neutralizing antibody titer) and both developed febrile respiratory illnesses. Of the 12 remaining men who had all shown evidence of infection with the ts-virus, 7 also developed infection with wild-type virus based on virus shedding (1 man) and/or an ≥4-fold rise in serum HAI or neutralizing antibody titer (7 men) and 3 developed respiratory illness, 2 with fever. Among 5 control subjects for the wild-type virus challenge, 1 man was excluded from analysis because of high titers of naturally acquired antibody; the remaining 4 all shed virus and developed ≥4-fold rises in HAI or neutralizing antibody, and 3 of the 4 developed respiratory illnesses, 2 with fever.

On 1/6/77, 18 additional men were inoculated intranasally with 8×10^5 $TCID_{50}$ of another live attenuated vaccine candidate, an influenza A/Victoria/75-cold-adapted recombinant virus strain. Of these men, 14 had initial serum neutralizing antibody titers of ≤1:4 and 13 of them became infected as manifested by an ≥4-fold rise in serum neutralizing antibody titer; two of the latter 13 men also shed virus and three developed mild, afebrile rhinitis. Of 4 men who initially had serum neutralizing antibody titers of 1:8 or 1:16, none shed virus nor became ill, but one developed a rise in antibody titer from 1:16 to 1:128.

In summary, the data obtained in these studies suggests that the influenza A/Victoria/75-ts-1[E] vaccine candidate strain retains the capacity to cause illness in about a third of persons with low titers of both HAI and antineuraminidase antibody, and the resistance imparted by this vaccine candidate strain against challenge with wild-type virus was less complete than anticipated. In contrast, illness caused by the A/Victoria/75-cold-adapted vaccine candidate strain was negligible and serum neutralizing antibody responses occurred with greater frequency than was observed with the ts-virus. Data concerning the resistance of recipients of the cold-adapted recombinant to challenge with wild-type virus and the resistance of men with naturally-acquired antibody to a similar challenge are needed to complete an evaluation of the efficacy of these two types of vaccine candidate strains.

Purpose. To evaluate the protection against wild-type influenza A/Victoria challenge afforded by previous intranasal infection with A/Victoria/75-cold adapted-recombinant vaccine candidate virus, and to compare these results with the protection afforded by previous naturally-acquired A/Victoria infection.

Description of Study. Volunteers who were previously vaccinated by means of intranasal inoculation with the influenza A/Victoria-cold-adapted-recombinant virus and 25 additional men who are 18-40 years old and selected to have a range of naturally acquired serum neutralizing antibody to influenza A/Victoria virus (up to 10 men having little or no detectable antibody) will be housed in the 11-Wing of Ramsey Unit I of the Texas Department of Corrections. After an initial history, physical examination, and laboratory evaluation (CBC, urinalysis, chest x-ray and electrocardiogram) to insure their good health, the men will be challenged intranasally with a similar dilution of

the same wild type influenza A/Victoria virus used in previous components of this study. This virus pool, supplied through NIAID, was grown in embryonated eggs and has satisfied safety requirements of the Bureau of Biologics, Federal Drug Administration. Volunteers will remain isolated in the 11-Wing and will be examined at least daily by a physician for respiratory illness for 8-14 days after inoculation, depending on the duration of any respiratory illnesses observed. Studies outlined on the attached protocol (appendix #1) will be performed to detect evidence of virus infection.

Discomfort to Subjects. The discomforts associated with this project are those of venipunctures, nasal wash collections, and possible influenza illness. Experience with several hundred such intranasal influenza virus challenges indicates that any illness which occurs will generally be mild and last only 3-4 days; no pneumonia or serious complications of these artificially-induced infections have occurred. The possibility that a volunteer may develop Guillain-Barre syndrome is considered remote.

8. HUMAN SUBJECTS

a) Subject population. Volunteers will be 18 to 40 year old male inmates of the Ramsey Unit, Texas Department of Corrections. Details of the selection process have been previously submitted. Volunteers must have no known allergy to chicken eggs or feathers, since the challenge virus was grown in embryonated eggs. Volunteers who complete the protocol will be offered $35. This level of remuneration is approximately equivalent to $4 for each blood specimen and $1 for each nasal wash specimen, the rate at which any volunteer who chooses to withdraw will be remunerated for specimens collected prior to his withdrawal.

b) Discomfort and Potential Hazards. Some discomfort will be associated with obtaining blood and nasal wash specimens for virus isolation. Acute allergic reactions to the intranasal virus inocula are remotely possible and all will be administered in the presence of a physician with emergency medications on hand if needed. Influenza illness may occur in some volunteers (see consent form). Volunteers will be seen at least daily by a physician, and all volunteers will have immediate access 24 hours a day to a medical aide who will notify the responsible physician so that care can be given as indicated. If illness should be severe enough to warrant care beyond facilities immediately available, arrangements have been made for hospitalizing individuals for more definitive care.

