UNIVERSITY OF
PENNSYLVANIA
HEALTH SYSTEM

Department of Medicine

Rheumatology Division

Peter E. Callegari, M.D.
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William V. Williams, M.D.

September 1997

Dear Friends,

The University of Pennsylvania is pleased to be able to collaborate in the Lyme Disease Project supported by the Lyme Disease Association of New Jersey.

We will perform PCR on urine specimens as previously performed at Fox Chase Cancer Center by Drs. Manfred and Margaret Bayer. In addition, we look forward to working with you and referring physicians to relate findings to clinical symptoms, course, treatments and Lyme serologies.

Furthermore, depending on additional funding, we plan to investigate some basic aspects of how Borrelia invade and possibly persist in tissues. Because of our long interest in arthritis, we will focus to some degree on Borrelia in joints but believe findings will apply also to the infection in other sites. In addition to urine analysis, we will study synovial biopsies (and, when available from surgery, cartilage specimens) using PCR and immuno-electron microscopy as we recently reported in Human Pathology to study if and where organisms persist after various treatments. As we have done with chlamydial infections in joints, we will develop in situ hybridization to localize the DNA or RNA of Borrelia burgdorferi. We will examine the cytokines produced by the cells surrounding the Borrelia to see, if as with chlamydia, certain people produce more cytokines (like IFN gamma, for example) that make it more difficult to eliminate infections. Measures other than antibiotics may be needed for such patients.

Dr. Bayer will lend his expertise as consultant and advise us in mattres of quality of the PCR testing including in situ hybridization and propagation of Borrelia in cultures necessary for some of the Lyme disease studies.

We look forward to continuing the Lyme Disease Project at the University of Pennsylvania and at the Veterans Hospital, and we are grateful for your support.

Sincerely,

H Ralph Schumacher

H. Ralph Schumacher, Jr., M.D.
Professor of Medicine, Division of Rheumatology
University of Pennsylvania, School of Medicine
Director, Rheumatology-Immunology Center
VAMC, Philadelphia, PA 19104

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TO: Physicians involved in Lyme Disease Research Project (PCR)

FROM: H. Ralph Schumacher, M.D. and M. E. Bayer, M. D.

DATE: June 1997

SUBJECT: Sample handling and shipment

All urine specimen shipments have to be initiated by a treating physician. Urine samples for PCR should be collected by the patient as either first morning urine, or as 4 p.m. urine. Urine collections must be placed in clean (50-100 ml) screw cap plastic containers. Place container(s) into a plastic bag. Freeze urine sample(s) (in plastic bag) and ship frozen (over dry ice) to:

OR
Blue ice paks

H. R. Schumacher, M D.
Arthritis Research
Veterans Affairs Medical Center
University & Woodland Avenues
Philadelphia, PA 19104

Direct delivery by patients will not be accepted. A background questionnaire (available to physicians from our laboratory) must accompany all shipments. Without the completed questionnaire, the study cannot be done. Information about PCR results will be available only to the treating physician, not to patients. (Patients are not to call in).

We would appreciate a donation from the patient, if possible, to the Lyme Disease Project. For this purpose, a minimum donation of $80.00 should be sent to the **Lyme Disease Association of New Jersey, Inc., P. O. Box 1438, Jackson, N.J. 08527.** The LDANJ continues to support this critical research.

CONSENT FORM FOR OBTAINING SAMPLES FOR PCR
FROM PATIENTS

PURPOSE:

Dr. _____ wishes to obtain a sample of my urine for studies of Lyme disease.

DESCRIPTION:

A 50 ml sample of first morning urine - midstream - will be collected by me in a clean container. This is to be wrapped in a plastic bag and frozen to be shipped on dry ice (to the lab). If necessary, my physician will instruct me on the procedure.
OR Blue ice

ASSURANCE OF CONFIDENTIALITY:

My urine sample will be given a code number. Information obtained from studying my urine will be stored using that number, not my name. All records pertaining to me will be kept in a locked cabinet.

If a significant abnormality is found, I will be informed by my physician of the result.

_____ _____
SIGNATURE OF PARTICIPANT DATE
(Parent or guardian if under age 18)

_____ _____
SIGNATURE OF PHYSICIAN DATE

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BACKGROUND DATA COLLECTION FORM
LYME DISEASE PROJECT

H. R. Schumacher, M.D.
Manfred E. Bayer, M.D.

(This questionnaire is to be completed by the treating physician)

FOR RESEARCH USE ONLY

Patient's Name_____ Age_____ Sex___

Physician's Name_____ Telephone Number_____ City/State _____
_____

Sample: Urine_____ Synovial Fluid_____ CSF_____ Tick in_____Date collected_____

Tick bite(Y/N) __ Date_____ Duration before removal of tick_____ ECM__ Physician observed?__

First episode (mo/day/yr)_____ Symptoms_____
_____
_____

Current episode: Symptoms_____
_____
_____

Other known diagnoses_____
_____

Geographic site where tick bite acquired_____
Current home area_____ Deer-populated? __ Is patient often outdoors?___

ARTHRITIS: (physician diagnosis of type)_____ Presence of joint inflammation (swelling)?_____
Joints involved_____ Date of onset_____ Persisting currently?_____
Joint Fluid Analysis_____

HEART INVOLVEMENT: AV block (degree)_____ EKG diagnosed?_____
Date of onset_____ Current symptoms?_____

NEUROLOGICAL SIGNS of Lyme disease? (circle and date)

Cranial neuritis (Bell's palsy)_____ Encephalomyelitis_____ Other_____

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Serological profile: (Test result and date of test)

Western blot_____ Date_____ Band profile (kDa)_____

ELISA_____ Date_____

CFS antibody to B. burgdorferi?_____ Titer higher than in serum?_____

Other test results? PCR_____ Date_____

MRI_____ Date_____

First antibiotic treatment: Start date_____ Antibiotic_____

Route of administration (oral, IV, IM)_____ Dosage_____

Duration of treatment_____ Clinical response (improved, same, worse)_____
Subsequent antibiotic treatment: (brief summary, including dates, drug, duration of treatment(s), clinical response)_____

Current clinical status (please circle): Recovered Remains ill (worse/better than at start of treatment). If still ill, describe clinical condition briefly)_____

Remarks (diagnostic alternatives?)_____

NOTE: THIS IS A PRIVATELY FUNDED RESEARCH PROJECT.