Spread of virus to persons not participating in the studies is a possibility, but minimal for several reasons. All subjects will be isolated during the period when they might be infectious. Furthermore, the virus to be used in this study belongs to the Hong Kong (H3N2) era which began in 1968;

infection with a member of this subtype of influenza A virus has been almost universal among adults, and a large proportion have been infected with the particular strain to be used, influenza A/Victoria. The level of immunity in the general population is sufficiently high to minimize any spread of the virus with which we will be working. Sick calls will be monitored, nevertheless, to make sure that there is no evidence of increased respiratory disease during the period of study, and appropriate diagnostic studies will be undertaken for any illnesses which do occur.

The hazard of one of the volunteers developing Guillain-Barre syndrome is considered remote. The volunteers and medical officers and aides at the Ramsey Unit will all be informed about the syndrome and they will all be asked to contact us if any suspicious signs or symptoms appear. In addition, the volunteers will be questioned about any suspicious signs or symptoms at the time of the collection of the blood sample 1 month after inoculation and again 3 months after inoculation. Any suspicious findings will be further evaluated and the volunteer will be aided in obtaining appropriate care.

c) Method of Obtaining Informed Consent. A general description of the study and the procedures to be performed will be given the volunteers verbally. Then, while they have the consent form (Appendix #2) in hand, the volunteers will be given a detailed explanation of what is to be done, including all known hazards, and they will be given an opportunity to ask any questions they desire. It will be made clear that the volunteer can remove himself from the study at any time, but that he may have to remain in isolation a few days if he is potentially infectious for others. Volunteers will then be asked to sign the consent form for the study.

d) Protection against Hazards. Protection against physical hazards has been outlined under section 8b above. Records concerning each volunteer's participation in this project will be maintained in a secure place in the Influenza Research Center. Any publication of results will not contain individual volunteers' identities.

e) Benefits to the Subject. Those subjects who have sufficient immunity to resist infection will obtain no direct benefit from these studies. Those volunteers who do become infected with the challenge virus should have long lasting protection against closely related viruses, a protection acquired with much less risk of serious illness than occurs with natural influenza virus infection. The major benefit of this study, however, is a societal one of helping in the attempt to develop more efficacious means of preventing influenza disease.

f) Risk-Benefit Ratio. The major risk of this study consists of having influenza illness, but an illness generally much less severe than the natural influenza illness to which these men would have otherwise also been susceptible. The incidence of Guillain-Barre syndrome does not appear to be significantly increased by natural influenza illness and there is no reason to believe that it would be by artificial infection with wild-type virus. Thus, the relative risks of this study seem acceptable when placed against the possibility of furthering the development of more effective means for reducing the morbidity and mortality caused by naturally occurring influenza virus infection.

Thomas R. Cate, M. D.
Principal Investigator

Robert B. Couch, M. D.
Director, Influenza Research Center

Vernon Knight, M. D.
Chairman, Dept. of Microbiology and Immunology

REFERENCES

1. Leibovitz, A., Coultrip, R. L., Kilbourne, E. D., et al: Correlated studies of a recombinant influenza virus vaccine. IV. Protection against naturally occurring influenza in military trainees. J. Inf. Dis. 124:481-487, 1971.

2. From the National Institutes of Health. Influenza Vaccines--Summary of Influenza Workshop V. J. Inf. Dis. 129:750-771, 1974.

3. Guillain-Barre Syndrome--United States. Morbidity and Mortality Weekly Report 25:401, 1976.

4. Center for Disease Control. Handout #4, January 7, 1977. (Note that components of the handout are dated February 3-4, 1977.)

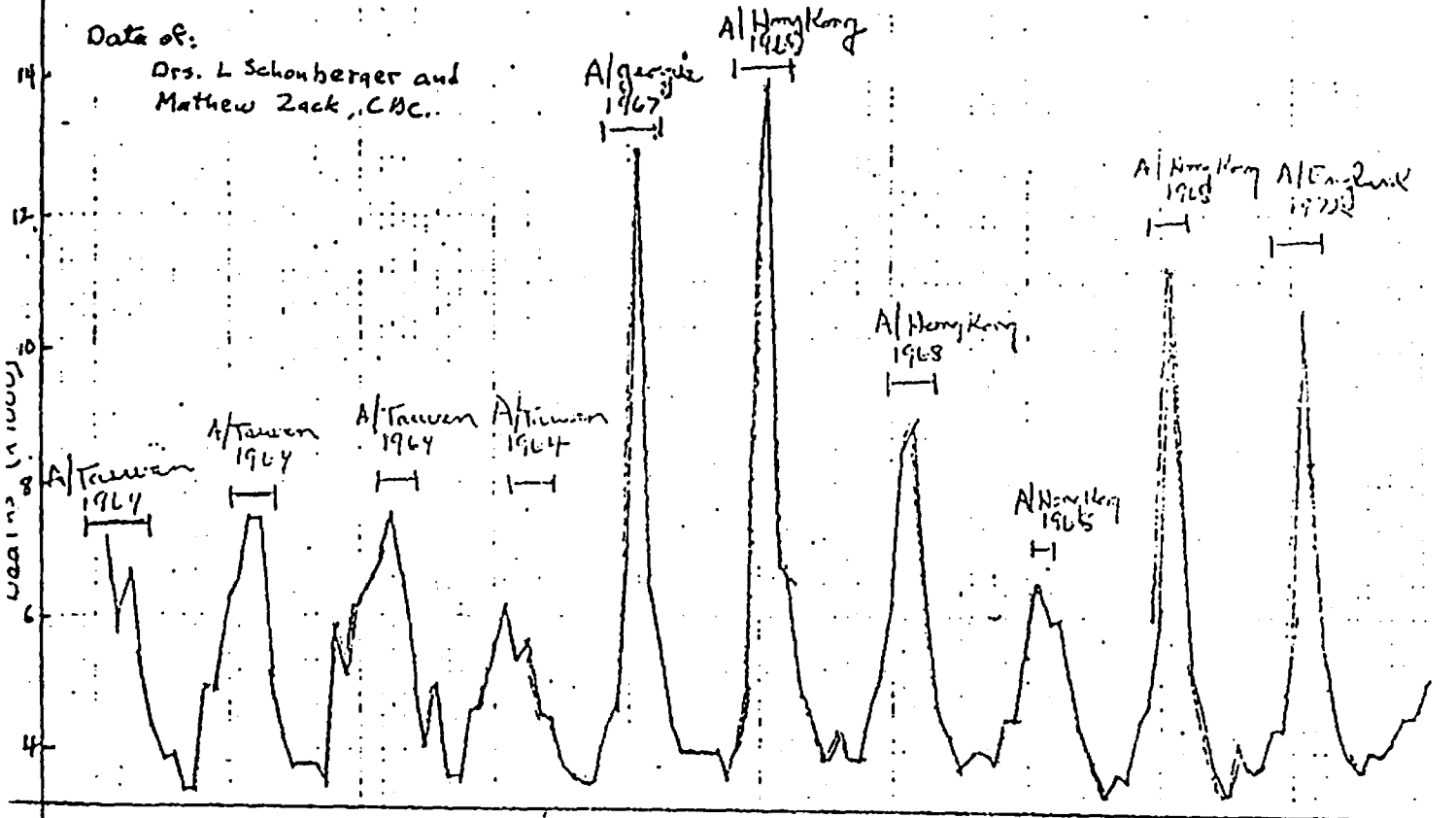
5. McFarland, H. R., and Heller, G. L.: Guillain-Barre disease complex: A statement of diagnostic criteria and analysis of 100 cases. Arch. Neurol. 14:196, 1966.

6. Wiederholt, W. C., Mulder, D. W., and Lambert, E. H.: The Landry-Guillain-Barre-Strohl syndrome or polyradiculoneuropathy: Historical review, report on 97 patients, and present concepts. Mayo Clinic Proceedings 39:427, 1964.

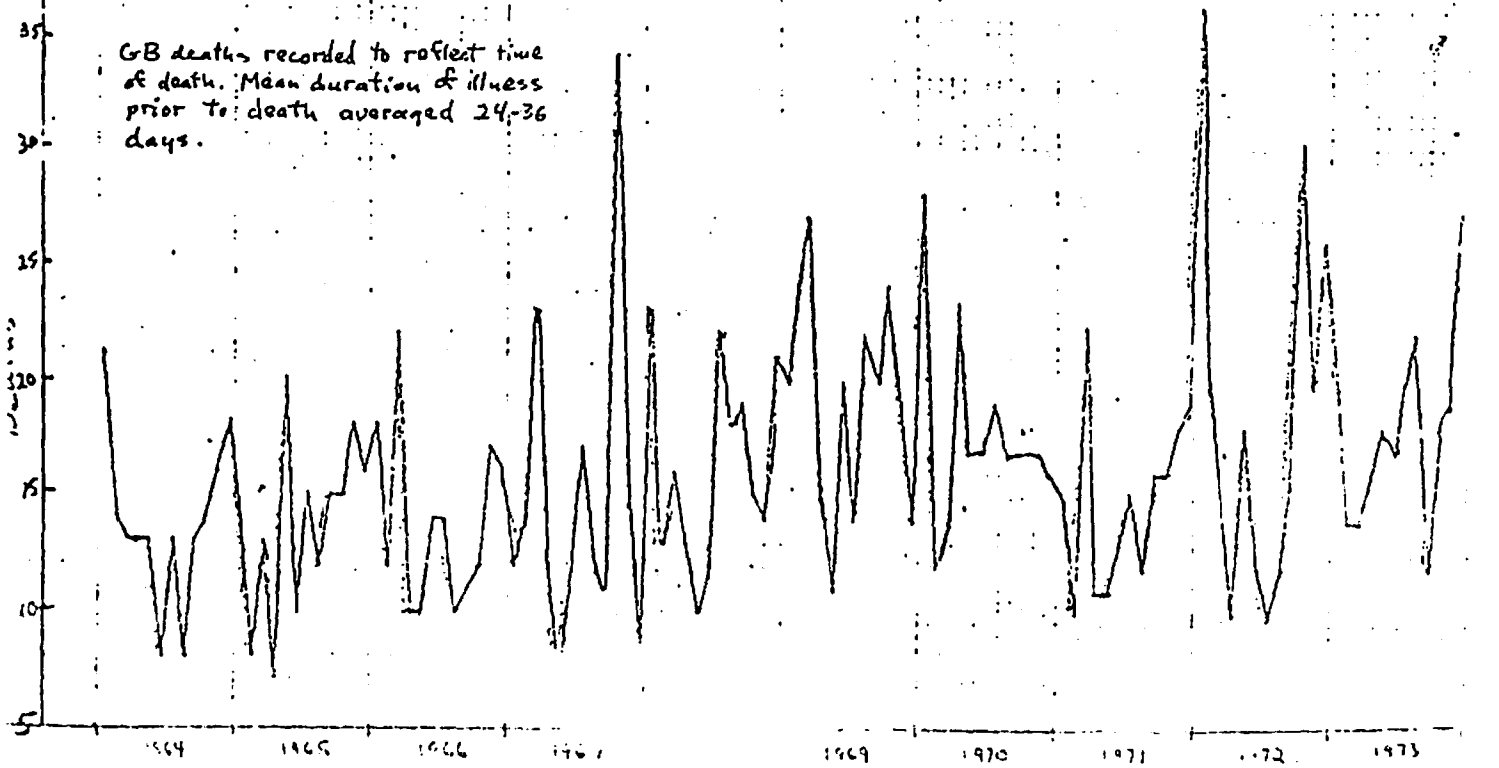
7. Melnick, S. C., and Flewett, T.H.: Role of infection in the Guillain-Barre syndrome. J. Neurol. Neurosurg. Psychiat. 27:395, 1964.

8. Data of Drs. L. Schonberger and Mathew Zack, CDC. Kindly provided by Dr. Robert M. Chanock.

MONTHLY TOTALS OF PNEUMONIA AND INFLUENZA DEATHS IN THE UNITED STATES : 1964 - 1973



MONTHLY TOTALS OF GUILLAIN BARRÉ DEATHS (ICD 364, 354) IN THE UNITED STATES : 1964 - 1973



INVESTIGATOR Thomas R. Cate, M. D.

Date	Day	CBC	Serology Blood Chemistries	Urinalysis	Stool O & P Nose/Throat Bacteria Stools for Enteric Pathogens	EKG	Chest X-Ray	Sinus X-Ray	Nasal wash (veal infusi broth for virus)	Throat swab	Anal swab	Nasal secretion (Lactate Ringer's for antibody)	Tube Clotted Blood For Antibody
Pre.		X		X		X	X		X	X	X	X	
Mon..	0								X			X	X
Tues.	1								X				
Wed.	2								X				
Thurs.	3								X				
Fri.	4								X				
Sat.	5								X				
Sun.	6								X				
Mon.	7								X				
Tues.	8								X				
Wed.	9								X				
Thurs.	10								X				
Fri.													
Sat.													
Sun.													
Mon.	14											X	X
Tues.													
Wed.													
Thurs.													
Fri.	28											X	X
Sat.	29											X	
Sun.													
Mon.													

Baylor College of Medicine
DEPARTMENT OF MICROBIOLOGY AND IMMUNOLOGY • 713 790-4472
Influenza Research Center • 713 790-4469

VOLUNTEER'S CONSENT FORM
Influenza A/Victoria Virus Challenge

I understand that I am consenting to have dropped into my nose a fluid which contains a live influenza virus. I understand that the virus was grown in chicken eggs and that I should not participate if I am allergic to chicken feathers or eggs.

I understand that the virus in the nose drops may give me the flu. Though the flu caused by nose drops in studies like these is usually very mild, I understand that I may have such symptoms as a runny nose, headache, muscle aches, joint aches, bad feeling, fever and even pneumonia. I understand that no currently available medicines can cure the flu and that recovery depends primarily on my body's defenses and usually takes a few days to a week. I understand that I will be confined to the 11-Wing for the period of time when I may be infectious for other persons (up to 2 weeks after the nose drops) and that I may not have visitors during this period.

I understand that blood samples of 15 ml (1 tablespoon) will be collected prior to the nose drops and 2 times over the following month. I understand that nasal wash specimens will be collected daily over approximately a 2-week period and 3 times over the following 2 weeks.

I understand that an illness consisting of progressive muscle weakness with pain or funny sensations (Guillain-Barre syndrome) sometimes occurs one or two months following mild respiratory illnesses; the incidence of this illness is less than 1 case per month for every million people but about 1 person in 20 who develop it die of complications. I understand that there is no evidence that influenza virus infection causes any increase in the frequency of this type of illness. However, I understand that I should report to the doctor, the medical officers or the medical aides if I develop any unusual weakness, pains, numbness or tingling so that the cause can be investigated.

I understand that these studies may help my body develop increased resistance to a type of flu virus which may spread next fall and winter.

I understand that I will receive $35 for completing these studies. I understand that I may withdraw from the study at any time without affecting my right to be in future studies or my care. I understand that if I withdraw, I may have to remain in isolation until I am no longer infectious for other persons, and that I will be paid $4 for each blood sample and $1 for each nasal wash sample collected up to the point I withdraw.

(continued on next page)

I understand that the Influenza Research Center at Baylor will retain a copy of this consent form with my name and identifying number, as well as other records concerning such things as any illness I may have and laboratory evidence of virus infection. I understand that I may obtain copies of all information concerning my participation in this study by writing to the address on the head of this form, giving my name and the approximate date of the study. I understand that any publication of results of these studies will not give my identity.

The proposed study has been clearly explained to me and I understand the hazards involved. I have been given the opportunity to ask any questions I may desire.

Signature_____ Date_____

Witness_____ Identifying No._____

I have carefully explained the nature, demands, and foreseeable risks of the above study to the normal volunteer.

Signature_____ Date_____

Baylor College of Medicine
DEPARTMENT OF MICROBIOLOGY AND IMMUNOLOGY • 713 790-4472
Influenza Research Center • 713 790-4469

April 11, 1977

Dr. Robert Chanock
Lab. of Infectious Disease, NIAID
National Institutes of Health
Building 7, Room 301
Bethesda, Maryland 20014

Dear Bob:

Thanks for sending me a copy of the proposed addendum concerning Guillain-Barre syndrome which you prepared for attachment to protocols concerning study of ts recombinant vaccine candidates of the H3N2 subtype of influenza A virus.

The suspension of studies concerning influenza in humans because of the increased incidence of Guillain-Barre syndrome following inactivated influenza vaccines caught us at a time when we had completed all of our planned administrations of ts-recombinant viruses. The only component of the studies remaining to be done from the previously approved protocol submitted from Baylor was a wild-type virus challenge of volunteers who received the cold-adapted recombinant. In addition, we would like to add a wild-type virus challenge of men with naturally acquired antibody for comparison purposes.

Enclosed is a copy of a protocol describing what we hope to do. I have incorporated some of your thoughts and information concerning Guillain-Barre syndrome. Even if your "generic" addendum is approved and thereby reactivates all previously approved protocols concerning ts-viruses, we will still need approval of the enclosed protocol because it adds a further wild-type virus challenge group (previous natural infection) for which we do not have previous approval.

Best wishes.

Sincerely yours,

Thomas R. Cate, M. D.
Associate Professor of
Microbiology and Medicine

TRC:lfs
cc: Dr. John La Montagne
Enclosure

Baylor College of Medicine
DEPARTMENT OF MICROBIOLOGY AND IMMUNOLOGY • 713 790-4472
Influenza Research Center • 713 790-4469

April 11, 1977

Dr. John La Montagne
Development and Applications Branch
NIAID, National Institutes of Health
Westwood Building
Bethesda, Maryland 20014

Dear John:

Enclosed is the protocol which I spoke to you about on the phone. Also enclosed is a copy of a letter which I have mailed to Bob Chanock which explains why we need approval of this protocol even if Bob's "generic" addendum for ts-virus protocols is approved.

Let me know if there are any questions I can help to clear up.

Sincerely yours,

Tom

Thomas R. Cate, M. D.
Associate Professor of
Microbiology and Medicine

TRC:lfs
Enclosures

1. Title: Development of Rhinovirus Type 3 Challenge System for Normal Volunteers

2. Principal Investigator and Associates: Robert B. Couch, M. D.
Stephen B. Greenberg, M. D.
Thomas R. Cate, M. D.
Maurice W. Harmon, Ph. D.

3. Department: Microbiology and Immunology

4. Granting Agency: NIH-NIAID Contract No. AI-32506

5. Period of Grant:

6. Location of Study: The Methodist Hospital General Clinical Research Center
Baylor College of Medicine

Additional Information for Methodist GCRC:

Duration of Study: 1 year

Number of Subjects to be Hospitalized: 12-24 volunteers

Duration of Occupancy of GCRC Bed by Each Subject: 4 weeks for prisoners; 10 days for students

Maximum Number of Patients to be Hospitalized at One Time: 12

7. Outline:

Background Information: Rhinoviruses appear to be the cause of a significant proportion of acute respiratory disease (ARD) in all age groups (1). Because of the reduced overall occurrence of ARD in adults, rhinoviruses assume a greater significance in this age group. Although lower respiratory disease is seen in infants and children, these viruses primarily produce a common cold syndrome. The major problems regarding prevention of rhinovirus infections are the numerous serotypes capable of producing the disease, the lack of a prevalence of particular serotypes, and the lack of a significant frequency of heterotypic antibody responses following infection. The latter two beliefs have been recently challenged by Fox (2). These beliefs, in combination with the minimal protective effect produced when inactivated vaccines were given by a parenteral route, provided the basis for the prevalent concept that control of the common cold is most likely to occur through the use of antivirals rather than vaccines.

If an antiviral is to be used for prevention or treatment of rhinovirus common colds, it would have to be very convenient and very safe. [illegible] compound specific for rhinovirus infection has been identified. [illegible]

a natural body substance produced in the course of virus infection and effective against a variety of viruses, is reasonable for consideration. Jackson and Douglas demonstrated that a small molecular weight interferon inducer when given topically was capable of modifying artificially induced common colds (3, 4). Similarly, Merigan has indicated that exogenous interferon is effective against a rhinovirus challenge in adult volunteers (5). However, notable in the latter studies is that very large doses (14,000,000 units) were used and yet only a partial protective effect was obtained.

In an attempt to ascertain the reasons for the apparent large dose required for prevention of rhinovirus common colds by interferon, Greenberg and Harmon have been systematically studying the effects of interferon in human nasal epithelial cell cultures and in adult volunteers (6, 7, 8). The tentative conclusions from those studies are that the difficulties with topical administration of interferon are a result of incomplete saturation of the nasopharyngeal mucosa with interferon and/or rapid mucociliary clearance. Studies are presently being conducted to attempt reduction of mucociliary clearance as well as to improve delivery to the nasopharynx. Studies thus far on the interaction of interferon with nasal epithelial cell cultures have involved vesicular stomatitis virus as a challenge virus for the culture system. Recently, rhinovirus type 3 has been shown to replicate in the nasal epithelial cell cultures and studies are underway to ascertain the kinetics of interaction of interferon and this rhinovirus with nasal epithelial cells in culture. The eventual goal of these studies is to use the information being obtained on optimal methods for delivery of interferon to the nasopharynx of man with that on required dosage for development of and maintenance of an antiviral effect in specific numbers of nasal epithelial cells for design of experiments involving challenge of adult volunteers with rhinovirus type 3. For that purpose, a rhinovirus type 3 challenge system is required and the current proposal is for development of that challenge system.

In earlier studies by us with adult volunteers challenged with rhinoviruses, we have shown that intranasal and small particle aerosol inoculation produces a common cold syndrome in about 2/3 of individuals and lasts about 2 to 3 days (9, 10, 11, 12). About 10% of individuals will develop fever of 1 to 3 days duration. The duration of virus shedding varies between 9 and 20 days although the maximum period of virus shedding is 3 to 4 days in association with the acute illness episode. We have experience with rhinovirus types 1, 13, 14, 15, 16, and 17 and all have produced similar results in adult volunteers. Approximately 500 healthy adult volunteers have been studied by us; no cases of pneumonia occurred and no unanticipated complications were noted. Similar studies have been conducted by Tyrrell, Jackson, Gwaltney, and Douglas with similar results.

Purpose of Project: To develop a reproducible challenge system for adult volunteers with rhinovirus type 3. The challenge system will be subsequently used to evaluate the effectiveness of topically administered interferon (approval not requested in this protocol) for prevention of rhinovirus common colds.

Description of Study: Studies will involve normal adult prisoner volunteers from the Texas Department of Corrections and students recruited from colleges in the Houston area. A volunteer inoculum has been prepared from a naturally occurring isolate of rhinovirus type 3 (kindly supplied by Dr. J. Gwaltney) in WI-38 human embryonic fibroblast tissue cultures and is currently being safety tested according to the attached protocol for adventitial agents.

Prisoner volunteers will be recruited by previously approved methods. Students will be recruited from groups responding to campus newspaper and posted notices. In both cases the volunteer groups will be met and a full explanation of the study will be given. After this, a candidate must indicate a desire to participate in the study before any further plans are made. A blood specimen will be obtained and only volunteers free of detectable serum antibody to rhinovirus type 3 will be eligible. Volunteers will be brought to the General Clinical Research Center of The Methodist Hospital in groups of 6 to 12, depending upon available beds. All persons will receive a complete history and physical examination and a variety of other tests designed to assess their state of normality. All "healthy" volunteers will be given a full explanation of the study again and will have an opportunity to withdraw. Those choosing to remain must sign a written consent form (see attached).

The initial study will consist of 6 volunteers; two will be given 100 50% tissue culture infectious doses ($TCID_{50}$), two will be given 10 $TCID_{50}$, and two will be given 1 $TCID_{50}$ by nasal drops. Subsequent studies, involving 6 to 12 volunteers, will be designed to determine the 50% human infectious dose for this virus pool. After inoculation, volunteers will be placed in isolation and will remain there for 5 to 7 days and each will be seen once or twice daily by a physician. Specimens for virus cultures and nasal secretion and serum antibody assays will be obtained according to the attached protocol. Follow-up sera will be obtained as necessary for those persons discharged from the GCRC before 1 month post-inoculation.

Discomfort to Subjects: Some discomfort is associated with drawings of blood and nasal washings, although both of these procedures are commonly performed by us and the discomforts are minimal. The only other discomfort associated with the investigation would be respiratory illness if it occurs. Rhinovirus illness is always accompanied by nasal obstruction and/or nasal discharge. Other symptoms frequently present include sore throat, headache, and malaise. If fever occurs (10% of persons), some myalgias and decrease in appetite may be noted. An occasional individual develops nonproductive cough and the findings of tracheobronchitis. Clouding of maxillary sinuses has been noted on follow-up sinus films in the past but without the clinical findings of acute sinusitis. This clouding has always cleared after antihistamine and vasoconstrictor therapy.

8. a. Subject population: The subject requirement is for normal healthy adults, ages 18-40. Methods for recruiting prisoner volunteers and obtaining informed consent have been previously reviewed and approved. In addition to prisoners, a number of studies will involve students.

b. Potential risks: The only known risks of the study are the development of a common cold and the possibility of a complication. In our experience, artificially induced rhinovirus common colds have been mild, short term, self-limited illnesses. We have never encountered acute otitis media, clinical acute sinusitis, or a primary viral or secondary bacterial pneumonia although each is possible.

c. Consent procedures: Methods leading up to the obtaining of consent are described under "Description of Study." The consent form to be utilized is attached. Subjects will be permitted to read the consent form, a full verbal explanation will be given by one of the investigators, and all questions answered before the subject signs the consent form.

d. Protection against potential risks: An awareness of the possible complications by examining physicians, a complete reevaluation after the illness episode is completed, and a statement to the subjects regarding the possible complications will be the methods used for detecting the potential risks. Treatment of any complication will be by accepted medical procedures. Records concerning each volunteer's participation in this project will be maintained in a secure place. Any publication of results will not contain individual volunteers' identities.

e. Potential benefits: Prisoner volunteers will be paid $5 a day for the duration they are hospitalized (a rate previously approved by the Texas Department of Corrections) and students will be paid $24 a day (a rate just established at the University of Houston for similar studies by others and based upon the supposition that a student could earn $3 per hour for an 8 hour work day were he not serving as a volunteer subject). An additional benefit is the obtaining of a complete assessment of health status. The potential benefit to society from the series of studies outlined under "Background" is the obtaining of a method for treatment of common colds.

f. Risk-Benefit ratio: Although the risk of any harm from rhinovirus challenge is low, the risk-benefit ratio of this study is still low for the individual subject because he experiences the risk of an illness and possible complications, whereas his tangible benefit is primarily financial. The potential benefit to society improves the risk-benefit ratio.

Further information for GCRC:

Uniqueness of the Project and Probability of Publishable Results: The information obtained from this specific protocol will not be publishable except in publications including more information on rhinoviruses. The planned use of the data obtained in studies with interferon will be publishable.

Possible Excessive Expense Associated with Study: None anticipated.

9. Signatures Required:

Robert B. Couch, M. D.
Principal Investigator

Vernon Knight, M. D.
Chairman, Department of Microbiology
and Immunology

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Baylor College of Medicine
DEPARTMENT OF MICROBIOLOGY AND IMMUNOLOGY • 713 790-4472
Influenza Research Center • 713 790-4469

VOLUNTEER'S CONSENT FORM
Rhinovirus Type 3 Challenge

I understand that I am consenting to have dropped into my nose a fluid which contains a live rhinovirus which came from a person with a common cold. I understand that I may or may not "catch" the cold. If I "catch it," it may or may not make me ill. If I develop an illness it may include nasal obstruction and discharge, sore throat, hoarseness, cough, and chest pain. I understand that fever may occur and I may develop headache, weakness, muscle aches and loss of appetite. I have been told that pneumonia may develop but that it is very unlikely. Fever usually lasts 2 to 4 days and symptoms from 7 to 10 days. I understand that other symptoms may occur and that it is possible, but unlikely, that illness will last longer than 10 days.

I understand that no currently available medicines can cure the cold and that recovery depends primarily on my body's defenses and usually takes a few days to a week.

I understand that frequent nasal washings, throat swab and cough specimens, and blood drawings will be performed and used for tests. X-rays and other tests will be performed as needed.

I understand that the information gained from this study will be of no direct benefit to me but that the information gained may be of benefit to other people. I understand that I will receive $5 per day ($24 per day for students) for the duration of my time in the hospital, at the completion of the study. For blood and nasal wash specimens obtained after leaving the hospital I will receive $5 each time this is done.

I understand the investigators will retain at Baylor College of Medicine a copy of this consent form with my name and identifying number, as well as other records concerning such things as any illness I may have and laboratory evidence of virus infection. I understand that I may obtain copies of all information concerning my participation in this study by writing to the address on the head of this form, giving my name and the approximate date of the study. I understand that any publication of results of these studies will not give my identity.

The proposed study has been clearly explained to me and I understand the hazards involved. I have been given an opportunity to ask any questions I might desire and I understand that I have the right to withdraw from the study at any time I may choose without prejudice to me.

Signature_____ Date_____

Witness_____ Identifying No_____

I have carefully explained the nature, demands, and foreseeable risks of the above study to the normal volunteer.

Signature_____ Date_____

SAFETY TEST PROCEDURE

Test System	Test Primarily Designed for	Volume and Method of Inoculation	Number of Test Units	Observation Period
Thioglycollate Broth	Bacteria, Fungi	1 ml per tube	3 tubes	15 days
Sabouraud Liquid Broth Modified	Fungi	1 ml per tube	3 tubes	15 days
Tissue Culture:	Contaminating viruses:			
Hep-2	Adenoviruses, Herpes and RS viruses	0.2 ml per tube	4 tubes, virus + serum 1 tube, virus alone 1 tube, serum alone 2 tubes, uninoculated	28 days with subpass as necessary
HEK[1]	Adenoviruses, Picornaviruses			
WI-38 (Fibroblasts)	Picornaviruses			
Rabbit Kidney	Herpes viruses			
Rhesus Monkey Kidney 37° C[2]	Myxoviruses			
Green Monkey Kidney 37° C	Simian virus 40			
Green Monkey Kidney 36° C[3,4,1]	Rubella virus		6 tubes, virus + serum 1 tube, virus alone 1 tube, serum alone 4 tubes, uninoculated	

TEXAS
DEPARTMENT OF CORRECTIONS

W. J. Estelle, Jr.
Director
Huntsville, Texas 77340

PAUL H. NEWTON
ASSISTANT DIRECTOR
IN CHARGE OF AGRICULTURE

April 14, 1977

Mr. Joe V. LaMantia, Jr.
115 Houston
McAllen, Texas 78501

Dear Mr. LaMantia:

Since our last meeting, we have made a considerable amount of progress on the 1977 crop. During the last three or four years, we have tooled up with larger tractors and equipment. This factor has enabled us to prepare land more rapidly, and in spite of the setback we experienced due to four months of wet weather, we are in relatively good shape. About a week ago, we had some light rains. Had we have gotten two inches, our planting on lower units would, with the exception of soybeans, be complete.

OUTSIDE SALES

Beets	Van DeWalle & Sons	20.975 Tons	$120/Ton	$2,517.00
Dogs	Baylor College of Medicine	5 ea.	$ 50 ea.	250.00
Hogs	Baylor College of Medicine	2 ea.	78.3¢ lb.	92.39

POULTRY PRODUCTION

Composite Poultry Report for February

Ave. No. Hens in Production	51,917
Ave. No. Eggs per day to Food Service Dept.	33,978
Poultry Slaughtered - Broilers	6,471
Dressed weight of poultry slaughtered in lbs.	23,735

Two additional broiler houses on Eastham are being completed and will be ready for delivery of broiler chicks by May 2, 1977.

Two additional broiler houses on Coffield are being completed and will be ready for delivery of broiler chicks by May 16, 1977 and June 16, 1977.

TEXAS DEPARTMENT OF CORRECTIONS
Authorization for Construction and/or Remodeling

Job No.: 747-77 Date Issued: 5-9-77

Proposed Project: John Sealy Hospital Project

Location: Unit n.a. Dept. _____ Property No. n.a.
(Remodeling Only)

Estimated Cost:		Source of Funds:	
Materials	_____	Appropriation	7-4107050 B43
Other	_____	Program	03
Total	$69,000	Activity	05

Justification for Project: To insure adequate medical attention is received by an increasing inmate population.

Plans by: Construction Div. Project Proposed By: Treatment Div.

Drawing No.: A-3199 Construction Superintendent Assigned:

Drawing Date: 4-19-77 Mr. Paul Guidry

Approved: A. Allen Assistant Director for Construction

Approved: O. L. Manning Asst. Director for another Division: Treatment

Approved: _____ Director, T.D.C.

Approved: Board Minutes, Sec. 1 Pg. _____ Board of Corrections

Budget Line Item Specifically Authorizes Project? [ ]yes
[ ]no

Required Approval:
$1000 or Less - Assistant Director for Construction
$2500 or Less - Director & Assistant Director for Construction
Above $2500 - Board of Corrections or Budget Line Item

Distribution: 1st Copy Business Division
2nd Copy Director
3rd Copy Construction Division
4th Copy Construction Superintendent
5th Copy Warehouse

00008 pek

1C802

Animal Inoculation:	Contaminating viruses and bacteria:			
Adult Mice	Neurotropic viruses (LCM, etc.)	0.03 ml IC[4]	20 animals, virus alone	28 days
Newborn Mice	Coxsackieviruses	0.01 ml IC and SC[5]	16 animals, virus alone 8 animals, saline	28 days
Adult Rabbits	Herpes viruses	0.1 ml ID[6] x 10 and 2 drops on searified cornea	2 animals	28 days
Guinea Pigs	Mycobacterium tuberculosis	1 ml IP[7]	3 animals	>42 days[8]
PPLO Agar	Mycoplasma sp.	0.1 ml per plate	4 plates (2 anaerobically, 2 aerobically)	28 days

[1] Challenge with Echovirus Type 11 at 28 days

[2] Hemadsorption test at 7, 14, and 28 days

[3] Challenge 2 controls and 2 virus plus serum with Echovirus Type 11 at 14 days

[4] Intracerebrally

[5] Subcutaneously

[6] Intradermally

[7] Intraperitoneally

[8] Autopsied for tuberculosis at termination

Note: Antiserum for rhinovirus type 3 used only in Hep-2, HEK, WI-38, and RhMK tests.

INVESTIGATOR R.B. Couch, M.D.

Date	Day	CBC	Serology Blood Chemistries	Urinalysis	Stool O & P	Nose/Throat Bacteria	Stools for Enteric Pathogens	BKG	Chest X-Ray	Sinus X-Ray				Throat Swab	Anal Swab	Nasal Wash for Virus		Nasal Secretions	Tube Clotted Blood For Antibody	
Pre.		X	X	X	X	X	X	X	X	X	X				X	X	X		X	2	
Mon.	1														X	X	X		X		
Tues.	2	–															X				
Wed.	3																X				
Thurs.	4																X				
Fri.	5																X				
Sat.	6																X				
Sun.	7																X				
Mon.	8																X				
Tues.	9																X				
Wed.	10																X				
Thurs.	11																				
Fri.	12	X		X	X				X	X	X						X				
Sat.	13																				
Sun.	14																X				
Mon.																			X	1	
Tues.																					
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